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Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Arevalo-Rodriguez I, Muñoz L, Godoy-Casasbuenas N, Ciapponi A, Arevalo JJ, Boogaard S, Roqué i Figuls M

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[Intervention Review]

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH)

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ABSTRACT

Background

Post-dural puncture headache (PDPH) is one of the most common complications of diagnostic and therapeutic lumbar punctures. PDPH is defined as any headache occurring after a lumbar puncture that worsens within 15 minutes of sitting or standing and is relieved within 15 minutes of the patient lying down. Researchers have suggested many types of interventions to help prevent PDPH. It has been suggested that aspects such as needle tip and gauge can be modified to decrease the incidence of PDPH.

Objectives

To assess the effects of needle tip design (traumatic versus atraumatic) and diameter (gauge) on the prevention of PDPH in participants who have undergone dural puncture for diagnostic or therapeutic causes.

Search methods

We searched CENTRAL, MEDLINE, Embase, CINAHL and LILACS, as well as trial registries via the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) search portal in September 2016. We adopted the MEDLINE strategy for searching the other databases. The search terms we used were a combination of thesaurus-based and free-text terms for both interventions (lumbar puncture in neurological, anaesthesia or myelography settings) and headache.

Selection criteria

We included randomized controlled trials (RCTs) conducted in any clinical/research setting where dural puncture had been used in participants of all ages and both genders, which compared different tip designs or diameters for prevention of PDPH

Data collection and analysis

We used the standard methodological procedures expected by Cochrane.

Main results

We included 70 studies in the review; 66 studies with 17,067 participants were included in the quantitative analysis. An additional 18 studies are awaiting classification and 12 are ongoing. Fifteen of the 18 studies awaiting classification mainly correspond to congress summaries published before 2010, in which the available information does not allow the complete evaluation of all their risks of bias and characteristics. Our main outcome was prevention of PDPH, but we also assessed the onset of severe PDPH, headache in general and adverse events. The quality of evidence was moderate for most of the outcomes mainly due to risk of bias issues. For the analysis, we undertook three main comparisons: 1) traumatic needles versus atraumatic needles; 2) larger gauge traumatic needles versus smaller gauge traumatic needles; and 3) larger gauge atraumatic needles versus smaller gauge atraumatic needles. For each main comparison, if data were available, we performed a subgroup analysis evaluating lumbar puncture indication, age and posture.

For the first comparison, the use of traumatic needles showed a higher risk of onset of PDPH compared to atraumatic needles (36 studies, 9378 participants, risk ratio (RR) 2.14, 95% confidence interval (CI) 1.72 to 2.67, $I^2 = 9\%$).

In the second comparison of traumatic needles, studies comparing various sizes of large and small gauges showed no significant difference in effects in terms of risk of PDPH, with the exception of one study comparing 26 and 27 gauge needles (one study, 658 participants, RR 6.47, 95% CI 2.55 to 16.43).

In the third comparison of atraumatic needles, studies comparing various sizes of large and small gauges showed no significant difference in effects in terms of risk of PDPH.

We observed no significant difference in the risk of paraesthesia, backache, severe PDPH and any headache between traumatic and atraumatic needles. Sensitivity analyses of PDPH results between traumatic and atraumatic needles omitting high risk of bias studies showed similar results regarding the benefit of atraumatic needles in the prevention of PDPH (three studies, RR 2.78, 95% CI 1.26 to 6.15; $I^2 = 51\%$).

Authors' conclusions

There is moderate-quality evidence that atraumatic needles reduce the risk of post-dural puncture headache (PDPH) without increasing adverse events such as paraesthesia or backache. The studies did not report very clearly on aspects related to randomization, such as random sequence generation and allocation concealment, making it difficult to interpret the risk of bias in the included studies. The moderate quality of the evidence for traumatic versus atraumatic needles suggests that further research is likely to have an important impact on our confidence in the estimate of effect.

PLAIN LANGUAGE SUMMARY

Needle characteristics that reduce the occurrence of post-dural puncture headache (PDPH)

Background

A lumbar puncture is a needle inserted into the lower part of the spine to draw fluid, to test for conditions affecting the brain and spinal cord. It can also be used for treatment (for instance, for the management of pain in caesarean section).

In general, lumbar punctures are considered safe; however, a number of adverse effects such as backache, tickling sensations (paraesthesia) or even post-dural puncture headache (PDPH) have been reported. These conditions are not life-threatening, but can impair the person's physical activity and can be very painful. Several different needle tips (classified as traumatic or atraumatic) and gauges (size/diameter) are used to perform a lumbar puncture. We compared different types of needles to assess the effects of the needle tip and its thickness on the prevention of post-dural puncture headache.

Study characteristics

We searched the medical literature for studies carried out in any setting comparing needles of different characteristics (i.e. different tip designs and sizes) for the prevention of PDPH. The evidence is current to September 2016. We included 70 studies and were able to include information from 66 of those studies (17,067 participants) in the numerical analysis. An additional 18 studies are awaiting classification and 12 are ongoing.

Key findings

We found that the use of needles with a traumatic tip resulted in a higher risk of PDPH when compared to needles with atraumatic tips. When we compared the different studies comparing various sizes of large and small traumatic gauges, we did not find any difference in effects in terms of the risk of PDPH. Finally, when we compared atraumatic needles with a higher gauge to those with a smaller gauge, we observed no significant differences in terms of the development of PDPH in any of the scenarios analysed. We also found no significant

differences in the use of traumatic versus atraumatic needles in the development of adverse effects such as paraesthesia, backache and severe PDPH.

Quality of the evidence

The studies did not report clearly on aspects of their design related to randomization. (This is a method that uses the play of chance to assign participants to comparison groups in a trial). This made it difficult for us to interpret the risk of bias in the included studies. We therefore considered the quality of the evidence for most of the outcomes assessed in this review to be moderate.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Traumatic needles compared to atraumatic needles for prevention of post-dural puncture headache (PDPH)

Traumatic needles compared to atraumatic needles for prevention of PDPH

Patient or population: patients undergoing lumbar punctures

Settings: all settings (countries: Argentina, Austria, Brazil, Canada, Denmark, Finland, France, Germany, India, Israel, Italy, Korea, Mexico, Nepal, Netherlands, Nigeria, Norway, Pakistan, Spain, Thailand, UK and USA)

Intervention: traumatic needles (Quincke, Greene, Hingson Ferguson, Lutz, Brace, Rovenstine, Lemmon)

Comparison: atraumatic needles (Whitacre, Atraucan, Sprotte, Cappe-Deutsh, Pajunk, Gertie Marx, Durasafe, Cappe, Deutsch and Eldor)

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
|------------------------------|--|---------------------------|--------------------------|------------------------------|---------------------------------|----------|
| | Assumed risk | Corresponding risk | | | | |
| | Atraumatic needles | Traumatic needles | | | | |
| Onset of PDPH | 30 per 1000 | 64 per 1000 (52 to 80) | RR 2.14 (1.72 to 2.67) | 9378 (36 studies) | ⊕⊕⊕⊖ moderate ¹ | — |
| Adverse events: paraesthesia | 52 per 1000 | 50 per 1000 (25 to 102) | RR 0.96 (0.47 to 1.96) | 573 (3 studies) | ⊕⊕⊕⊖ moderate ¹ | — |
| Adverse events: backache | 155 per 1000 | 147 per 1000 (118 to 183) | RR 0.94 (0.78 to 1.13) | 3027 (12 studies) | ⊕⊕⊕⊖ moderate ¹ | — |
| Severe PDPH | 0 per 1000 | 10 per 1000 | RD 0 (0.00 to 0.01) | 6420 (24 studies) | ⊕⊕⊖⊖ low ^{1,2} | — |
| Any headache | 221 per 1000 | 290 per 1000 (228 to 367) | RR 1.35 (1.17 to 1.57) | 4104 (18 studies) | ⊕⊕⊕⊖ moderate ¹ | — |

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **PDPH:** post-dural puncture headache; **RD:** risk difference; **RR:** risk ratio

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹Risk of bias downgraded by one level due to unclear reporting (especially related to allocation concealment and random sequence generation issues).

²Inconsistency downgraded by one level due to presence of considerable heterogeneity ($I^2 = 42\%$), caused by one study focused on diagnostic lumbar punctures (Muller 1994).

Summary of findings 2. Larger traumatic needles compared to smaller traumatic needles for prevention of post-dural puncture headache (PDPH)

Traumatic needle(major gauge) compared to traumatic needle (minor gauge) for prevention of PDPH

Patient or population: patients undergoing lumbar punctures with traumatic needles (Quincke, Greene, Hingson Ferguson, Lutz, Brace, Rovenstine, Lemmon)

Settings: all settings (countries: Finland, Germany, India, Italy, Korea, Pakistan and USA)

Intervention: traumatic needle - larger gauge (Quincke, Greene, Hingson Ferguson, Lutz, Brace, Rovenstine, Lemmon)

Comparison: traumatic needle - smaller gauge (Quincke, Greene, Hingson Ferguson, Lutz, Brace, Rovenstine, Lemmon)

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
|--|--|---------------------------------|---------------------------------------|------------------------------|--------------------------------------|---|
| | Assumed risk | Corresponding risk | | | | |
| | Traumatic needle - smaller gauge | Traumatic needle - larger gauge | | | | |
| Onset of PDPH | — | — | RR ranged from 0.86 to 6.47 | 2288 (10 studies) | ⊕⊕⊕⊖ low ^{1,3} | We decided against overall pooling of results because the gauge of a needle could be considered small in one comparison but large in another. |
| Adverse events: paraesthesia - not reported | See comment | See comment | Not estimable | — | See comment | We did not identify any studies reporting this outcome. |
| Adverse event: backache | — | — | RR ranged from 0.81 to 2.00 | 948 (3 studies) | ⊕⊕⊕⊖ moderate ¹ | We decided against overall pooling of results because the gauge of a needle could be considered small in one comparison but large in another. |
| Severe PDPH | — | — | RD ranged from 0.00 to 0.00 | 1128 (6 studies) | ⊕⊕⊕⊖ low ^{1,2} | We decided against overall pooling of results because the gauge of a needle could be considered small in one comparison but large in another. |

| | | | | | | |
|---------------------|---|---|--|--------------------|--------------------------------------|---|
| Any headache | — | — | RR ranged from 0.75 to 1.56 | 771 (3 studies) | ⊕⊕⊕⊖ moderate ¹ | We decided against overall pooling of results because the gauge of a needle could be considered small in one comparison but large in another. |
|---------------------|---|---|--|--------------------|--------------------------------------|---|

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **PDPH:** post-dural puncture headache; **RD:** risk difference; **RR:** risk ratio

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹Risk of bias downgraded by one level due to unclear reporting (especially related to allocation concealment and random sequence generation issues).

²Imprecision downgraded by one level due to few events reported in each arm.

³Imprecision downgraded by one level due to unclear clinical decisions indicated by each confidence interval limit.

Summary of findings 3. Larger atraumatic needles compared to smaller atraumatic needles for prevention of post-dural puncture headache (PDPH)

Atraumatic needle (major gauge) compared to atraumatic needle (minor gauge) for prevention of PDPH

Patient or population: patients undergoing lumbar punctures with atraumatic needles (Whitacre, Atraucan, Sprotte, Cappe-Deutsh, Pajunk, Gertie Marx, Durasafe, Cappe, Deutsch and Eldor)

Settings: all settings (countries: Canada, France, India, Italy, Spain, UK and USA)

Intervention: atraumatic needle - larger gauge (Whitacre, Atraucan, Sprotte, Cappe-Deutsh, Pajunk, Gertie Marx, Durasafe, Cappe, Deutsch and Eldor)

Comparison: atraumatic needle - smaller gauge (Whitacre, Atraucan, Sprotte, Cappe-Deutsh, Pajunk, Gertie Marx, Durasafe, Cappe, Deutsch and Eldor)

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
|----------------------|--|----------------------------------|--------------------------------------|------------------------------|-----------------------------------|---|
| | Assumed risk | Corresponding risk | | | | |
| | Atraumatic needle - smaller gauge | Atraumatic needle - larger gauge | | | | |
| Onset of PDPH | — | — | RR ranged from 0.38 to 9.3 | 3134 (13 studies) | ⊕⊕⊖⊖ low ^{1,2} | We decided against overall pooling of results because the gauge of a needle could be considered small in one comparison but large in other. |

| | | | | | | |
|-------------------------------------|---|---|------------------------------------|---------------------|--------------------------------------|---|
| Adverse events: paraesthesia | — | — | RR ranged from 1.03 to 7.61 | 439 (2 studies) | ⊕⊕⊕⊖ moderate ¹ | We decided against overall pooling of results because the gauge of a needle could be considered small in one comparison but large in other. |
| Adverse events: back-ache | — | — | RR ranged from 0.95 to 5.00 | 526 (4 studies) | ⊕⊕⊕⊖ moderate ¹ | We decided against overall pooling of results because the gauge of a needle could be considered small in one comparison but large in other. |
| Severe PDPH | — | — | RD ranged from 0 to 0.01 | 1983 (8 studies) | ⊕⊕⊖⊖ low ^{1,2} | We decided against overall pooling of results because the gauge of a needle could be considered small in one comparison but large in other. |
| Any headache | — | — | RR ranged from 1.13 to 2.17 | 1791 (7 studies) | ⊕⊕⊕⊖ moderate ¹ | We decided against overall pooling of results because the gauge of a needle could be considered small in one comparison but large in other. |

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **PDPH:** post-dural puncture headache; **RD:** risk difference; **RR:** risk ratio

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹Risk of bias downgraded by one level due to unclear reporting (especially related to allocation concealment and random sequence generation issues).

²Imprecision downgraded by one level due unclear clinical decisions indicated by each confidence interval limit.

BACKGROUND

Description of the condition

Post-dural (post-lumbar or post-spinal) puncture headache (PDPH) is one of the most common complications of diagnostic, therapeutic or inadvertent lumbar punctures (Bezov 2010; Davignon 2002; Raskin 1990; Sadashivaiah 2009). PDPH is defined as any headache after a lumbar puncture that worsens within 15 minutes of sitting or standing and is relieved within 15 minutes of the patient lying down (González-Martínez 2005; Headache Classification Subcommittee IHS 2004). Most PDPHs occur within three days of the procedure and more than 50% start within the first 48 hours (Turnbull 2003).

The pathophysiology of PDPH has not been fully established. It is well known that puncture of the dura allows cerebrospinal fluid (CSF) to leak from the subarachnoid space, which results in decreased CSF volume and pressure (Grande 2005). This CSF volume loss may cause a downward pull on pain-sensitive structures, which could explain the occurrence of PDPH (Ahmed 2006; Baumgarten 1987; Davignon 2002; Denny 1987; Harrington 2004). In addition, loss of CSF may cause an increase in blood flow, leading to arterial and venous vasodilatation, which could result in PDPH. A third PDPH mechanism may involve the role of substance P (neurotransmitter/neuromodulator involved in pain perception) and the regulation of neurokinin 1 receptors (NK1Rs) (Clark 1996). Defects in manufactured needles have also been described as a possible source of PDPH (Parker 1997). Laboratory studies have shown significant alteration of the tips of traumatic needles when their introducer needle protrudes through the inner hole of the needle. These altered tips can produce holes in the dura mater of increased diameter, which may require longer healing times and consequently increase the time allowed for leakage of CSF (Bezov 2010; Calthorpe 2004; Parker 1997).

Studies about the incidence of PDPH have reported a wide range of estimates, depending on target populations, types of needles and lumbar puncture techniques (Alstadhaug 2012; Arendt 2009; Lavi 2006; Shaikh 2008; Vallejo 2000). For example, during anaesthetic procedures such as epidural anaesthesia, PDPH is most commonly caused by an unintentional dural puncture (Thew 2008; Turnbull 2003). However, in diagnostic or therapeutic lumbar punctures, the need for adequate CSF flow requires an intentional lesion that may trigger the PDPH phenomenon (Kuczkowski 2006). Estimated frequencies of this event vary from less than 10% after spinal anaesthesia (Vallejo 2000) to 36% after diagnostic lumbar puncture (Lavi 2006; Vallejo 2000), and up to 81% in obstetric patients with inadvertent dural puncture during active labour (Berger 1998; Choi 2003).

The characteristics of PDPH are often variable. It may be accompanied by neck stiffness, tinnitus, hearing loss, photophobia and nausea, among other symptoms. Other characteristics such as the location and duration of the headache are also unpredictable (Grande 2005). Although PDPH is not a life-threatening condition, physical activity is often restricted. Patients are usually required to stay in bed for the entire day, and length of hospital stay and use of medical services are increased (Angle 2005). The variability in symptom profiles makes PDPH a diagnosis of exclusion. Alternative diagnoses (e.g. viral meningitis, sinus headache, intracranial haemorrhage) should be ruled out first (Turnbull 2003).

Once PDPH is diagnosed, initial treatment involves conservative measures such as bed rest and analgesics. If PDPH continues for longer than 72 hours, more specific treatment is indicated (Ahmed 2006). Severe PDPH may respond to some therapeutic drugs and to an epidural blood patch (Boonmak 2010; Lavi 2006).

Description of the intervention

Many interventions have been suggested for the prevention of PDPH (e.g. body postures and fluid intake after lumbar puncture). One of the most relevant strategies involves the features of the needles (Arendt 2009). Although the choice of the needle depends mostly on the purpose of the lumbar puncture, several experts have remarked that facets such as the tip and the gauge could be modified to decrease the incidence of PDPH (American Society of Anesthesiologists 2007; Armon 2005).

According to tip design, needles can be divided into traumatic and atraumatic types. Atraumatic needles include Whitacre, Atraucan, Sprotte, Cappe and Deutsch, among others. Traumatic needles include Quincke, Greene, Hingson Ferguson, Lutz, Brace and Rovenstine, among others. Traumatic needles are characterized by a bevelled tip that cuts the dura mater. In contrast, atraumatic needles are characterized by a pencil-point design. It has been stated that noncutting or atraumatic needles produce a separation of the tissue fibres that heals easily after removal of the needle. Cutting or traumatic needles, on the other hand, favour loss of tissue and trigger a large inflammatory reaction that requires a long time to heal (Calthorpe 2004; Lynch 1992; Wu 1991).

The external diameter of the needle is another factor that may be involved in the mechanisms of PDPH. The external diameter is determined by the cross-sectional area of the needle; larger diameters are expected to produce larger orifices in the dura mater, thereby allowing increased CSF leakage. Larger gauges are represented by smaller numbers (e.g. 16 gauge, 17 gauge), and smaller gauges are represented by larger numbers (e.g. 29 gauge, 32 gauge) (Calthorpe 2004).

How the intervention might work

Studies that have compared needle internal diameters have found that needles of larger diameter produce larger holes in the dura mater and this could lead to a greater risk of post-dural puncture headache (Bezov 2010; Lavi 2006; Shaikh 2008; Santanen 2004). However, evidence also suggests that the use of thinner needles increases the difficulty of the procedure and hence the number of bone punctures, causing needle tip deformities (Angle 2003). Some authors advocate the use of needles with cutting/traumatic tips based on the theory that these needles can cause larger lesions than are produced by pencil-point/atraumatic needles (Calthorpe 2004; Lynch 1992a; Srivastava 2010a). Pencil-point needles were thought to penetrate and then separate dura mater fibres, resulting in less trauma and subsequently less loss of CSF and a lower incidence of PDPH (Arendt 2009). A large inflammatory reaction caused by larger lesions can lead to faster closing of the injury through rapid migration of the cells involved in scar formation. Microscopic analyses of corpses have revealed that injuries produced by pencil-point needles are more complex than those produced by cutting needles (Arendt 2009).

Why it is important to do this review

Lumbar puncture is part of everyday clinical practice and is associated with potential adverse effects (Evans 2009; Grande 2005). Prevention strategies should be preferred over treatment of adverse effects (Turnbull 2003). Morbidities associated with CSF loss, besides PDPH, include peripartum seizures, cranial subdural haematomas and subdural fluid collections (Arendt 2009; Janssens 2003). Even though most cases of PDPH are resolved within a few days, a significant number of patients experience at least one week of disability, and others require prolonged or recurrent hospitalizations (van Kooten 2008). Prevention strategies, such as the use of a prophylactic epidural blood patch, caffeine or different postures after lumbar puncture, have not proved effective for the prevention of PDPH in several Cochrane Reviews (Arevalo-Rodriguez 2013; Basurto 2013; Boonmak 2010).

OBJECTIVES

To assess the effects of needle tip design (traumatic versus atraumatic) and diameter (gauge) on the prevention of post-dural puncture headache (PDPH) in participants who have undergone dural puncture for diagnostic or therapeutic causes.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) conducted in any clinical/research setting where dural puncture has been used.

Types of participants

We included participants of all ages and both genders who have undergone lumbar puncture for medical reasons.

Types of interventions

We included studies in participants undergoing lumbar puncture that assessed one of the following interventions.

- A needle tip design/bevel used for lumbar puncture (i.e. traumatic or atraumatic) versus another needle tip design/bevel.
- A specified needle gauge (i.e. from 16 gauge to 32 gauge) versus another needle gauge for the same type of tip design (i.e. traumatic or atraumatic).
- Any combination of the above.

Types of outcome measures

Primary outcomes

- Onset of PDPH, defined as each headache that worsens within 15 minutes of sitting or standing and is relieved within 15 minutes of lying down after a lumbar puncture. We used the valid PDPH diagnostic criteria specified by the International Headache Society (Headache Classification Subcommittee IHS 2004).
- Adverse events related to lumbar puncture: total adverse events and total serious adverse events. We defined an adverse event as "any untoward medical occurrence that may present during treatment with a pharmaceutical product but that does not necessarily have a causal relationship with this treatment". Due

to heterogeneity in the report of adverse events, we choose paraesthesia and backache as the most important adverse events, additional to PDPH, related to needle gauge and tip. This is a difference from our protocol (Arevalo-Rodriguez 2013a) and it is explained in the Differences between protocol and review section.

Secondary outcomes

- Severe PDPH, according to the definition used in each study, which could be based on specific features (e.g. duration of PDPH), a visual analogue scale (VAS) or other criteria such as the need for specialized treatments to manage the episode of headache (e.g. epidural blood patch).
- Any headache subsequent to a lumbar puncture, to incorporate any possible data that had not been catalogued as PDPH, according to the definition used in each study.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL 2016, Issue 9) (see Appendix 2 for details of the search strategy), PubMed, MEDLINE (1966 to September 2016, see Appendix 3), EMBASE via Ovid SP (1982 to September 2016, see Appendix 4), CINAHL (EBSCOhost, 1982 to September 2016, see Appendix 5) and LILACS (1982 to September 2016 see Appendix 6).

We adopted the MEDLINE search strategy in searching the other databases. The search terms are a combination of thesaurus-based and free-text terms for both the intervention (lumbar puncture in neurological, anaesthesia or myelography settings) and the headache. We did not impose any language restriction.

Searching other resources

We searched trial registries via the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) search portal up to September 2016. In addition, we searched the reference lists from retrieved studies, information from clinical trial registration websites and conference proceedings.

Data collection and analysis

Selection of studies

Two review authors (JJA and LM) independently selected studies for eligibility using Early Review Organizing Software (EROS) (Ciapponi 2011; Ciapponi 2011a; Glujovsky 2010). We reviewed the titles and abstracts of all identified studies to determine whether they fulfilled the inclusion criteria. We assessed the full texts of selected studies to confirm their relevance for inclusion. We resolved any disagreement by consulting with a third review author (AC). We were not blinded to the authors' names and institutions, the journal of publication or the study results at any stage of the review.

Data extraction and management

Three review authors (NG-C, SB and LM) independently used pre-designed data forms to extract information from the original study reports about participants, methods of randomization, blinding, comparisons of interest, numbers of participants originally randomly assigned by arm, follow-up losses and outcomes (double data entry) (Appendix 7). We recorded the reasons for exclusion of

potential studies in the [Characteristics of excluded studies](#) table. We resolved any disagreement by discussion with a fourth review author (IA-R). We entered the extracted data into Review Manager 5 for the analyses ([RevMan 5.3](#)).

Assessment of risk of bias in included studies

Two review authors (NG-C and IA-R) independently assessed the risk of bias of included studies using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). We considered seven domains (random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias). We did not consider blinding of personnel because of the nature of the intervention (lumbar puncture). We resolved any disagreements by discussion with a third review author (MRF).

Measures of treatment effect

We presented results as summary risk ratios (RRs) for incidence of PDPH, adverse events, severe PDPH and any headache along with 95% confidence intervals (CIs). We calculated the number needed to treat for an additional beneficial outcome (NNTB) as the reciprocal of risk differences (RDs) ([McQuay 1998](#)).

Unit of analysis issues

We did not expect to encounter any unit of analysis issues, as we did not expect to find cross-over studies or cluster-randomized trials. However, we identified four such studies with our search strategies and excluded them from quantitative analysis. This is a difference from our protocol ([Arevalo-Rodriguez 2013a](#)) and is explained in the [Differences between protocol and review](#) section.

Dealing with missing data

For all outcomes we carried out analyses, as far as possible, on an intention-to-treat (ITT) basis (i.e. we attempted to include in the analyses all randomized patients in the denominator of the assessed groups).

Assessment of heterogeneity

We assessed statistical heterogeneity of effect sizes by means of the I^2 statistic. The I^2 statistic describes the percentage of total variation across trials that is due to heterogeneity rather than to sampling error ([Higgins 2003](#); [Higgins 2011](#)). If we identified at least moderate heterogeneity (i.e. $I^2 > 30\%$), we explored it by performing prespecified subgroup analyses. If we identified substantial heterogeneity ($I^2 > 80\%$), we did not present the pooled result.

Assessment of reporting biases

We assessed reporting bias through careful attention to assessment of quality, particularly the quality of study methodology. We also used funnel plot analysis to assess publication bias.

Data synthesis

We summarized the findings using random-effects models with the DerSimonian-Laird method. We carried out statistical analyses using Review Manager 5 ([RevMan 5.3](#)).

Subgroup analysis and investigation of heterogeneity

For the primary outcomes, we considered subgroup analyses for the following factors, as appropriate.

- Participants undergoing dural puncture for anaesthesia only, diagnosis only or myelography only.
- Pregnant women only.
- Gender: it has been reported that women are at twice the risk of men ([Alstadhaug 2012](#); [Bezov 2010](#); [Evans 2009](#)).
- Age (younger than 18 years of age, older than 65 years of age and 18 to 65 years of age). Due to heterogeneity in the reporting of age, we classified studies into three groups: a) only children; b) no distinctions about age; c) 60 years or more. This is a difference from our protocol ([Arevalo-Rodriguez 2013a](#)) and is explained in the [Differences between protocol and review](#) section
- Posture during the lumbar puncture (e.g. lateral, sitting).
- Type of surgery: in participants receiving anaesthesia, we analysed the primary outcome by type of surgical procedure if data were available. As we mentioned in the [Background](#), some patients such as obstetric women have an increased risk of PDPH. This is a difference from our protocol ([Arevalo-Rodriguez 2013a](#)) and is explained in the [Differences between protocol and review](#) section.

Sensitivity analysis

We performed a sensitivity analysis to compare the results from using only those RCTs classified as having a 'low risk of bias' in three core domains: allocation concealment, incomplete outcome data and blinding of outcome assessment ([Higgins 2011](#)). In addition, we performed a sensitivity analysis to measure the risk difference (RD) in those analysis that presented zero events in both treatment arms. This is a difference from our protocol ([Arevalo-Rodriguez 2013a](#)) and is explained in the [Differences between protocol and review](#) section.

'Summary of findings' tables

We used the principles of the GRADE system ([Guyatt 2008](#)) to assess the quality of the body of evidence associated with all outcomes (onset of PDPH and adverse events), and we constructed a 'Summary of findings' table using the GRADE profiler software. The GRADE approach appraises the quality of a body of evidence based on the extent to which one can be confident that an estimate of effect or association reflects the item being assessed. Evaluation of the quality of a body of evidence considers within-study risk of bias, directness of the evidence, heterogeneity of the data, precision of effect estimates and risk of publication bias ([Balslem 2011](#); [Guyatt 2011](#); [Guyatt 2011a](#); [Guyatt 2011b](#); [Guyatt 2011c](#); [Guyatt 2011d](#); [Guyatt 2011e](#); [Guyatt 2011f](#); [Guyatt 2011g](#)). For assessments of the overall quality of evidence for each outcome that included pooled data from RCTs only, we downgraded the evidence from 'high quality' by one level for serious (or by two for very serious) study limitations. We included the following outcomes in the 'Summary of findings' tables: onset of PDPH, adverse events (i.e. paraesthesia, backache), severe PDPH and any headache.

RESULTS

Description of studies

See [Characteristics of included studies](#) and [Characteristics of excluded studies](#).

Results of the search

We searched the databases in February 2015, identifying a total of 1201 references. We found four additional references using other research strategies. After reviewing the references by title and abstract, we selected 138 of them to review as full texts (see [Figure 1](#)). After reading the articles, we included 70 studies (distributed in 75 references). We excluded 35 studies. We classified 12 as ongoing

studies and 15 as studies awaiting assessment. We reran the search in September 2016, identifying a total of 96 new references. We selected a further three studies for in-depth review ([Castrillo 2015](#); [Fama 2015](#); [Hong 2015](#)). We added these three potential new studies of interest to a list of '[Characteristics of studies awaiting classification](#)' and we will incorporate them into the formal review findings during the review update.

Figure 1. Study flow diagram

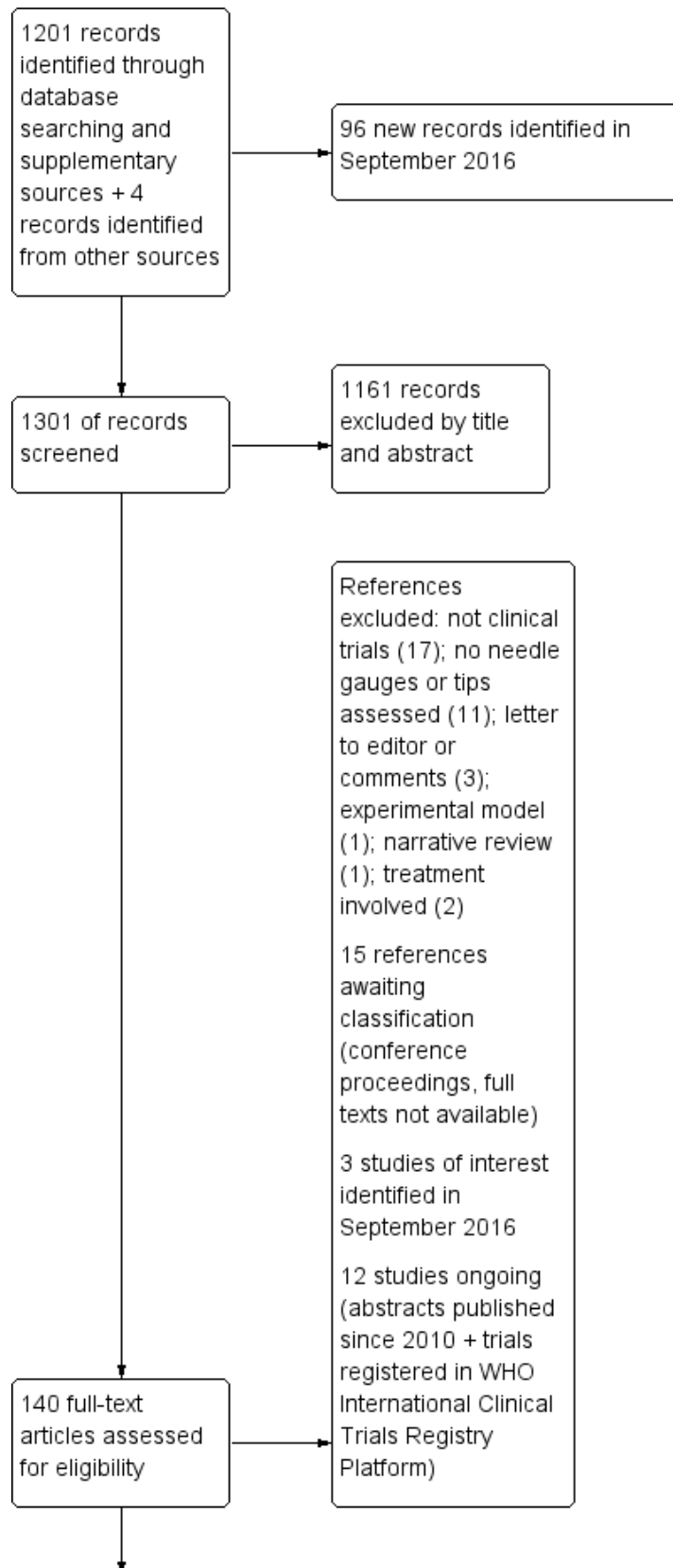
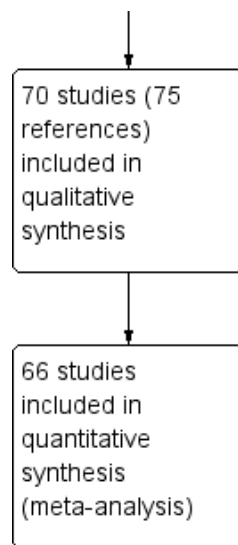


Figure 1. (Continued)



Included studies

We included 70 studies in the qualitative synthesis of the review, accounting for 75 references (see [Figure 1](#) and [Characteristics of included studies](#)). However, we excluded four of these from the quantitative data analysis as their results were obtained using a different unit of analysis to the one planned for this review (procedures instead of participants: four studies). One of these studies was a study with a cross-over design ([Crock 2014](#)), and it included children receiving treatment for leukaemia. The remaining three were parallel-group trials that included all the lumbar punctures undertaken on the participants during the lifespan of the study ([Hafer 1997](#); [Kokki 1999](#); [Lavi 2006](#)); however, in some cases it was not clear if the procedures or the participants were randomized ([Kokki 1999](#); [Lavi 2006](#)).

The quantitative analysis included 66 studies with a total of 17,067 participants (mean 258.6 participants; standard deviation (SD) 236.7; interquartile range (IQR) 100 to 311), published between 1972 and 2013. The sample sizes of the studies included ranged from 40 to 1522 participants (see [Characteristics of included studies](#)).

We classified the studies according to the needle tip design used, as follows: traumatic needles = Quincke, Greene, Hingson Ferguson, Lutz, Brace, Rovenstine, Lemmon; atraumatic needles = Whitacre, Atraucan, Sprotte, Cappe-Deutsh, Pajunk, Gertie Marx, Durasafe, Cappe, Deutsch and Eldor. Thirty-nine studies (10,715 participants) compared traumatic needles versus atraumatic needles. Eleven studies compared traumatic needles of different gauges (2896 participants) and 15 studies compared atraumatic needles of different gauges (4095 participants). Four studies provided information for two different comparisons ([Kokki 1998](#); [Shah 2010](#); [Shaikh 2008](#); [Shutt 1992](#)). The type of needle tip used could not be determined in seven of the studies ([Geurts 1990](#); [Harrison 1993](#); [McGann 1992](#); [Rasmussen 1989a](#); [Rasmussen 1989b](#); [Tourtellotte 1972](#); [Wilkinson 1991](#)). In one case, a hybrid point needle (a combination of diamond and pencil points) was compared to an atraumatic needle ([Standl 2004](#)). Two references provided information on two studies in the same publication and

we analysed these as two independent groups of data ([Rasmussen 1989a](#); [Rasmussen 1989b](#); [Srivastava 2010a](#); [Srivastava 2010b](#)).

Most of the studies included both genders, however 20 only included women and one only included men ([Saenghirunvattana 2008](#)). Similarly, most of the studies included patients in all age ranges; three only included under 18 year-olds ([Kokki 1996](#); [Kokki 1998](#); [Kokki 2000](#)), and one study only included over 60 year-olds ([Kim 2011](#)). The 25 gauge needle was the most frequently assessed (414 groups), followed by the 22 gauge (20 groups). In one study, it was not possible to identify the gauge of the needle used or its brand ([Kokki 2000](#)). A Quincke needle was used in 57 groups, followed by Whitacre needles (31 groups) and Sprotte (21 groups).

Among the indications for lumbar puncture, 57 studies undertook this procedure to administer anaesthesia. The most common reasons for the administration of anaesthesia were caesarean section (15 studies), followed by orthopaedic interventions (eight studies). The remaining studies combined different types of subumbilical surgery such as urologic surgery, outpatient surgery and tubal ligation among others. Five studies used lumbar puncture as a diagnosis method, including for the detection of infections, while a further seven studies used lumbar puncture for myelography. The most common site for puncture was between lumbar vertebrae (L) 2-3 and 3-4 (12 studies), followed by L3 to 4 (nine studies). Nineteen studies did not report puncture site and 25 studies reported that the puncture was undertaken by trained and experienced professionals, whereas 35 studies did not provide such information. The most common body position during the procedure was a lateral position (23 studies) and a seated position (21 studies).

Excluded studies

We excluded a total of 35 studies from the review as most of them were not clinical trials. In 11 cases, the studies were not designed to evaluate needles, their gauge or tip for the prevention of PDPH. Readers can find more information in the [Characteristics of excluded studies](#) table.

Studies awaiting classification

In total we classified 18 studies as awaiting classification. We found 15 of these during the February 2015 search (Bano 2004; Buttner 1990; De Andres 1994; Fyनेface-Ogan 2006; Harrison 1994; Jager 1995; Jensen 1999; Kaul 1996; Knudsen 1998; Lim 1992; Maclean 1994; Mignonsin 1991; Palmieri 1993; Puolakka 1997; Vandana 2004). These 15 studies mainly correspond to congress summaries published before 2010, in which the available information does not allow the complete evaluation of all their risks of bias and other characteristics. Also, the fact that they were written so long ago makes the likelihood of them being published as complete articles very low. We also classified articles that could not be obtained as full texts from the authors, the Cochrane Anaesthesia, Critical and Emergency Care (ACE) Group and the Iberoamerican Cochrane Centre as awaiting assessment.

We reran the search in September 2016 and selected a further three studies for in-depth review (Castrillo 2015; Fama 2015; Hong 2015).

Ongoing studies

We classified 12 studies as ongoing (Ahmed 2012; Akdemir 2011; Bertolotto 2014; Bertolotto 2014a; Bham 2010; IRCT201009292080N4; Lorthe 2014; NCT00370604; NCT01821807; NCT02384031; Shah 2011; Shaikh 2013), given that we were only able to find summaries of their results. However, we considered that they could be subject to publication in a short time given the year of reference (after 2010). See [Characteristics of ongoing studies](#).

Risk of bias in included studies

We assessed the risk of bias of the studies in seven categories. We provide a summary of our assessment of the risk of bias of the included studies in [Figure 2](#) and [Figure 3](#).

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

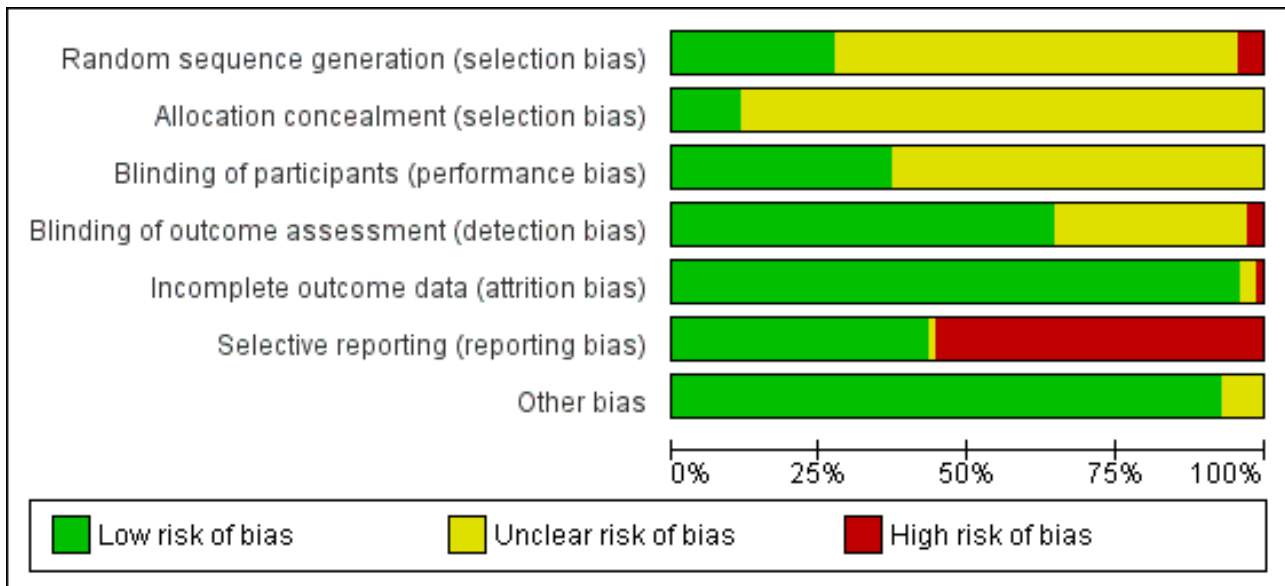


Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

| | Random sequence generation (selection bias) | Allocation concealment (selection bias) | Blinding of participants (performance bias) | Blinding of outcome assessment (detection bias) | Incomplete outcome data (attrition bias) | Selective reporting (reporting bias) | Other bias |
|------------------|---|---|---|---|--|--------------------------------------|------------|
| Amuzu 1995 | ? | ? | ? | ? | + | - | + |
| Brattebo 1995 | ? | ? | + | + | + | - | ? |
| Buettner 1993 | ? | ? | + | + | + | - | + |
| Campbell 1993 | + | ? | + | + | + | + | + |
| Chaudhry 2011 | ? | ? | ? | ? | + | - | + |
| Corbey 1997 | ? | ? | + | + | + | - | + |
| Crock 2014 | + | + | + | + | + | - | + |
| De Andres 1999 | + | ? | ? | + | + | ? | + |
| Despond 1998 | ? | ? | ? | + | + | + | + |
| Devic 1993 | ? | ? | ? | + | + | - | + |
| Fernandez 1993 | ? | ? | ? | ? | + | - | + |
| Fernandez 2003 | ? | ? | ? | + | + | - | + |
| Flaatten 2000 | ? | ? | + | + | + | - | + |
| Fox 1996 | ? | ? | ? | ? | + | + | + |
| Geurts 1990 | ? | ? | ? | + | + | - | + |
| Gonzalez 2000 | ? | ? | ? | ? | + | - | + |
| Grover 2002 | ? | ? | ? | + | + | + | + |
| Hafer 1997 | + | ? | + | + | + | + | + |
| Harrison 1993 | - | ? | ? | ? | + | - | + |
| Hopkinson 1997 | ? | + | ? | + | + | + | + |
| Imarengiaye 2002 | + | ? | + | + | + | + | + |
| Iskhaloni 1997 | - | ? | + | ? | + | + | + |

Figure 3. (Continued)

| | | | | | | | |
|------------------------|---|---|---|---|---|---|---|
| Immarengaye 2002 | + | ? | + | + | + | + | + |
| Imbelloni 1997 | - | ? | + | ? | + | + | + |
| Kang 1992 | ? | ? | + | + | + | - | ? |
| Kim 2011 | ? | ? | + | + | + | - | + |
| Kleyweg 1995 | + | + | ? | + | + | + | + |
| Kokki 1996 | ? | ? | ? | ? | + | + | + |
| Kokki 1998 | ? | ? | ? | ? | + | + | + |
| Kokki 1999 | ? | ? | + | + | + | + | + |
| Kokki 2000 | + | ? | + | - | + | + | + |
| Kuusniemi 2013 | ? | + | + | ? | + | + | + |
| Lavi 2006 | ? | ? | + | + | + | - | + |
| Lynch 1992a | ? | ? | ? | ? | + | - | + |
| Mayer 1992 | ? | ? | ? | ? | + | + | + |
| McGann 1992 | ? | ? | ? | + | + | + | + |
| Morros-Vinolas 2002 | ? | ? | ? | + | + | - | + |
| Muller 1994 | ? | ? | + | + | + | - | + |
| Oberoi 2009 | + | ? | ? | + | + | - | + |
| Pan 2004 | + | ? | ? | + | + | - | ? |
| Pedersen 1996 | ? | ? | ? | ? | + | + | + |
| Peterman 1996 | + | + | + | + | + | - | ? |
| Pippa 1995 | - | ? | ? | + | + | - | + |
| Pittoni 1995 | ? | ? | ? | + | + | + | + |
| Prager 1996 | ? | ? | ? | + | + | - | + |
| Rafique 2014 | ? | ? | ? | ? | + | - | + |
| Rasmussen 1989a | ? | ? | + | + | + | - | + |
| Rasmussen 1989b | ? | ? | + | + | + | - | + |
| Riley 2002 | ? | ? | ? | ? | + | + | + |
| Saenghirunvattana 2008 | ? | ? | ? | ? | + | + | + |
| Santanen 2004 | + | ? | + | + | - | - | + |
| Schmittner 2010 | + | + | + | + | + | - | + |
| Schmittner 2011 | + | + | ? | + | + | - | + |
| Schultz 1998 | ? | ? | ? | ? | + | + | + |

Figure 3. (Continued)

| | | | | | | | |
|-------------------|---|---|---|---|---|---|---|
| Schmittner 2011 | + | + | ? | + | + | - | + |
| Schultz 1996 | ? | ? | ? | ? | + | + | + |
| Sears 1994 | ? | ? | ? | + | + | - | + |
| Shah 2010 | + | ? | ? | + | + | - | + |
| Shaikh 2008 | + | ? | + | + | + | - | + |
| Sharma 1995 | + | ? | ? | + | + | + | + |
| Shutt 1992 | + | ? | ? | + | + | + | + |
| Smith 1994 | ? | ? | ? | + | + | + | + |
| Srivastava 2010a | ? | ? | + | ? | + | - | + |
| Srivastava 2010b | ? | ? | + | ? | + | - | + |
| Standl 2004 | + | ? | ? | + | + | + | + |
| Strupp 2001 | ? | ? | ? | ? | ? | - | + |
| Tabedar 2003 | ? | ? | ? | ? | + | - | + |
| Tarkkila 1992 | ? | ? | ? | ? | ? | + | + |
| Tarkkila 1994 | ? | ? | ? | - | + | + | + |
| Thomas 2000 | + | + | ? | + | + | + | ? |
| Tourtellotte 1972 | ? | ? | + | + | + | + | + |
| Wiesel 1993 | ? | ? | + | + | + | - | + |
| Wilkinson 1991 | ? | ? | ? | ? | + | + | + |
| Zela 1994 | ? | ? | ? | + | + | - | + |

Allocation

In 19 studies, the authors reported a valid method of randomization (Campbell 1993; Crock 2014; De Andres 1999; Hafer 1997; Imarengiaye 2002; Kleyweg 1995; Kokki 2000; Oberoi 2009; Pan 2004; Peterman 1996; Santanen 2004; Schmittner 2010; Schmittner 2011; Shah 2010; Shaikh 2008; Sharma 1995; Shutt 1992; Standl 2004; Thomas 2000), whereas this information was not clearly reported in the remaining 48 studies. As mentioned above, in three studies the authors reported an invalid method of randomization (Harrison 1993; Imbelloni 1997; Pippa 1995), and we rated them as at high risk of selection bias.

Eight studies undertook and reported adequate random allocation concealment (Crock 2014; Hopkinson 1997; Kleyweg 1995; Kuusniemi 2013; Peterman 1996; Schmittner 2010; Schmittner 2011; Thomas 2000), whereas this information was absent in the rest of the included studies.

Blinding

Twenty-six studies reported blinding of participants (Brattebo 1995; Buettner 1993; Campbell 1993; Corbey 1997; Crock 2014;

Flaatten 2000; Hafer 1997; Imarengiaye 2002; Imbelloni 1997; Kang 1992; Kim 2011; Kokki 1999; Kokki 2000; Kuusniemi 2013; Lavi 2006; Muller 1994; Peterman 1996; Rasmussen 1989a; Rasmussen 1989b; Santanen 2004; Schmittner 2010; Shaikh 2008; Srivastava 2010a; Srivastava 2010b; Tourtellotte 1972; Wiesel 1993), and we assessed them as at low risk of bias. However, the remaining 44 studies did not report this information clearly. Two studies reported an open assessment process to the researchers and assessors, and we considered them to have a high risk of bias for blinding of outcome assessment (Kokki 2000; Tarkkila 1994). Twenty-one studies did not provide enough information to assess the blinding of outcome assessment, and in the remaining 47 studies we classified the risk of bias as low. In 21 studies we classified the risk of bias as low for both blinding of participants and blinding of outcome assessment (Brattebo 1995; Buettner 1993; Campbell 1993; Corbey 1997; Crock 2014; Flaatten 2000; Hafer 1997; Imarengiaye 2002; Kang 1992; Kim 2011; Kokki 1999; Lavi 2006; Muller 1994; Peterman 1996; Rasmussen 1989a; Rasmussen 1989b; Santanen 2004; Schmittner 2010; Shaikh 2008; Tourtellotte 1972; Wiesel 1993).

Incomplete outcome data

Significant numbers of patients were lost or excluded from the final analysis of one study (Santanen 2004), and two further studies presented unclear data (Strupp 2001; Tarkkila 1992). In the studies with minimal attrition bias, we often found that the data analyses were undertaken by protocol and we took this into account for data gathering, including all the randomized patients in the denominators of the assessed groups.

Selective reporting

A full report of adverse events associated with the different types of needle is fundamental for the complete assessment of their usefulness in the assessed clinical scenarios. We found that 39 studies did not report other adverse events associated with the needles (such as paraesthesia and backache) (Amuzu 1995; Brattebo 1995; Buettner 1993; Chaudhry 2011; Corbey 1997; Crock 2014; Devcic 1993; Fernandez 1993; Fernandez 2003; Flaatten 2000; Geurts 1990; Gonzalez 2000; Harrison 1993; Kang 1992; Kim 2011; Lavi 2006; Lynch 1992a; Morros-Vinoles 2002; Muller 1994; Oberoi 2009; Pan 2004; Peterman 1996; Pippa 1995; Prager 1996; Rafique 2014; Rasmussen 1989a; Rasmussen 1989b; Santanen 2004; Schmittner 2010; Schmittner 2011; Sears 1994; Shah 2010; Shaikh 2008; Srivastava 2010a; Srivastava 2010b; Strupp 2001; Tabedar 2003; Wiesel 1993; Zela 1994), whereas the remaining studies reported at least one additional adverse event to PDPH.

Other potential sources of bias

We found other sources of bias in five studies, mainly related to the unclear role of the sponsors in the development of the research

(Brattebo 1995; Kang 1992; Pan 2004; Schmittner 2010; Thomas 2000). We identified no additional sources of bias in the remaining studies.

Effects of interventions

See: **Summary of findings for the main comparison** Traumatic needles compared to atraumatic needles for prevention of post-dural puncture headache (PDPH); **Summary of findings 2** Larger traumatic needles compared to smaller traumatic needles for prevention of post-dural puncture headache (PDPH); **Summary of findings 3** Larger atraumatic needles compared to smaller atraumatic needles for prevention of post-dural puncture headache (PDPH)

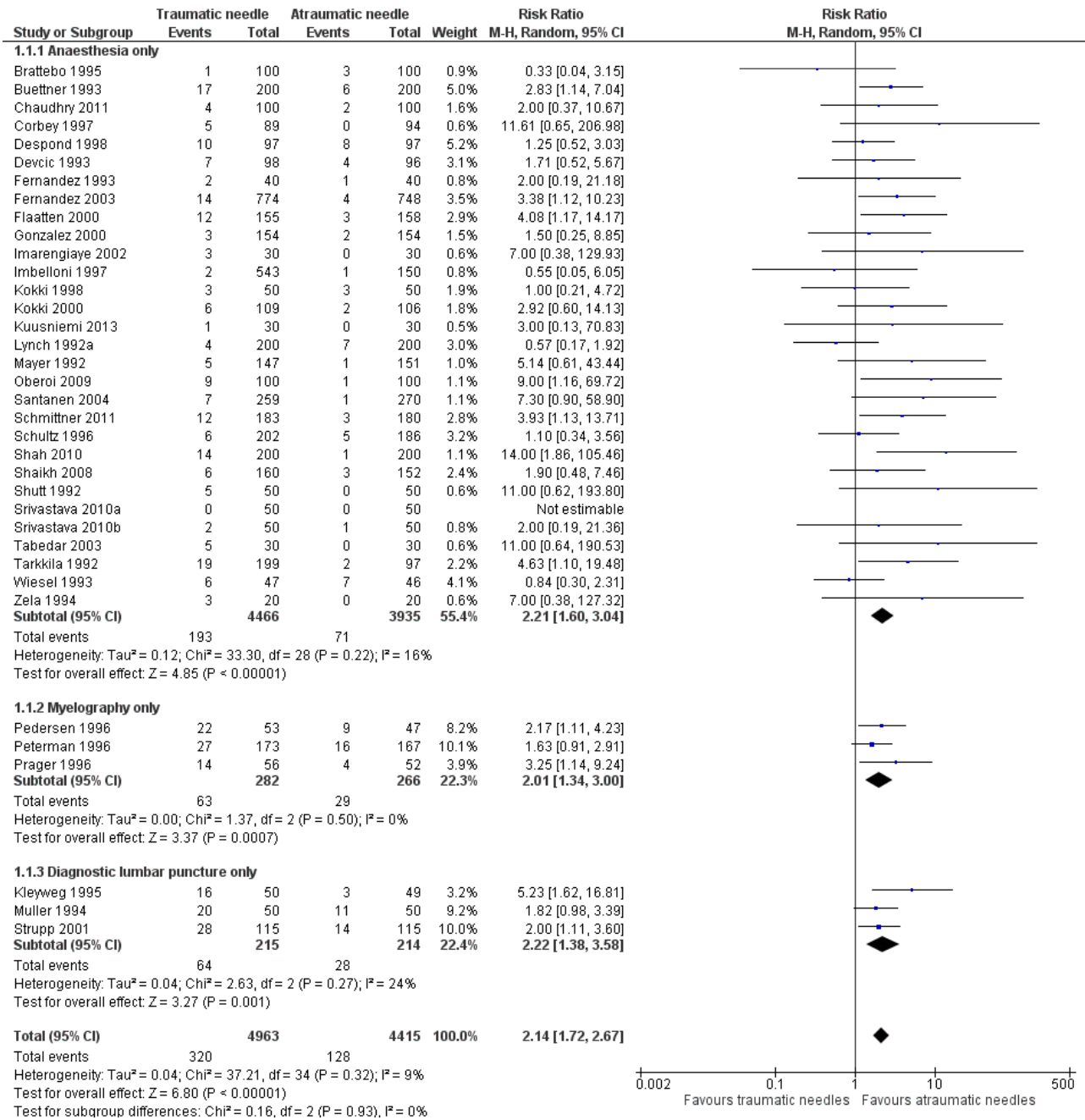
See: **Summary of findings for the main comparison**; **Summary of findings 2**; **Summary of findings 3**.

Comparison between traumatic and atraumatic needles

Primary outcome: Onset of post-dural puncture headache (PDPH)

This comparison included information from 36 studies with a total of 9378 participants and 448 events (incidence of PDPH = 4.77%). The traumatic needles showed a greater risk of PDPH compared with the atraumatic ones (risk ratio (RR) 2.14, 95% confidence interval (CI) 1.72 to 2.67), with low heterogeneity among the studies ($I^2 = 9\%$) (Analysis 1.1; Figure 4). We downgraded the quality of evidence from high to moderate due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation. (See **Summary of findings for the main comparison**).

Figure 4. Forest plot of comparison: 1 Traumatic needle versus atraumatic needle, outcome: 1.1 PDPH by indication.



In the subgroup analysis of needle gauge size, 20 studies (6213 participants) compared 22, 25 or 27 gauge traumatic and atraumatic needles (Buettner 1993; Chaudhry 2011; Corbey 1997; Despond 1998; Fernandez 1993; Flaatten 2000; Kleyweg 1995; Kuusniemi 2013; Oberoi 2009; Pedersen 1996; Peterman 1996; Prager 1996; Santanen 2004; Schmittner 2010; Shah 2010; Shaikh 2008; Srivastava 2010a; Srivastava 2010b; Strupp 2001; Tabedar 2003). We observed no significant heterogeneity between the three subgroups (I² subgroup test = 0%). The estimated RR for each of these subgroups is similar to the overall estimate reported above (22 gauge RR 2.15, 95% CI 1.56 to 2.97; 25 gauge RR 2.48, 95% CI 1.56 to 3.95; 27 gauge RR 2.87, 95% CI 1.81 to 4.53) (Analysis 1.2), with

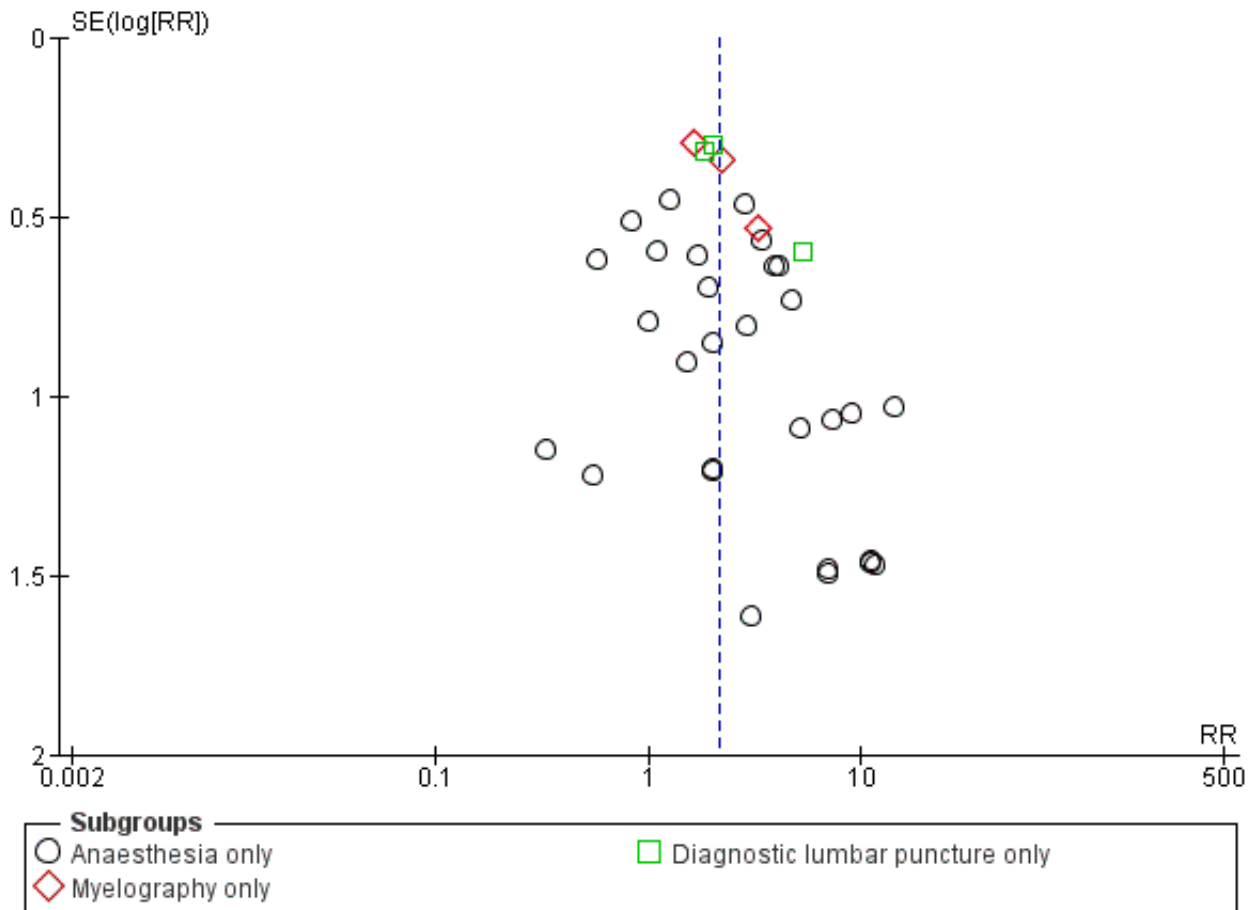
no evidence of significant heterogeneity in any of the subgroups (I² = 0%).

In the subgroup analysis performed for indication of lumbar puncture, we observed no differences in the results (I² subgroup test = 0%). Most of the studies involved anaesthesia procedures (30 studies, 8401 participants, incidence of PDPH = 3.14%). In this subgroup, the atraumatic needles presented significantly less risk of PDPH in comparison with the use of traumatic needles, similar to the analysis using the whole sample (RR 2.21, 95% CI 1.60 to 3.04; I² = 16%) (Analysis 1.1). The results were similar for the myelography by lumbar puncture subgroup (three studies:

Pedersen 1996; Peterman 1996; Prager 1996) (RR 2.01, 95% CI 1.34 to 3; $I^2 = 0\%$), and the diagnostic lumbar puncture subgroup (three studies: Kleyweg 1995; Muller 1994; Strupp 2001) (RR 2.22, 95%

CI 1.38 to 3.58; $I^2 = 24\%$). The funnel plot figure indicates slight asymmetry related to the studies with small sample sizes and null or favourable outcomes when using traumatic needles (Figure 5).

Figure 5. Funnel plot of comparison: 1 Traumatic needle versus atraumatic needle, outcome: 1.1 PDPH by indication.



In addition, we identified nine studies that only included women (mostly in labour) (Devic 1993; Imarengiaye 2002; Mayer 1992; Oberoi 2009; Pedersen 1996; Shaikh 2008; Shutt 1992; Srivastava 2010b; Tabedar 2003) and we found no studies that only included men (Analysis 1.3).

In the subgroup analysis for the type of surgery used in the anaesthesia studies, there were no significant subgroup differences between caesarean section, orthopaedic interventions and subumbilical or lower limb surgeries (test of subgroup differences: $I^2 = 12\%$). Orthopaedic surgical studies presented moderate heterogeneity ($I^2 = 55\%$), but there was no significant difference in risk between traumatic and atraumatic needles (RR 1.35, 95% CI 0.58 to 3.19). In contrast, the risk of PDPH for caesarian and other surgeries was lower in the atraumatic needle group, with no or minimal heterogeneity ($I^2 = 0\%$ and 18% , respectively) (Analysis 1.4).

In addition, in the subgroup analysis performed for body position during the lumbar puncture there was heterogeneity (I^2 subgroup test = 76.9%) (Analysis 1.5). These differences may be due to the

results observed in the subgroup of punctures administered to patients in a lateral position, in which the risk associated with traumatic needles increased significantly when compared to the global result (nine studies, RR 4.70, 95% CI 2.39 to 9.24; $I^2 = 0\%$). In the subgroup of punctures administered to sitting participants, with traumatic needles the risk ratio was similar to the analysis including the whole sample (11 studies, RR 2.11, 95% CI 1.52 to 2.94; $I^2 = 0\%$).

Finally, in the subgroup analysis performed for age range, we observed no differences (I^2 subgroup test = 0%). In this comparison, only two studies focused on children under 18 (Kokki 1998; Kokki 2000), and the estimate in this subgroup was not precise (RR 1.69, 95% CI 0.56 to 5.12; $I^2 = 0\%$), due to the low number of events (14 in total) (Analysis 1.6).

Primary outcome: adverse events/paraesthesia

Paraesthesia was reported in three studies, which included a total of 573 participants and 29 paraesthesias (incidence of paraesthesia = 5.06%) (Imarengiaye 2002; Kuusniemi 2013; Mayer 1992). We

found no differences between the use of traumatic needles versus atraumatic needles for this adverse event (RR 0.96, 95% CI 0.47 to 1.96; $I^2 = 0\%$) ([Analysis 1.7](#)). We downgraded the quality of evidence from high to moderate due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation. (See [Summary of findings for the main comparison](#)).

Primary outcome: adverse events/backache

Backache was reported in 12 studies ([Brattebo 1995](#); [Chaudhry 2011](#); [Flaatten 2000](#); [Imarengiaye 2002](#); [Imbelloni 1997](#); [Kokki 1998](#); [Kokki 2000](#); [Kuusniemi 2013](#); [Lynch 1992a](#); [Mayer 1992](#); [Schultz 1996](#); [Thomas 2000](#)), including a total of 3027 participants and 454 backache events (incidence of backache = 14.9%). We found no differences between the use of traumatic needles versus atraumatic needles for this adverse event (RR 0.94, 95% CI 0.78 to 1.13; $I^2 = 14\%$) ([Analysis 1.8](#)). We downgraded the quality of evidence from high to moderate due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation. (See [Summary of findings for the main comparison](#)).

Secondary outcome: severe PDPH

For this comparison, we analysed the information taken from 24 studies with a total of 6420 participants and 87 events (incidence of severe PDPH = 1.35%) ([Brattebo 1995](#); [Chaudhry 2011](#); [Corbey 1997](#); [Despond 1998](#); [Devic 1993](#); [Fernandez 1993](#); [Fernandez 2003](#); [Imbelloni 1997](#); [Kokki 1998](#); [Lynch 1992a](#); [Mayer 1992](#); [Muller 1994](#); [Pedersen 1996](#); [Peterman 1996](#); [Prager 1996](#); [Shah 2010](#); [Shaikh 2008](#); [Shutt 1992](#); [Srivastava 2010a](#); [Srivastava 2010b](#); [Strupp 2001](#); [Tabedar 2003](#); [Tarkkila 1992](#); [Wiesel 1993](#)). Nine studies presented zero events in both arms and they do not count for the RR analysis ([Brattebo 1995](#); [Fernandez 1993](#); [Imbelloni 1997](#); [Kokki 1998](#); [Lynch 1992a](#); [Mayer 1992](#); [Shah 2010](#); [Srivastava 2010a](#); [Srivastava 2010b](#)). A sensitivity analysis measuring the risk difference (RD) allowed us to include all the studies and presents a similar risk between traumatic and atraumatic needles, with considerable heterogeneity (RD 0.00, 95% CI 0.00 to 0.01; $I^2 = 42\%$). The heterogeneity observed in this analysis is due to the study focused on diagnostic lumbar punctures ([Muller 1994](#)). Excluding this study eliminates the heterogeneity completely and maintains the non-significant results ([Analysis 1.9](#)). We downgraded the quality of evidence from high to low due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation, as well the presence of the aforementioned considerable heterogeneity. (See [Summary of findings for the main comparison](#)).

Secondary outcome: any headache

For this comparison, we analysed the information taken from 18 studies with a total of 4104 participants and 636 events (general incidence of any headache = 15.4%) ([Brattebo 1995](#); [Buettner 1993](#); [Chaudhry 2011](#); [Corbey 1997](#); [Despond 1998](#); [Flaatten 2000](#); [Fox 1996](#); [Imarengiaye 2002](#); [Kokki 1998](#); [Kuusniemi 2013](#); [Lynch 1992a](#); [Mayer 1992](#); [Peterman 1996](#); [Prager 1996](#); [Saenghirunvattana 2008](#); [Santanen 2004](#); [Shutt 1992](#); [Thomas 2000](#)). The estimated RR for this outcome was 1.35 (95% CI 1.17 to 1.57) ([Analysis 1.10](#)), with minimal heterogeneity ($I^2 = 5\%$). We downgraded the quality of evidence from high to moderate due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation. (See [Summary of findings for the main comparison](#)).

Comparison between larger gauge traumatic needles versus smaller gauge traumatic needles

Primary outcome: Onset of PDPH

For this comparison, we analysed the information taken from 10 studies with a total of 2288 participants and 185 events (incidence of PDPH = 8.09%) ([Grover 2002](#); [Kang 1992](#); [Kim 2011](#); [Kokki 1996](#); [Pippa 1995](#); [Rafique 2014](#); [Schmittner 2010](#); [Shah 2010](#); [Shaikh 2008](#); [Tarkkila 1994](#)). We decided against overall pooling of results because a needle gauge could be considered small in one comparison but large in another (for example, a 25 gauge needle could be considered as smaller in a 23 versus 25 gauge comparison, but larger in a 25 versus 27 gauge comparison). Instead, we grouped and analysed studies according to the gauges evaluated (23 versus 25 gauge, 25 versus 27 gauge, 25 versus 29 gauge, 26 versus 27 gauge and 21 versus 25 gauge). The RRs for these comparisons ranged from 0.86 to 6.47 and they were not statistically significant except for a single study in the 26 versus 27 gauge subgroup (23 versus 25 gauge RR 2.08, 95% CI 0.20 to 21.55; 25 versus 27 gauge RR 1.82, 95% CI 0.98 to 3.39; 25 versus 29 gauge RR 2.13, 95% CI 0.46 to 9.78; 26 versus 27 gauge RR 6.47, 95% CI 2.55 to 16.43; 21 versus 25 gauge RR 0.86, 95% CI 0.30 to 2.44) ([Analysis 2.1](#)).

The results obtained when comparing 29 with 25 gauge needles present the greatest heterogeneity ($I^2 = 69\%$; [Analysis 2.1](#)). We downgraded the quality of evidence from high to low due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation, as well as imprecision. (See [Summary of findings 2](#)).

All the studies included in this comparison were undertaken using anaesthesia and included a mixed population, which is the reason why we did not carry out a subgroup analysis for indication for lumbar puncture or gender. Analysis by type of surgery showed no subgroup differences. The estimates presented in the caesarean section subgroup and the orthopaedic surgeries subgroup showed no differences in the risk of PDPH with the use of traumatic needles of any gauge ([Analysis 2.2](#)). In the analyses performed for age subgroups, we found no differences by subgroup. In the studies in children and the over 60 years age group there were no significant differences in the risk of PDPH between the use of larger or smaller gauges; however, this information was derived from only one study for each of the subgroups mentioned ([Analysis 2.3](#)). In studies in the no age distinction group, we found a significantly higher risk of PDPH for larger gauge needles (RR 2.09, 95% CI 1.11 to 3.95), but with significant heterogeneity ($I^2 = 69\%$, $P = 0.002$). There were no significant differences in the risk of PDPH between the use of larger or smaller gauges in the subgroup analyses by body position ([Analysis 2.4](#)).

Primary outcome: adverse events/paraesthesia

No studies in this comparison reported this outcome.

Primary outcome: adverse events/backache

Backache was reported in three studies that included a total of 948 participants and 188 events (backaches) (incidence of backache = 19.8%) ([Grover 2002](#); [Kang 1992](#); [Tarkkila 1994](#)). The RRs for these comparisons ranged from 0.81 to 2.00 and were not statistically significant (25 versus 29 gauge RR 2.00, 95% CI 1.00 to 4.02; 26 versus 27 gauge RR 0.91, 95% CI 0.66 to 1.24; 25 versus 27 gauge RR 0.81, 95% CI 0.44 to 1.49) ([Analysis 2.5](#)). We downgraded the quality

of evidence from high to moderate due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation. (See [Summary of findings 2](#)).

Secondary outcome: severe PDPH

For this outcome, we analysed the information from six studies with a total of 1128 participants and three events (incidence of severe PDPH = 0.2%) ([Grover 2002](#); [Kim 2011](#); [Pippa 1995](#); [Rafique 2014](#); [Shah 2010](#); [Shaikh 2008](#)). We grouped and analysed studies according to the gauges evaluated (23 versus 25 gauge, 25 versus 27 gauge, 25 versus 29 gauge and 21 versus 25 gauge). We conducted analyses with risk differences, which allowed us to incorporate all studies in the estimate. The RDs for these comparisons were 0.00 in all cases and were not statistically significant (23 versus 25 gauge RD 0.00, 95% CI -0.07 to 0.07; 25 versus 27 gauge RD 0.00, 95% CI -0.01 to 0.01; 25 versus 29 gauge RD 0.00, 95% CI -0.04 to 0.04; 21 versus 25 gauge RD 0.00, 95% CI -0.02 to 0.02) ([Analysis 2.6](#)). We downgraded the quality of evidence from high to low due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation, as well as the few events reported. (See [Summary of findings 2](#)).

Secondary outcome: any headache

For this comparison, we analysed the information taken from three studies with a total of 771 participants and 195 events (incidence of any headache = 25.2%) ([Kang 1992](#); [Kim 2011](#); [Kokki 1996](#)). The RRs for these comparisons ranged from 0.75 to 1.56 and were not statistically significant (23 versus 25 gauge RR 1.29, 95% CI 0.98 to 1.68; 25 versus 29 gauge RR 1.56, 95% CI 0.86 to 2.82; 26 versus 27 gauge RR 0.75, 95% CI 0.18 to 3.07) ([Analysis 2.7](#)). We downgraded the quality of evidence from high to moderate due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation. (See [Summary of findings 2](#)).

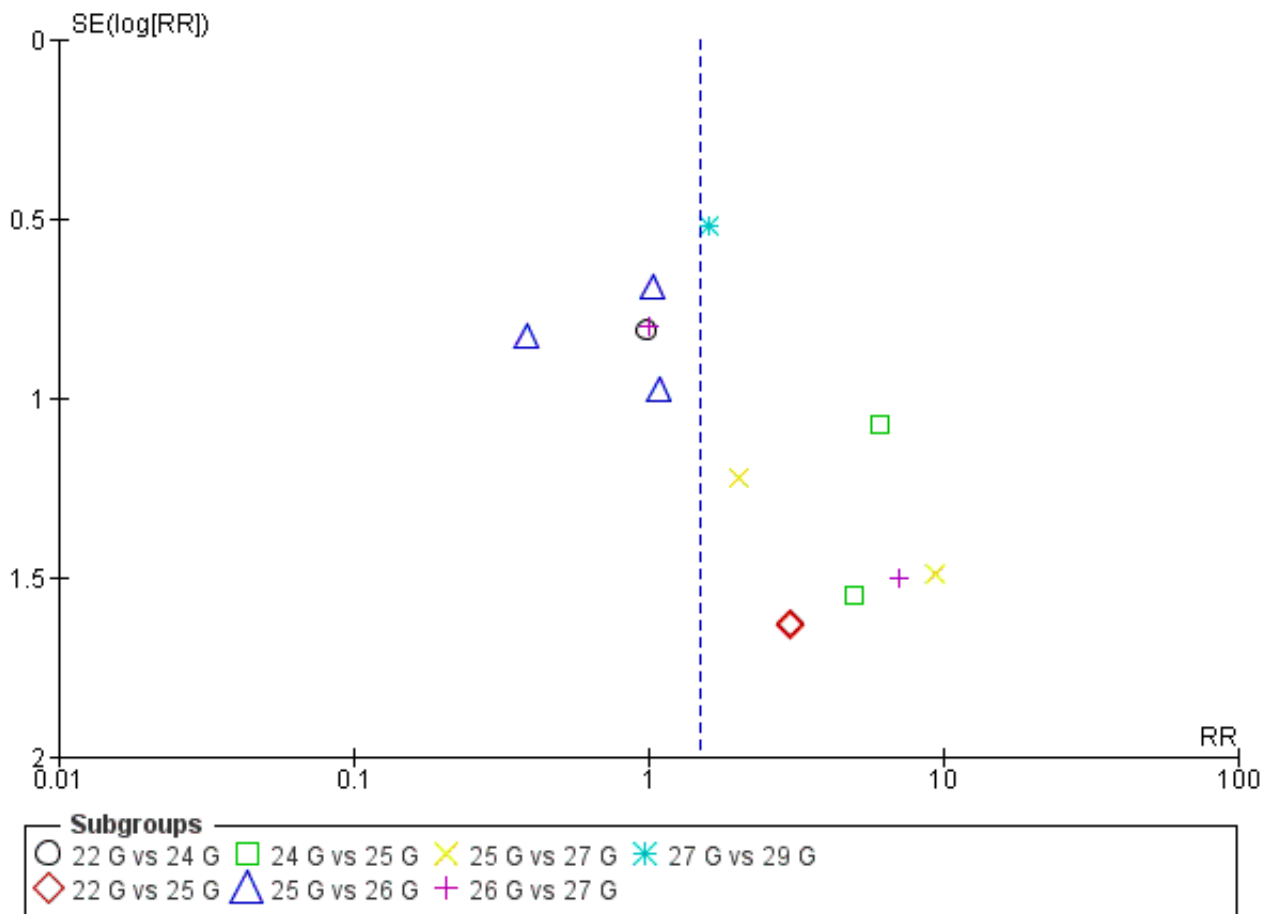
Comparison between larger gauge atraumatic needles versus smaller gauge atraumatic needles

This comparison involved all studies that compared different gauges of atraumatic needles. From each study we selected only comparisons between larger gauge versus smaller gauge needles for this analysis.

Primary outcome: Onset of PDPH

For this comparison, we analysed the information taken from 13 studies with a total of 3134 participants and 75 events (incidence PDPH = 2.33%) ([Amuzu 1995](#); [Campbell 1993](#); [De Andres 1999](#); [Hopkinson 1997](#); [Kokki 1998](#); [Morros-Vinolas 2002](#); [Pan 2004](#); [Pittoni 1995](#); [Sears 1994](#); [Shah 2010](#); [Sharma 1995](#); [Shutt 1992](#); [Smith 1994](#)). As we mentioned above, we decided against overall pooling of results because a needle gauge could be considered small in one comparison but large in other (for example, a 25 gauge needle could be considered as smaller in a 23 versus 25 gauge comparison, but larger in a 25 versus 27 gauge comparison). We found no significant differences in the analyses comparing gauges (22 versus 24 gauge RR 0.98, 95% CI 0.20 to 4.81; 22 versus 25 gauge RR 3.00, 95% CI 0.32 to 28.50; 24 versus 25 gauge RR 5.62, 95% CI 1.00 to 31.67; 25 versus 26 gauge RR 0.76, 95% CI 0.30 to 1.90; 25 versus 27 gauge RR 3.72, 95% CI 0.59 to 23.64; 26 versus 27 gauge RR 1.79, 95% CI 0.30 to 10.73; 27 versus 29 gauge RR 1.59, 95% CI 0.58 to 4.37) ([Analysis 3.1](#)). We found few incidence data for each of the gauge subgroups mentioned and we did not find benefits derived from the use of smaller atraumatic needles compared to larger ones. The funnel plot figure does not show any asymmetry in relation to the data classified by gauge ([Figure 6](#)). We downgraded the quality of evidence from high to low due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation, as well as imprecision. (See [Summary of findings 3](#)).

Figure 6. Funnel plot of comparison: 3 Atraumatic needles: different gauges, outcome: 3.1 PDPH major gauge versus minor gauge by number.



The studies included in this comparison had participants with indication for anaesthesia. Analyses by type of surgery showed no effect derived from the type of needles with respect to the presentation of PDPH (Analysis 3.2). The subgroup analyses performed for gender and body position also showed no differences in the results for PDPH.

Primary outcome: adverse events/paraesthesia

Two studies that included a total of 439 participants reported 51 paraesthesias (incidence of paraesthesia = 11.6%) (Hopkinson 1997; Sharma 1995). We found no statistically significant difference in paraesthesia related to the size of gauge used; the pooled estimate presented considerable heterogeneity (RR 2.19, 95% CI 0.31 to 15.30; $I^2 = 72%$) (Analysis 3.5). We downgraded the quality of evidence from high to moderate due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation. (See Summary of findings 3).

Primary outcome: adverse events/backache

Four studies including a total of 526 participants reported 105 incidences of backache (incidence = 19.9%) (De Andres 1999; Kokki 1998; Sharma 1995; Smith 1994). The RRs for these comparisons ranged from 0.95 to 5.00 and they were not statistically significant (25 versus 29 gauge RR 5.00, 95% CI 0.62 to 40.28; 26 versus 27 gauge

RR 1.29, 95% CI 0.69 to 2.40; 25 versus 27 gauge RR 0.95, 95% CI 0.56 to 1.61; 25 versus 26 gauge RR 1.19, 95% CI 0.58 to 2.42) (Analysis 3.6). We downgraded the quality of evidence from high to moderate due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation. (See Summary of findings 3).

Secondary outcome: severe PDPH

For this outcome, we analysed the information taken from eight studies with a total of 1983 participants and five events (incidence of severe PDPH = 0.25%) (Campbell 1993; De Andres 1999; Morros-Vinoles 2002; Pan 2004; Pittoni 1995; Sears 1994; Sharma 1995; Smith 1994). We grouped and analysed studies according to the gauges evaluated (22 versus 24 gauge, 22 versus 25 gauge, 24 versus 25 gauge, 25 versus 26 gauge, 25 versus 27 gauge, 26 versus 27 gauge and 27 versus 29 gauge). We conducted analyses with RDs, which allowed us to incorporate all studies in the estimate. The RDs for these comparisons ranged from 0.00 to 0.01 and they were not statistically significant (22 versus 24 gauge RD 0.00, 95% CI -0.01 to 0.01; 22 versus 25 gauge RD 0.00, 95% CI -0.02 to 0.02; 24 versus 25 gauge RD 0.01, 95% CI -0.02 to 0.03; 25 versus 26 gauge RD 0.01, 95% CI -0.01 to 0.03; 25 versus 27 gauge RD 0.01, 95% CI -0.02 to 0.04; 26 versus 27 gauge RD 0.00, 95% CI -0.02 to 0.02; 27 versus 29 gauge RD 0.00, 95% CI -0.01 to 0.01) (Analysis 3.7). We downgraded the

quality of evidence from high to low due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation, as well as imprecision. (See [Summary of findings 3](#)).

Secondary outcome: any headache

For this outcome, we analysed the information taken from seven studies with a total of 1791 participants and 206 events (incidence of any headache = 11.5%) ([Campbell 1993](#); [Hopkinson 1997](#); [Morros-Vinolas 2002](#); [Pan 2004](#); [Pittoni 1995](#); [Sharma 1995](#); [Smith 1994](#)). We grouped and analysed studies according to the gauges evaluated (22 versus 25 gauge, 24 versus 25 gauge, 25 versus 26 gauge, 25 versus 27 gauge and 27 versus 29 gauge). The RRs for these comparisons ranged from 1.13 to 2.17 and they were not statistically significant (22 versus 25 gauge RR 2.17, 95% CI 0.85 to 5.51; 24 versus 25 gauge RR 1.17, 95% CI 0.49 to 2.77; 25 versus 26 gauge 1.13, 95% CI 0.65 to 1.99; 25 versus 27 gauge RR 1.87, 95% CI 0.65 to 5.39; 27 versus 29 gauge RR 1.80, 95% CI 0.85 to 3.83) ([Analysis 3.8](#)). We downgraded the quality of evidence from high to moderate due to risk of bias issues such as unclear reporting of allocation concealment and random sequence generation. (See [Summary of findings 3](#)).

Sensitivity analysis

In accordance with our protocol, we selected studies with a low risk of bias for allocation concealment, blinding of outcome assessment and presence of incomplete data (attrition bias). Six studies fulfilled these requirements for the main outcome of onset of PDPH ([Hopkinson 1997](#); [Kleyweg 1995](#); [Peterman 1996](#); [Schmittner 2010](#); [Schmittner 2011](#); [Thomas 2000](#)). Only three of them could be analysed together as they made similar comparisons (traumatic needles versus atraumatic needles) and possessed data regarding the main outcome (PDPH) ([Kleyweg 1995](#); [Peterman 1996](#); [Schmittner 2011](#)). The analysis of these three studies showed significant risk of PDPH when using traumatic needles (RR 2.78, 95% CI 1.26 to 6.15), but with moderate heterogeneity ($I^2 = 51%$) ([Analysis 1.11](#)).

DISCUSSION

Summary of main results

We assessed the evidence from 66 studies in 17,067 participants, which showed several important aspects for each comparison analysed.

Firstly, in the comparison between traumatic versus atraumatic needles, after analysing information from 9378 participants, we found that the risk of post-dural puncture headache (PDPH) is almost doubled when a traumatic needle is used (risk ratio (RR) 2.14, 95% confidence interval (CI) 1.72 to 2.67). The number of participants required to be treated with atraumatic needles to prevent an additional new episode of PDPH (NNTB) is 24 (95% CI 20 to 30 participants undergoing lumbar punctures). We observed these results regardless of lumbar puncture indication, gender, age or risk of bias issues. Likewise, we found that only three of the studies included in this review reported paraesthesia as a possible primary outcome after lumbar puncture, with an incidence of 5.06% ([Imarengiaye 2002](#); [Kuusniemi 2013](#); [Mayer 1992](#)). We identified no difference in the occurrence of paraesthesia between traumatic and atraumatic needles. This may be due to the low number of events. Twelve studies reported backache, with an incidence of 14.9% ([Brattebo 1995](#); [Chaudhry 2011](#); [Flaatten 2000](#); [Imarengiaye 2002](#);

[Imbelloni 1997](#); [Kokki 1998](#); [Kokki 2000](#); [Kuusniemi 2013](#); [Lynch 1992a](#); [Mayer 1992](#); [Schultz 1996](#); [Thomas 2000](#)). Despite the higher number of events, we found no important differences between the two needle types. Finally, we found significant differences in the risk of any headache in this comparison (RR 1.35, 95% CI 1.17 to 1.57), but not in the risk of severe PDPH or backache.

Secondly, with respect to the comparison of different gauges of traumatic needles, after analysing the information from 2288 participants of both genders, we found heterogeneous results about the risk associated with larger gauges versus smaller gauges. Overall, studies comparing various sizes of large and small gauges showed no significant differences in the effects on risk of PDPH. We analysed this information by factors such as type of surgery, age and body position, but these factors did not explain the heterogeneity. In addition, we found a scarcity of data related to adverse events: only three studies reported backache and found no differences in risk according to gauge ([Grover 2002](#); [Kang 1992](#); [Tarkkila 1994](#)).

Finally, in the comparison of gauges for atraumatic needles, after analysing the information from 3134 participants, we found a large number of gauge comparisons, all with few data. Studies comparing various gauge sizes (large and small) showed no significant differences in the effects on risk of PDPH. Similarly, we did not find significant differences in adverse events, severe PDPH or any headache.

Overall completeness and applicability of evidence

We carried out a thorough search and identified a reasonable number of studies evaluating the effectiveness and safety of different gauges and needle types for the prevention of PDPH. The 66 studies included in the numerical analysis enrolled 17,067 participants. Needle tips, gauges, indications for lumbar puncture and operators all varied and participants were from different age groups and genders. The studies were also conducted over a long period of time. The included studies represent the characteristics of the population usually undergoing lumbar puncture procedures either for diagnostic or therapeutic reasons, which is important for the external validity of this review and should increase the applicability of the results.

The systematic search for study selection and data extraction that we undertook should have minimized the likelihood of missing relevant studies. Also, the funnel plots we produced were highly symmetric, suggesting that a minimal chance of having missed relevant studies and that there is no evidence of publication bias.

The evidence presented consistently showed benefits derived from the use of atraumatic needles and is sufficient to address the main objectives of this review. However, new studies (including those that are ongoing) could help to increase the precision of the different measures of effect, as well as to clarify the actual risk in some selected subgroups (for instance, the comparison between traumatic needles by gauge). Similarly, we think that new studies could also help to provide additional data on adverse events related to the use of needles, or even information about technical difficulties related to the use of smaller gauge needles.

Finally, we did not find any information related to gauge differences in diagnostic and myelography settings. New studies might help

to identify any benefits related to greater gauge versus finer gauge needles in these specific scenarios.

Quality of the evidence

We considered the quality of the evidence for the first comparison (traumatic versus atraumatic needles) to be moderate for most of the outcomes assessed. We downgraded the quality of the evidence in these cases due to lack of reporting of aspects related to randomization, such as random sequence generation and allocation concealment, which made it difficult for us to interpret the risk of bias for the included studies. Given that it is not possible to blind the personnel to the needle used, we only assessed the blinding of participants. However, we found that participant blinding was only reported in 50% of included studies. Likewise, we found that a considerable number of studies did not report other adverse events associated with the use of needles, for example paraesthesia and backache. The quality of the evidence for the secondary outcome of severe PDPH was also downgraded from high to low due to both the presence of risk of bias and inconsistency (42%), which was caused by one study focusing on diagnostic lumbar punctures. The secondary outcome 'any headache' was affected by similar reporting problems to those previously mentioned for the primary outcomes and we therefore reduced the quality of this evidence to moderate from high.

The primary outcomes for the second comparison (larger gauge versus smaller gauge traumatic needles) were also affected by concerns about risk of bias and we downgraded the quality of the evidence from high to moderate. The secondary outcomes were not affected by heterogeneity but we considered the quality of the evidence to be moderate due to concerns about risk of bias, similar to those related to the primary outcomes.

Finally, we considered the quality of evidence for the outcomes in the third comparison (larger gauge versus smaller gauge atraumatic needles) to be moderate for most of the outcomes, due to imprecision and risk of bias issues.

Potential biases in the review process

We followed the methodology for systematic reviews outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

This review was comprehensive in identifying clinical trials addressing the issue of the effectiveness and safety of needle gauges and tips in the prevention of post-dural puncture headache. However, 18 studies did not provide enough information to be able to classify them as included or excluded, because they were published only as conference proceedings, or because we did not have access to the full texts when we were completing this review. Also, we considered 12 of the studies to be 'ongoing' due to their date of publication as abstracts. We may be able to decide whether or not to include these studies once they have been published as full texts.

A potential source of bias in the review process was that we made some decisions about the analysis after seeing the data from the included studies. First, in order to assess adverse events, we had to define those events (except PDPH) related to the use of needles in anaesthesia, myelography and diagnostic lumbar punctures after the publication of the protocol. Most of the events usually reported in studies, such as nausea and vomiting, were already included

in the definition of PDPH; we therefore selected paraesthesia and backache as the two most important adverse events related to the intervention assessed. In this review, we did not consider other events related to technical difficulties with the use of smaller needles; for example, the number of attempts before a successful puncture or the anaesthesiologist's satisfaction regarding the use of these needles. Secondly, we did not expect to encounter any unit of analysis issues, as we do not expect to find cross-over studies or cluster-randomized trials. However, we did identify one cross-over study with our search strategies. In order to avoid bias in the development of our review, we did not include numerical results related to this study in our analyses because we consider that the patients' history of PDPH could be an important factor to take into account when analysing the possibility of a new episode of PDPH. In a future update we can examine other analysis options in order to try to deal with this information. Finally, we modified the subgroup analysis for age due to heterogeneity in the reporting of this outcome. We classified studies into three groups: a) only children; b) no distinctions about age; c) 60 years or more, and we analysed the numerical information in these three new categories. Although we planned to present risk ratios, in cases where there were no events in one of the arms we presented risk differences. However, we also presented risk ratios in these cases as a sensitivity analysis.

It is also important to mention as a potential source of bias in the review process the fact that we reran the search strategy in September 2016 and found three studies of interest. We added these studies to the list of [Studies awaiting classification](#) and we will incorporate them into the review during a review update.

Agreements and disagreements with other studies or reviews

The literature includes a number of examples of reviews that have evaluated several issues related to the use of needles for different purposes. One of our identified studies included a meta-analysis of other trials using 27 gauge atraumatic versus 27 gauge traumatic needles, which found a RR of developing PDPH of 0.38 (95% CI 0.19 to 0.75) in the atraumatic group compared to the traumatic group (Flaatten 2000). In our review, we found an effect in all the gauges assessed (22, 25 and 27 gauge), confirming the conclusions presented by these authors. Likewise, Halpern 1994 compared noncutting spinal needles (Sprotte or Whitacre) with cutting needles and larger spinal needles with smaller needles. They found a reduction in the incidence of severe PDPH when noncutting spinal needles were used rather than cutting needles (odds ratio (OR) 0.26, 95% CI 0.11 to 0.62) and no important difference in back pain. They also found a reduction in severe PDPH when a small spinal needle was used compared with a large needle of the same type (OR 0.18, 95% CI 0.09 to 0.36). There was no important difference in the incidence of back pain. The direction of the effect is consistent with our findings.

Bradbury et al assessed different methods to decrease accidental dural punctures and interventions to reduce PDPH following these punctures in parturients (Bradbury 2013). They identified 14 randomized controlled trials with 11,536 epidural insertions, finding that prophylactic epidural blood patch, lateral positioning of the epidural needle bevel upon insertion, use of Sprotte needles, epidural morphine and administration of cosyntropin reduce PDPH. In the same subgroup of participants, Choi et al found that the use of atraumatic spinal needles with a smaller

gauge decreased the risk of PDPH in the obstetric population (Choi 2003). However, the authors remarked that the incidence of this complication in labour is considerable, with an estimate of 52.1% accidental dural punctures (95% CI 51.4% to 52.8%). We found similar benefits in the subgroup of obstetric participants when atraumatic needles were used.

Other reviews included other factors related to needles but these are not assessed in the present review. In 2006, Richman assessed the effect of lumbar puncture needle bevel direction on the incidence of post-dural puncture headache in adult participants when cutting needles were used (Richman 2006). The authors also evaluated the use of a parallel versus a perpendicular orientation during needle insertion. The results derived from five trials suggested that a parallel/longitudinal insertion resulted in a lower incidence of PDPH (OR 0.29, 95% CI 0.17 to 0.50). Our review did not include information about bevel orientation but we noticed that the needles used in spinal anaesthesia are larger than those usually used. Likewise, Tung et al in 2012 developed a decision-analytic model to determine the cost of diagnostic lumbar punctures using atraumatic versus traumatic needles (Tung 2012). The authors assumed a healthcare system perspective and determined that the difference in estimated costs between the two needles was the economic outcome measure selected. They found that lumbar punctures performed with an atraumatic needle are associated with an average cost saving of USD 26.07 per patient. Average total healthcare costs with traumatic needles are USD 192.15 versus 166.08 using atraumatic needles in diagnostic lumbar punctures.

AUTHORS' CONCLUSIONS

Implications for practice

There is moderate-quality evidence that atraumatic needles reduce the risk of post-dural puncture headache (PDPH) without increasing adverse events such as paraesthesia or backache. The moderate quality of the evidence suggests that further research is likely to have an important impact on our confidence in this estimate. Health professionals in charge of lumbar punctures in daily clinical practice (anaesthesiologists, neurologists or radiologists, among others) could choose to use atraumatic needles in order to avoid the onset of PDPH.

We found variable results when we assessed the risk associated with larger versus smaller needle gauges, which precludes conclusions about needle size. However, our results for anaesthesia procedures found benefits in terms of the prevention of 'any headache' with the use of fine-gauge needles. It is important to point out, however, that practitioners would need to be well trained in the use of such needles in order to avoid additional complications such as an increased number of attempts.

Implications for research

The relative benefit of using atraumatic needles is modest and their widespread use should be determined by additional economic evaluations, which assess the costs of newer needles against the excess cases of post-dural puncture headache from traumatic needles. Likewise, because we only found moderate-quality evidence for two adverse events (paraesthesia and backache), we think that large, well-designed cohort studies are necessary to evaluate the occurrence of other neurological complications from the use of atraumatic needles. Due to the low quality of the evidence related to severe PDPH, additional studies are needed to determine which factors are associated with its occurrence and the interaction of these factors with needle tip designs. This is important because while non-severe case of PDPH will continue to occur, it is the cases of severe PDPH that are the largest burden to patients and account for the extra healthcare costs.

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Wu YW, Hui YL, Tan PP. Incidence of post-dural puncture headache with 25-gauge Quincke spinal needle. *Anaesthesiologica Sinica* 1991;**29**(1):538-41. [PUBMED: 1758245]

References to other published versions of this review
Arevalo-Rodriguez 2013a

Arevalo-Rodriguez I, Muñoz L, Arevalo Jimmy J, Ciapponi A, Roqué iFM. Needle gauge and tip designs for preventing post-dural puncture headache (PDPH). *Cochrane Database of Systematic Reviews* 2013, Issue 10. [DOI: [10.1002/14651858.CD010807](https://doi.org/10.1002/14651858.CD010807); CD010807]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES
Characteristics of included studies [ordered by study ID]
Amuzu 1995

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group, 2 arms • Country: USA • Multisite: no • Needle tip used: atraumatic point • Needle diameter used: 26 vs 25 • Number of attempts: 1.81 ± 0.13 vs 1.55 ± 0.08 • Procedure: anaesthesia • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: unknown • Type of anaesthetic: hyperbaric bupivacaine + fentanyl |
| Participants | <p>1. 208 patients enrolled (obstetric patients undergoing elective caesarean section)</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • Atraucan spinal needle-ASN (102, 49.03%) • Whitacre spinal needle-WSN (106, 50.96%) <p>2. No randomized patients were excluded</p> <p>3. No patients lost to follow-up</p> <p>4. Main characteristics of patients: unclear. "There were no significant differences between the patients in the two groups in terms of age, weight, height, previous history of c-section and past history of headache"</p> |
| Interventions | <ol style="list-style-type: none"> 1. ASN group (intervention): 26 G. "the spinal needle was advanced through a 1% lidocaine skin wheal at the L2-3 or L3-4 interspace until CSF return occurred". "patient (was) placed in the sitting position". 2. WSN group (control): 25 G. "the spinal needle was advanced through a 1% lidocaine skin wheal at the L2-3 or L3-4 interspace until CSF return occurred". "Patient (was) placed in the sitting position" |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Number of attempts to achieve successful dural puncture |

Amuzu 1995 (Continued)

3. Surgical anaesthesia
4. Level of sensory blockade

- Notes
1. Trial registration: not stated
 2. Funder: not stated
 3. Role of funder: not stated
 4. A priori sample size estimation: no
 5. Conducted: not stated
 6. Declared conflicts of interest: no

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Quote: "were randomly assigned to..." (page 150) |
| Allocation concealment (selection bias) | Unclear risk | Quote: "were randomly assigned to..." (page 150) |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Brattebo 1995

- Methods
- Design: parallel-group, 2 arms
 - Country: Norway
 - Multisite: no
 - Needle tip used: atraumatic vs traumatic
 - Needle diameter used: 24 vs 27
 - Number of attempts (> 2) = 7% (95% CI 4 to 11)
 - Procedure: anaesthesia
 - Site of the puncture: L2 to L5
 - Training level of those who administered the puncture: unknown
 - Median or paramedian technique: unknown
 - Type of anaesthetic: lidocaine or bupivacaine
 - Patient position: sitting or lateral supine position
- Participants
1. 200 patients enrolled (patients scheduled for surgery in the lower part of the body)

Brattebo 1995 (Continued)

- Patients randomized to:
 - * Quincke 27 G (100, 50%)
 - * Sprotte 24 G (100, 50%)
- 2. 2 patients randomized to Quincke group were excluded due to failures in identification of subarachnoidal space
- 3. No patients lost to follow-up
- 4. Main characteristics of patients:
 - Gender - male (number): Quincke group: 52; Sprotte group: 49
 - Age (mean, SD): Quincke group: 29.6, 7.5; Sprotte group: 29, 7.8
 - Position- lateral supine (number): Quincke group: 93; Sprotte group: 94
 - Site of the puncture L3-4 (number): Quincke group: 75; Sprotte group: 75
 - Number of attempts at dural puncture > 2: Quincke group: 9; Sprotte group: 4

| | |
|---------------|---|
| Interventions | 1. Quincke 27 G = disposable 27 G Quincke bevelled needle (Becton Dickinson Yale). The bevel was kept parallel to the spine. 2. Sprotte 24 G = 24 G needle (Pajunk) 3. Co-interventions: most patients received midazolam 1 mg to 5 mg as premedication |
| Outcomes | Outcomes were not classified as primary or secondary 1. PDPH: defined as a position dependent headache limiting daily activities 2. Severe PDPH: need for an epidural blood patch 3. Technical ease of the needle insertion: described on an arbitrary 3-point scale, from easy to difficult 4. Back pain 5. Non-specific headache 6. Number of puncture attempts 7. Spread of anaesthesia: adequate or insufficient |
| Notes | 1. Trial registration: not stated 2. Funder: Medisinsk forskning I Finnmark 3. Role of funder: financial support 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Quote: "... were randomised into two groups after written informed consent was obtained" (page 535) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "The patients did not know which needle was used" |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "After 72 hours all patient were contacted personally or by telephone, and questioned in a structured interview about problems or symptoms which could have been a result of the spinal anaesthetic. This interview was done by a nurse anaesthetist who was unaware of which needle that had been used, and whether any problems had occurred during the anaesthetic." (page 536) |

Brattebo 1995 (Continued)

| | | |
|--|--------------|--|
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Unclear risk | The role of the funder during the study was unclear (Medisinsk forskning I Finnmark) |

Buettner 1993

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group, 2 arms • Country: Germany • Multisite: no • Needle tip used: atraumatic vs traumatic • Needle diameter used: 25 • Number of attempts: unknown • Procedure: anaesthesia • Site of the puncture: L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: unknown • Type of anaesthetic: 2 ml to 3.5 ml 0.5% bupivacaine (isobaric or hyperbaric solution with 8% glucose) or 1.5 ml to 2 ml 4% mepivacaine (hyperbaric solution with 9.5% glucose) |
| Participants | <p>1. 400 women enrolled (consecutive patients receiving spinal anaesthesia for orthopaedic operations of the lower extremities)</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • Whitacre (200, 50%) • Quincke (200, 50%) <p>2. No randomized patients lost to follow-up</p> <p>4. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): Whitacre group: 41.2, 16.2; Quincke group: 40.4, 17.7 • Weight (mean, SD): Whitacre group: 76.1, 14.9; Quincke group: 76.1, 13.2 • Height (mean, SD): Whitacre group: 173.5, 8.2; Quincke group: 173.2, 2 • Gender - male (number): Whitacre group: 150; Quincke group: 142 |
| Interventions | <ol style="list-style-type: none"> 1. 25 G Whitacre needle 2. 25 G Quincke needle. The bevel was held parallel to the dural fibres. |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH: postural headache, aggravated by standing, or sitting up, and relieving by lying down 2. Non-postural headache 3. Severity of headache: scored on a 10 cm visual analogue scale 4. Duration of headache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated |

Buettner 1993 (Continued)

3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: not stated
6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomly assigned to (...)" (page 166) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "Neither the interviewer nor the patient were aware of the kind of needle that had been used". (page 167) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Neither the interviewer nor the patient were aware of the kind of needle that had been used" (page 167) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Campbell 1993

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group, 2 arms • Country: Canada • Multisite: no • Needle tip used: atraumatic needles • Needle diameter used: 24 vs 25 • Number of attempts (1st or 2nd attempt): 90% vs 91% • Procedure: anaesthesia • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: unknown • Type of anaesthetic: hyperbaric 0.75% bupivacaine (Sterling-Winthrop) and preservative-free morphine (AH Robins Canada Inc) and Fentanyl (Janssen Pharmaceutica Inc) |
| Participants | <ol style="list-style-type: none"> 1. 354 women enrolled (ASA 1 and 2 undergoing spinal anaesthesia for elective caesarean section) <p>Patients randomized to:</p> <ul style="list-style-type: none"> • Sprotte (152, 50%) • Whitacre (152, 50%) <ol style="list-style-type: none"> 2. 4 patients (2 for each group) with failure to identify the subarachnoid space were excluded |

Campbell 1993 (Continued)

Patients analysed:

- Sprotte (150, 98.6%)
- Whitacre (150, 98.6%)

3. Main characteristics of patients:

- Age (mean, SD): Sprotte group: 32, 4.7; Whitacre group: 32, 5.3
- Weight (mean, SD): Sprotte group: 73.9, 12.7; Whitacre group: 73.5, 11.4
- Height (mean, SD): Sprotte group: 158.8, 7.5; Whitacre group: 158.7, 6.9
- ASA I (number, %): Sprotte group: 137, 91%; Whitacre group: 135, 90%

| | |
|---------------|--|
| Interventions | <ol style="list-style-type: none"> 1. 24 G Sprotte (Pajunk GmbH Medecin Technik, West Germany) 2. 25 G Whitacre (Becton Dickinson, Rutherford, New Jersey) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH: postural headache, aggravated by standing, or sitting up, and relieving by lying down 2. Number of attempts at spinal needle insertion 3. Dose of bupivacaine 4. Block level 5. Incidence of hypotension 6. Severity of headache: mild, moderate, severe 7. Non-spinal headache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: Becton Dickinson and Company, Rutherford, New Jersey 3. Role of funder: supplementation of 25 G Whitacre spinal needles 4. A priori sample size estimation: yes 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Low risk | Quote: "They were randomized, using a randomization table, into two groups (...)". (page 1132) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "All patients were blinded to the needle utilized". (page 1132) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Patients were assessed after operation by an investigator blinded to the needle and not involved in their perioperative care". (page 1132) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 1.31% patients enrolled were not analysed |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |

Campbell 1993 (Continued)

| | | |
|------------|----------|---------------------------------|
| Other bias | Low risk | No other biases were identified |
|------------|----------|---------------------------------|

Chaudhry 2011

| | |
|---------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group, 2 arms • Country: Pakistan • Multisite: no • Needle tip used: atraumatic vs traumatic • Needle diameter used: 25 G • Number of attempts: unknown • Procedure: anaesthesia • Site of the puncture: L2-3 or L4-5 • Training level of those who administered the puncture: unknown • Median or paramedian technique: median approach • Type of anaesthetic: hyperbaric 0.5% bupivacaine 2 ml to 4 ml |
| Participants | <p>1. 200 patients enrolled (patients from different surgical departments of Nawaz Sharif Social Security Hospital Lahore having different surgical procedures on the lower abdomen and lower limbs such as hernias, amputations, debridements, vesicolithotomy, total hip replacements, tibial nailing or plating, external fixators, caesarian sections and hysterectomies)</p> <p>Excluded patients: patients with systemic disease such as uncontrolled diabetes mellitus and hypertension, congestive cardiac failure, severe anaemia, pulmonary oedema, coagulopathies and vertebral column deformities</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • Pencil point (100, 50%) • Quincke (100, 50%) <p>2. No patients were excluded</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SEM): pencil point group: 45.9, 2.81; Quincke group: 40.9, 2.05 • Weight (mean, SEM): pencil point group: 63.9, 3; Quincke group: 61.7, 2.13 • Gender - male (number): pencil point group: 65; Quincke group: 70 |
| Interventions | <p>1. 25 G pencil point needle</p> <p>2. 25 G Quincke needle</p> <p>Co-intervention: needle directed cephalic slightly upwards towards umbilicus</p> |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH: postural headache, aggravated by standing, or sitting up, and relieving by lying down 2. Characteristics of headache: severity, localization, character, duration, presence or absence of associated symptoms 3. Factors: grade the dural click as distinct or indistinct, speed of CSF back flow was immediate, delayed or slow, aspiration of CSF as easy, slow or impossible, ease of injection as acceptable or unacceptable |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no |

Chaudhry 2011 (Continued)

5. Conducted: not stated
6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Two groups consisting 100 patients each were randomly chosen". (page 1) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Several outcomes unreported in results section: speed of CSF back flow, aspiration of CSF, ease of injection |
| Other bias | Low risk | No other biases were identified |

Corbey 1997

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group, 2 arms • Country: Denmark • Multisite: no • Needle tip used: Quincke vs Whitacre • Needle diameter used: 27 G • Number of attempts: unknown • Procedure: spinal anaesthesia • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: unknown • Type of anaesthetic: Hyperbaric lignocaine 75-100 mg, or hyperbaric bupivacaine 12.5-15 mg, |
| Participants | <ol style="list-style-type: none"> 1. 200 patients enrolled (less than 45 years of age, presenting for daycare surgery on the lower half of the body to be performed under spinal anaesthesia) <p>Excluded patients: unclear</p> <ul style="list-style-type: none"> • Patients randomized to: <ul style="list-style-type: none"> * 27 G Quincke (100, 50%) * 27 G Whitacre (100, 50%) <ol style="list-style-type: none"> 2. 9 patients failed to return their questionnaires and 2 patients were recorded as failures 3. Main characteristics of patients: |

Corbey 1997 (Continued)

- Age (range): Quincke group: 31.77 to 32.1; Whitacre group: 31.4 to 32
- Weight (mean, SEM): no reported
- Gender - male (number): no reported

| | |
|---------------|--|
| Interventions | Spinal anaesthesia with either a 27 G Quincke needle or 27 G Whitacre <ul style="list-style-type: none"> • 27-gauge Quincke (external diameter 0.41 mm Becton-Dickinson [B-D] Meylan, Spain) • 27-gauge Whitacre spinal needle (external diameter 0.41 mm [BD] Spain). |
| Outcomes | Outcomes were not classified as primary or secondary <ol style="list-style-type: none"> 1. PDPH: postural headache, aggravated by standing, or sitting up, and relieving by lying down 2. Postdural puncture-related headache (PDPR-H) 3. Non-specific headache 4. Grading of severity of headache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The patients were randomly allocated to receive spinal anaesthesia" (page 780) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "Patients were not aware of which needle had been used to perform the anaesthesia". (page 780) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "The replies to the questionnaires were assessed by one of the authors who was not aware of which needle had been used to perform the anaesthesia". (page 780) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Crock 2014

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> • Design: 4-period cross-over, blinded • Country: Australia • Multisite: no |
|---------|---|

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Crock 2014 (Continued)

- International: no
- Needle tip used: 22 G or 25 G standard cutting point
- Needle diameter used: 22 G or 25 G
- Number of attempts: single needle insertion 94%
- Procedure: leukaemia treatment
- CSF collection and methotrexate intrathecal (except in 4 procedures)
- Site of the puncture: not stated
- Training level of those who administered the puncture: experienced doctor
- Median or paramedian technique: not stated

Participants

1. 133 children having LP as part of their standard treatment protocol for leukaemia, recruited during visits to the Day Surgery Unit of the Royal Children's Hospital. Aged 4 to 15 years at the time of first procedure.

Exclusion criteria: excluded if they had insufficient LPs remaining in their planned treatment, had significant coexisting medical problems causing headache or were routinely using 25 G needles at parental request, or if there were significant social or communication problems.

3. 40 were excluded for meeting exclusion criteria

- Insufficient LPs remaining (24)
- Communication problems (10)
- Using 25 G for all procedures (2)
- Continuous headache (1)
- Family declined to take part (3)

4. 93 were allocated to a random sequence of 4 LPs, 2 with 22 G (A) and 2 with 25 G (B), and completed 341 LPs

- Random sequence of 4 LPs: 2 with 22 G and 2 with 25 G
- Analysis grouped interventions with 22 G and 25 G

2. No randomized patients were excluded

3. 18 patients lost to follow-up: 2 children had their last LP after their 16th birthday (excluded). 16 did not complete all 4 procedures for reasons such as moving interstate or finishing their treatment protocol, giving a total of 341 procedures (167 with the 22 G and 174 with the 25 G needle)

4. Main characteristics of patients (not specifying groups):

- Age: median 6.5 years (IQR 4.6 to 9.7)
- Percentage/number of men: 63 (68%)
- Time between procedures (median, IQR): 49 (7 to 336)

Interventions

1. 25 G (intervention): under general anaesthesia, lumbar puncture using 25 G for collection of CSF and then administered methotrexate intrathecal. LP position not stated. The needle was inserted with the orientation of the bevel parallel to the long axis of the dural fibres.
2. 22 G (control): under general anaesthesia, lumbar puncture using 22 G for collection of CSF and then administered methotrexate intrathecal. LP position not stated. The needle was inserted with the orientation of the bevel parallel to the long axis of the dural fibres.

Outcomes

Primary outcomes:

1. The presence of LP headache, defined as occurring within 7 days after the procedure, being worse within 15 minutes of standing up and improving within 30 minutes of lying down

Secondary outcomes: assessed by a 1-page questionnaire and telephone interview on days 1, 3 and 7 following the procedure

1. Presence of any headache within 7 days

Crock 2014 (Continued)

2. CSF collection time
3. Total procedure time
4. Number of failed needle attempts
5. Impact of headache on the family and the child

| | |
|-------|--|
| Notes | <ol style="list-style-type: none"> 1. Trial registration: Australia and New Zealand CTR 12605000052639 2. Funder: Perpetual philanthropy 3. Role of funder: Funding for this project. "No person associated with the funding body had any role or involvement in any aspect of the study at any time" (page 206) 4. A priori sample size estimation: no 5. Conducted: May 2005 to May 2007 6. Declared conflicts of interest: yes (page 206) |
|-------|--|

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "The treatment allocation was computer-generated by an independent statistician." (page 204) |
| Allocation concealment (selection bias) | Low risk | Quote: "Patients were allocated a sequential study number which corresponded to a large envelope containing four smaller sealed envelopes, labelled a, b, c and d, containing details of the needle sizes to be used for four procedures" (page 204) |
| Blinding of participants (performance bias) | Low risk | Quote: "All LPs were performed under general anaesthesia by the same experienced doctor (CC) who was given the relevant sealed envelope immediately before the procedure. This doctor was not involved in data collection after the procedure. All other staff and study participants were blinded to the needle gauge." (page 204) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "A study researcher blinded to the needle size recorded the time from first needle insertion to successful commencement of CSF collection and the time required for collection of 22 drops of CSF (approximately 1 mL) (...) Following each procedure, parents were given a one-page questionnaire to take home which asked them to record details of any headache in the child on days 1, 3 and 7 following the procedure (...) A researcher also phoned families on days 1, 3 and 7 after each procedure to ensure the data were recorded, and confirm the nature of any headache." (page 204) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 8.3% (31 out of 372 procedures) were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

De Andres 1999

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Spain • Multisite: no • International: no |
|---------|---|

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

De Andres 1999 (Continued)

- Needle type design used: Atraucan 26 vs Whitacre 27
- Needle diameter used: 26 vs 27
- Procedure: subarachnoid anaesthesia
- Number of attempts: 1.4 vs 1.5 attempts
- Site of the puncture: unknown
- Training level of those who administered the puncture: experienced anaesthesiologists
- Median or paramedian technique: midline approach
- Type of anaesthesia: 3 mL of 0.5% bupivacaine
- Patient position: lateral position

| | |
|---------------|--|
| Participants | <p>1. 158 patients enrolled during a 12-month period (ASA I and II, aged from 20 to 40 years, undergoing lower limb orthopaedic surgery)</p> <p>Exclusion criteria: presence of hypovolaemia, coagulation disorders, infection at the puncture site, use of general anaesthesia, history of headaches, chronic back pain or pregnancy</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 26 G Atraucan group: 79 patients (%) • 27 G Whitacre group: 79 patients (%) <p>2. No patients were excluded from further analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): Atraucan group: 26.8, 7.2; Whitacre group: 27.4, 7.8 • Weight (mean, SD): Atraucan group: 75.8, 18.4; Whitacre group: 77.4, 18.5 • Height (mean, SD): Atraucan group: 168, 18.8; Whitacre group: 172, 13.6 |
| Interventions | <ul style="list-style-type: none"> • 26 G Atraucan: B. Braun Medical, Melsungen Germany • 27 G Whitacre group: Becton Dickinson, Madrid, Spain |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Technical parameters 2. Quality of analgesia 3. Headache (nonspecific, PDPH) 4. Headache associated symptoms 5. Other postoperative side effects |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "On arrival at the operating room, the patients were assigned to one of two groups using a randomization table: (...)." (page 548) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |

De Andres 1999 (Continued)

| | | |
|---|--------------|--|
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "After surgery, close follow-up of patients was performed by an investigator blinded to the study protocol". (page 549) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Unclear risk | Information about non-specific headaches is unclear |
| Other bias | Low risk | No other biases were identified |

Despond 1998

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) (a third arm, 20 patients, chose general anaesthesia) • Country: Canada • Multisite: no • International: no • Needle type design used: Quincke vs Whitacre • Needle diameter used: 27 • Procedure: spinal anaesthesia • Number of attempts (1 attempt): 90 vs 94 • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline approach • Type of anaesthesia: 0.5% hyperbaric lidocaine • Patient position: sitting position |
| Participants | <p>1. 200 patients ASA I and II, aged 18 to 45 years and scheduled for knee arthroscopy were randomly assigned to 2 groups</p> <p>Unclear if patients were enrolled but not randomized</p> <p>Exclusion criteria: history of migraine headaches, previous PDPH</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • Quincke group: 100 patients (50%) • Whitacre group: 100 patients (50%) <p>2. 6 patients were excluded from analysis because exclusion criteria had been missed or they could not be contacted</p> <p>Patients analysed:</p> <ul style="list-style-type: none"> • Quincke group: 97 patients (48.5%) • Whitacre group: 97 patients (48.5%) <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean): Quincke group: 32.5; Whitacre group: 31.7 • Men (number): Quincke group: 74; Whitacre group: 71 |

Despond 1998 (Continued)

| | |
|---------------|--|
| Interventions | <ul style="list-style-type: none"> • 27 G Quincke: Becton Dickinson • 27 G Whitacre group: Becton Dickinson |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Headache 2. Severity of headache (VAS scores) 3. Satisfaction with technique |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias Quote: "...were randomly assigned to two groups." (page 1107) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "The interview was conducted by an anaesthetist unaware of the anaesthetic technique used..." (page 1107) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 6 patients (3%) were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Devic 1993

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> • Design: factorial 2 x 2 (needle x fentanyl) • Country: USA • Multisite: no • Needle tip used: 24 G Sprotte vs 25 G Quincke • Needle diameter used: 24 vs 25 • Number of attempts: unknown • Procedure: spinal anaesthesia • Site of the puncture: L2-5 • Training level of those who administered the puncture: unknown |
|---------|---|

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Devvic 1993 (Continued)

- Median or paramedian technique: midline approach
- Type of anaesthetic: hyperbaric 0.75% bupivacaine local anaesthetic with/without 20 µg of fentanyl
- Patient position: sitting or lateral position

Participants

1. 200 patients enrolled (healthy obstetric patients requiring caesarean section)

Exclusion criteria: patients in whom labour epidural analgesia had been attempted or performed previously, or in whom a spinal anaesthetic had been attempted with other needles

4 patients in the Sprotte group (3 Sprotte with fentanyl and 1 Sprotte with plain local anaesthetic) and 2 in the Quincke group (1 randomized to receive fentanyl and 1 Sprotte with plain local bupivacaine) were not available for follow-up

- Patients randomized to:
 - * 24 G Sprotte + fentanyl: 47 (94%)
 - * 24 G Sprotte only: 49 (98%)
 - * 25 G Quincke + fentanyl: 49 (98%)
 - * 25 G Quincke only: 49 (98%)

2. 6 (6%) patients randomized were excluded because exclusion criteria had been missed or because they could not be contacted

- Patients analysed:
 - * 24 G Sprotte + fentanyl: 47
 - * 24 G Sprotte only: 49
 - * 25 G Quincke + fentanyl: 49
 - * 25 G Quincke only: 49

3. Main characteristics of patients:

- Age (mean, SD):
 - * 24 G Sprotte + fentanyl: 28.2, 5.8
 - * 24 G Sprotte only: 29.5, 4.4
 - * 25 G Quincke + fentanyl: 28.3, 5.6
 - * 25 G Quincke only: 28.7, 5.5
- Weight (mean, SD):
 - * 24 G Sprotte + fentanyl: 76.2, 15.8
 - * 24 G Sprotte only: 78.3, 15.4
 - * 25 G Quincke + fentanyl: 82.6, 16.1
 - * 25 G Quincke only: 79.9, 18.1
- Height (mean, SD):
 - * 24 G Sprotte + fentanyl: 165.1, 8.4
 - * 24 G Sprotte only: 163.9, 7.9
 - * 25 G Quincke + fentanyl: 165.3, 7.6
 - * 25 G Quincke only: 163.9, 7

Interventions

1. 24 G Sprotte + fentanyl
2. 24 G Sprotte only
3. 25 G Quincke + fentanyl: needle bevel was oriented parallel to the longitudinal fibres
4. 25 G Quincke only: needle bevel was oriented parallel to the longitudinal fibres

Outcomes

Outcomes were not classified as primary or secondary

1. PDPH
2. Severity of headache

Notes

1. Trial registration: not stated

Devicic 1993 (Continued)

2. Funder: not stated
3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: not stated
6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "This randomized, blinded study (...)" (page 222) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "all patients were evaluated daily during the first 4 postoperative days by the designated nurse, who was blinded to the type of needle and medication used (...) Investigators conducting telephone follow-up were blinded to the type of needle and anesthetic solution used". (page 223) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 4 patients (8%) were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Fernandez 1993

| | |
|--------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms). A third arm, 20 patients, chose general anaesthesia). • Country: Argentina • Multisite: no • International: no • Needle type design used: Quincke vs Whitacre • Needle diameter used: 25 vs 24 • Procedure: anaesthesia • Number of attempts (first): 86% vs 84% • Site of the puncture: L2-3 • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline approach • Type of anaesthesia: 0.5% hyperbaric bupivacaine • Patient position: sitting position |
| Participants | <p>1. 80 patients undergoing different surgical procedures and receiving regional anaesthesia were randomized. Unclear if patients were enrolled but not randomized.</p> <p>Patients randomized to:</p> |

Fernandez 1993 (Continued)

- Quincke group: 40 patients (50%)
 - Whitacre group: 40 patients (50%)
2. No patients were excluded from analysis
3. Main characteristics of patients:
- Age (mean, SD): Quincke group: 37, 21; Whitacre group: 35, 28
 - Men (number): Quincke group: 28; Whitacre group: 26
 - Weight (mean, SD): Quincke group: 72, 18; Whitacre group: 75.14

| | |
|---------------|--|
| Interventions | <ul style="list-style-type: none"> • 25 G Quincke: no details provided • 24 G Whitacre group: no details provided |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Headache (any, PDPH) 2. Severity of headache 3. Duration of headache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Individuals were randomly assigned to receive..." (page 241) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Fernandez 2003

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Spain • Multisite: no • Needle tip used: 27 G Whitacre/Pencan vs 27 G Quincke/Spinocan • Needle diameter used: 27 G • Number of attempts: 1 to 2 attempts (easy technique): 27 G Whitacre: 84.8% vs 27 G Quincke: 78.8% • Procedure: spinal anaesthesia for lower abdominal surgery • Site of the puncture: L2-3, L3-4, L4-5 • Training level of those who administered the puncture: experienced anaesthesiologists • Median or paramedian technique: medial • Type of anaesthetic: bupivacaine 0.5% with glucose 8% (bupivacaine 0.5% hiperbaric; Inibsa laboratories) |
| Participants | <p>1. 1555 patients enrolled (ASA I-II patients undergoing lower abdominal surgery and hospitalization no more than 24 hours)</p> <p>Exclusion criteria: history of PDPH in previous surgeries</p> <p>Number of patients randomized per group: unclear</p> <p>2. 33 patients randomized were excluded due to (unclear numbers by group):</p> <ul style="list-style-type: none"> • Inability to follow-up • Prolonged bed rest • Re-operations • Etc. (not specified) <p>3. 1522 patients were analysed in 2 groups:</p> <ul style="list-style-type: none"> • Group I: 27 G Whitacre (N = 748) • Group II: 27 G Quincke (N = 774) <p>4. No patients were lost to follow-up</p> <p>4. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 27 G Whitacre (50.08, 16.23) vs 27 G Quincke (49.59, 14.4) • Gender - female (number): 27 G Whitacre (464) vs 27 G Quincke (465) • Weight (mean, SD): 27 G Whitacre (69.8, 12.3) vs 27 G Quincke (70.1, 12.4) • Height (mean, SD): 27 G Whitacre (164.5, 11.5) vs 27 G Quincke (165.02, 9.4) |
| Interventions | <ol style="list-style-type: none"> 1. Whitacre group: Pencan 27 G, pencil point needle (B. Braun Melsungen AG) 2. Quincke group: Spinocan 27 G, needle bevel cutting (B. Braun Melsungen AG) 3. Quincke needle type was introduced with the bevel parallel to the longitudinal axis of the column and the Whitacre needle with the hole facing downwards 4. Co-intervention: loracepam 1 mg oral, night before surgery |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Incidence of PDPH 2. Technical difficulties: number of attempts 3. Successful block 4. Severity of headache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated |

Fernandez 2003 (Continued)

4. A priori sample size estimation: yes
5. Conducted: not stated
6. Declared conflicts of interest: not reported

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Quote: "Distribution of patients in each group were randomly using the last two digits of their medical history" (page 183) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Once the patient had started mobilisation was visited by a team member who did not know the type of needle used and asked specifically for headache occurrence." (page 183) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Flaatten 2000

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Norway • Multisite: no • Needle tip used: pencil vs diamond • Needle diameter used: 27 G • Number of attempts (mean): 1.09 vs 1.27 • Procedure: spinal or epidural anaesthesia • Site of the puncture: unknown • Training level of those who administered the puncture: consultant anaesthesiologist • Median or paramedian technique: unknown • Type of anaesthetic: not standardized • Patient position: sitting or lateral supine position |
| Participants | <p>1. 313 patients aged 18 to 55 years were enrolled (scheduled for non-obstetric outpatient surgery below the umbilicus to be performed during spinal anaesthesia)</p> <p>Exclusion criteria: unclear</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 27 G Pencan group: 158 (50.4%) • 27 G Quincke group: 155 (49.5%) |

Flaatten 2000 (Continued)

2. 12 patients were excluded from analysis
 - No CSF found: 2
 - Too old: 2
 - Drunk during follow-up: 1
 - Lost to follow-up: 7
3. 301 patients were analysed (lost to follow-up: 3.83%)
 - 27 G Pencan group: 153
 - 27 G Quincke group: 148
3. Main characteristics of patients:
 - Age (mean, SD): 27 G Pencan: 37.2, 9.8; 27 G Quincke: 37.8, 10.7
 - Gender - male (number): 27 G Pencan: 101; 27 G Quincke: 90
 - Arthroscopy (number, %): 27 G Pencan: 94, 63.5%; 27 G Quincke: 103, 67.3%

| | |
|---------------|---|
| Interventions | <ol style="list-style-type: none"> 1. 27 G Pencan group: 0.40 mm O.D. B Braun, Germany 2. 27 G Quincke group: Spinocan 27 G, B. Braun, Germany. The bevel of the Quincke-type spinal needle was kept parallel to the longitudinal direction of the dural sac. |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Postoperative backache 2. Headache 3. PDPH 4. Duration of headache (days) 5. Intensity scale (NRS) |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Randomisation was performed using the sealed envelope technique..." (page 643) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Randomisation was performed using the sealed envelope technique..." (page 643) |
| Blinding of participants (performance bias) | Low risk | Quote: "All patients were blinded to the choice of spinal needle, and only the needle size of the spinal needle was documented in the anaesthetic record." (page 644) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "All patients were followed up by a single anaesthesiologist (HF) also blinded to the choice of spinal needle." (page 644) |

Flaatten 2000 (Continued)

| | | |
|--|-----------|---|
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 3.83% patients were lost to follow-up |
| Selective reporting (re-reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Fox 1996

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: factorial 2 x 2 (needle x temperature of the contrast agent) • Country: Germany • Multisite: no • Needle tip used: pencil vs diamond • Needle diameter used: 21 G vs 22 G • Number of attempts: unknown • Procedure: myelography • Site of the puncture: unknown • Training level of those who administered the puncture: experienced neuroradiologists • Patient position: sitting |
| Participants | <p>1. 412 patients undergoing thoracic/cervical or lumbar myelographies were enrolled</p> <p>Exclusion criteria: unclear</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 21 G Sprotte group: 206 patients (50%) • 22 G Quincke group: 206 patients (50%) <p>Also patients inside each group were randomized to:</p> <ul style="list-style-type: none"> • 37 °C warm cold contrast agent • 21 °C warm cold contrast agent <p>2. No patients were excluded from analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 21 G Sprotte group: 53.4, 7.3; 22 G Quincke group: 54.8, 7.4 • Gender - male (number): 21 G Sprotte group: 104; 22 G Quincke group: 107 • Lumbar myelography (number): 21 G Sprotte group: 110; 22 G Quincke group: 120 • Number of unsuccessful punctures: 21 G Sprotte group: 10; 22 G Quincke group: 9 |
| Interventions | <ol style="list-style-type: none"> 1. 21 G Sprotte group: Fa.Pajunkâ, Außendurchmesser: 0.8 mm 2. 22 G Quincke group: Fa. Becton-Dickinson, Außendurchmesser: 0.7 mm 3. Co-intervention: after myelography, all patients were prescribed bed rest for at least 2 hours without special storage recommendation and were recommended additional fluid intake of 2 to -3 L |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Headaches, their duration, intensity and character 2. Nausea, vomiting, tinnitus, dizziness and neck stiffness |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Fox 1996 (Continued)

2. Funder: not stated
3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: August 1995 to July 1996
6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "In a prospective randomized trial the incidence of complaints after lumbar puncture..." (page 922) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Geurts 1990

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Netherlands • Multisite: no • Needle tip used: unknown • Needle diameter used: 25 vs 29 • Number of attempts: unknown • Procedure: anaesthesia • Site of the puncture: L 3-4 or L 4-5 • Training level of those who administered the puncture: experienced anaesthesiologists • Median or paramedian technique: unknown • Type of anaesthetic: 2.5 ml to 4.0 ml of hyperbaric bupivacaine 0.5% • Patient position: lateral position |
| Participants | <p>1. 40 patients healthy ASA I patients under 40 years of age were enrolled. Indications for surgery varied, but all operations were subumbilical.</p> <p>Exclusion criteria: patients complaining of pre-existing headache or backache</p> <p>Patients randomized to:</p> |

Geurts 1990 (Continued)

- 25 G group: 40 patients (50%)
 - 29 G group: 40 patients (50%)
2. No patients were excluded from analysis
 3. Main characteristics of patients:
 - Age (mean, SD): 25 G group: 27.1, 5.9; 29 G group: 27.9, 7
 - Gender - male (number): 25 G group: 31; 29 G group: 23
 - Lumbar myelography (number): 21 G Sprotte group: 110; 22 G Quincke group: 120
 - Arthroscopy and surgery of the knee (number): 21 G Sprotte group: 19; 22 G Quincke group: 13

| | |
|---------------|--|
| Interventions | <ol style="list-style-type: none"> 1. 25 G group: the bevel of the needle was kept parallel to the dural fibres 2. 29 G group: no attention was paid to the direction of the bevel |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Atypical headache 3. Backache 4. Differences in mean block height 5. Volumes of bupivacaine used |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "a restricted randomised double-blind study to ensure equal numbers in each group was initiated..." (page 350). |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The use of a 0.90 mm introducer needle ensured that the patients were unable to differentiate between the two spinal needles." (page 350) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Postoperatively, patients were visited by two of the authors (MCH and RMW), who had no knowledge of which needle size had been used for spinal anaesthesia." (page 350) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Gonzalez 2000

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Mexico • Multisite: no • Needle tip used: diamond vs pencil • Needle diameter used: 26 vs 25 • Number of attempts = (1): all patients • Procedure: anaesthesia • Site of the puncture: L 2-3 or L 3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline • Type of anaesthetic: bupivacaine 0.5%, 3 ml • Patient position: lateral position |
| Participants | <p>1. 308 patients aged 18 to 45, ASA I, undergoing surgery in lower limbs</p> <p>Exclusion criteria: column injuries, cognitive or coagulation comorbidities, infection in site of lumbar puncture</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 26 G Quincke group: 154 patients (50%) • 25 G Whitacre group: 154 patients (50%) <p>2. No patients were excluded from analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 26 G Quincke group: 28.6, 6.72; 25 G Whitacre group: 30.5, 7.1 • Gender - male (number): 26 G Quincke group: 111; 25 G Whitacre group: 111 • Ambulatory patients (number): 26 G Quincke group: 72; 25 G Whitacre group: 64 |
| Interventions | <ol style="list-style-type: none"> 1. 26 G Quincke group: no further details 2. 25 G Whitacre group: no further details |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Acceptance of anaesthetic technique in the future |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomly assigned to one of two groups..." (page 162) |

Gonzalez 2000 (Continued)

| | | |
|---|--------------|---|
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Grover 2002

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: India • Multisite: no • Needle tip used: diamond • Needle diameter used: 25 vs 29 • Number of attempts: unknown • Procedure: anaesthesia • Site of the puncture: L 3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline approach • Type of anaesthetic: 2.5 ml to 3.5 ml of 0.5% bupivacaine in 8% dextrose • Patient position: unknown |
| Participants | <p>1. 100 ASA Grade I and II of either sex in the age group between 25 to 45 years, who were to receive spinal anaesthesia to undergo subumbilical surgery</p> <p>Exclusion criteria: obstetric patients, patients with abnormalities of spine, soft tissue infection at the site of needle insertion, acute ear infection and respiratory tract infection, coagulation disorders and neurological symptoms</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Quincke group: 50 patients (50%) • 29 G Quincke group: 50 patients (50%) <p>2. No patients were excluded from analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 25 G Quincke group: 34, 7.2; 29 G Quincke group: 33, 7.35 • Gender - male (number): 25 G Quincke group: 27; 29 G Quincke group: 31 • Educational status/illiterate (number): 25 G Quincke group: 20; 29 G Quincke group: 19 |
| Interventions | <p>1. 25 G Quincke group: no additional details</p> |

Grover 2002 (Continued)

2. 29 G Quincke group: no additional details

Co-intervention: patients were premedicated with tablet diazepam 5 mg a night before and 5 mg on the morning of surgery. Morphine sulphate 0.15 mg/kg and promethazine 0.5 mg/kg was also administered intramuscularly to all patients 45 minutes before anaesthesia.

| | |
|----------|--|
| Outcomes | Outcomes were not classified as primary or secondary <ol style="list-style-type: none"> 1. PDPH 2. Severity of PDPH 3. Backache, atypical headache 4. Number of redirection of the needle 5. Complications |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomly divided into two groups..." (page 1) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "All the patients were visited at the end of 24 hours and then on the third and fourth post-operative day by an anaesthetist who was not present during the performance of spinal anaesthesia." (page 2) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Hafer 1997

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (4 arms) • Country: Germany • Multisite: no • Needle tip used: diamond vs pencil • Needle diameter used: 26 vs 27 • Number of attempts: unknown |
|---------|---|

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Hafer 1997 (Continued)

- Procedure: anaesthesia
- Site of the puncture: L 3-4
- Training level of those who administered the puncture: unknown
- Median or paramedian technique: midline approach
- Type of anaesthetic: isobaric bupivacaine 0.5% or hyperbaric mepivacaine 4%
- Patient position: sitting position

Participants

1. 493 ASA Grade I to III patients undergoing orthopaedic surgery of the lower limbs were included

19 patients receive 2 surgeries, therefore the authors included 512 procedures in this study. However, 12 patients were excluded due to anatomical factors (1 procedure).

500 procedures randomized to:

- 26 G Quincke group: 125 (25%)
- 27 G Quincke group: 125 (25%)
- 26 G Atraucan group: 125 (25%)
- 27 G Whitacre group: 125 (25%)

Also patients were assigned to different regimes of mobilization (not analysed in the present review)

2. No patients were excluded from analysis

3. Main characteristics of patients:

- Age (mean, SD): 26 G Quincke group: 41.7, 17.8; 27 G Quincke group: 40.7, 17.1; 26 G Atraucan group: 39.1, 16.8; 27 G Whitacre group: 42.5, 17.3
- Gender - male (number): 26 G Quincke group: 67; 27 G Quincke group: 68; 26 G Atraucan group: 70; 27 G Whitacre group: 68
- Height (mean, SD): 26 G Quincke group: 172.3, 10.4; 27 G Quincke group: 172.1, 10; 26 G Atraucan group: 172.5, 9.6; 27 G Whitacre group: 172.8, 9.8
- Weight (mean, SD): 26 G Quincke group: 76.1, 15.3; 27 G Quincke group: 73.2, 14; 26 G Atraucan group: 74.6, 15; 27 G Whitacre group: 76.1, 14

Interventions

1. 26 G Quincke group: no further details were provided
2. 27 G Quincke group: no further details were provided
3. 26 G Atraucan group: no further details were provided
4. 27 G Whitacre group: no further details were provided

Outcomes

Outcomes were not classified as primary or secondary

1. PDPH
2. Other headaches
3. Back pain
4. Complications

Notes

1. Trial registration: not stated
2. Funder: not stated
3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: 1994 to 1996
6. Declared conflicts of interest: not stated

Risk of bias

Bias

Authors' judgement Support for judgement

Hafer 1997 (Continued)

| | | |
|---|--------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "According with a random list patients were assigned to one of four groups" (page 861) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "Examiners and patients had no knowledge of the needle type used (double-blind)." (page 861) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Examiners and patients had no knowledge of the needle type used (double-blind)." (page 861) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Harrison 1993

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Canada • Multisite: no • Needle tip used: unclear • Needle diameter used: 22 G versus 27 G • Number of attempts: unknown • Procedure: myelography • Site of the puncture: upper lumbar • Training level of those who administered the puncture: radiology residents • Median or paramedian technique: unclear • Patient position: supine position |
| Participants | <ol style="list-style-type: none"> 1. 128 patients referred to lumbar, thoracic, cervical or total column myelography were included <p>128 patients assigned to:</p> <ul style="list-style-type: none"> • 22 G group: 64 (50%) • 25 G group: 64 (50%) <ol style="list-style-type: none"> 2. 15 patients were lost to follow-up and excluded from analysis 3. Main characteristics of patients: <ul style="list-style-type: none"> • Age (mean): 22 G group: 52.9; 25 G group: 53.4 • Gender - male (number): not reported • Height (mean, SD): not reported • Weight (mean, SD): not reported |
| Interventions | <ol style="list-style-type: none"> 1. 22 G group: no further details were provided 2. 25 G group: no further details were provided |

Harrison 1993 (Continued)

Outcomes Outcomes were not classified as primary or secondary

1. Headache after lumbar puncture
2. Severity of headache

Notes

1. Trial registration: not stated
2. Funder: not stated
3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: 1989 to 1990
6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | High risk | Quote: "Patients were numbered sequentially: in even-numbered patients a 22 gauge needle was used and for odd-numbered patients, a 25 gauge needle " (page 487) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 11% of patients (15) were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Hopkinson 1997

Methods

- Design: parallel-group (4 arms)
- Country: UK
- Multisite: yes
- Needle tip used: 25 G Whitacre, 25 G Polymedic, 24 G Sprotte, 24 G Polymedic
- Needle diameter used: 25 vs 24
- Number of attempts (= 1): 123 vs 134 vs 121 vs 126
- Procedure: anaesthesia
- Site of the puncture: unknown
- Training level of those who administered the puncture: unknown
- Median or paramedian technique: unknown
- Type of anaesthetic: hyperbaric 0.5% bupivacaine
- Patient position: decided by anaesthetist

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Hopkinson 1997 (Continued)

| | |
|---------------|---|
| Participants | <p>1. 688 women undergoing caesarean section in whom spinal anaesthesia was clinically indicated</p> <p>Exclusion criteria: anticoagulation therapy, aortic valve disease, NYHA class 3 or 4 cardiac symptomology, sepsis at the site of injection, severe pre-eclampsia and systemic hypotension</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Whitacre group: 170 (24.7%) • 25 G Polymedic group: 170 (24.7%) • 24 G Sprotte group: 173 (25.1%) • 24 G Polymedic group: 168 (24.4%) <p>2. 7 patients were not studied because 1 withdrew and 5 were entered twice</p> <p>A further 16 were excluded from the analysis of headache due to protocol deviations</p> <p>Patients analysed (3.34% lost to follow-up):</p> <ul style="list-style-type: none"> • 25 G Whitacre group: 164 • 25 G Polymedic group: 167 • 24 G Sprotte group: 170 • 24 G Polymedic group: 164 <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 25 G Whitacre group: 28.5, 5.3; 25 G Polymedic group: 28.8, 5.02; 24 G Sprotte group: 29.7, 5.33; 24 G Polymedic group: 28.2, 5.13 • Height (mean, SD): 25 G Whitacre group: 160.7, 7.41; 25 G Polymedic group: 160.6, 8.02; 24 G Sprotte group: 162, 7.19; 24 G Polymedic group: 160.8, 7.08 • Weight (mean, SD): 25 G Whitacre group: 74.2, 12.8; 25 G Polymedic group: 74.9, 14.36; 24 G Sprotte group: 76.8, 14.9; 24 G Polymedic group: 76.4, 14.3 |
| Interventions | <ol style="list-style-type: none"> 1. 25 G Whitacre with a Yale spinal introducer (Becton Dickinson, NJ, USA) 2. 24 G Sprotte (Rüsh, Rommelshausen, Germany). Used their own introducer packed with the needle. 3. 24 G Polymedic (Te Ma Na Sar, Bondy, France). Used their own introducer packed with the needle. 4. 25 G Polymedic (Te Ma Na Sar, Bondy, France). Used their own introducer packed with the needle. |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Any headache 2. PDPH 3. Number of attempts to achieve satisfactory dural puncture 4. Paraesthesia 5. Inability to locate the subarachnoid space 6. Failure to achieve an adequate block 7. Hypotension |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|------|--------------------|-----------------------|
|------|--------------------|-----------------------|

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Hopkinson 1997 (Continued)

| | | |
|---|--------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Randomisation was achieved using sealed envelopes, which contained the needle to be used as well as the documentation" (page 1006) |
| Allocation concealment (selection bias) | Low risk | Quote: "Randomisation was achieved using sealed envelopes, which contained the needle to be used as well as the documentation" (page 1006) |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "all patients were seen within 48 h of surgery by a member of the study team who had not been involved with the performance of the block" (page 1007) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 3.34% of patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Imarengiaye 2002

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Nigeria • Multisite: no • Needle tip used: 25 G Quincke vs 24 G Gertie Marx • Needle diameter used: 25 vs 24 • Number of attempts (= 1): 18 vs 19 • Procedure: anaesthesia • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: unknown • Type of anaesthetic: 0.5% bupivacaine • Patient position: sitting position |
| Participants | <p>1. 60 women ASA I or II scheduled for elective caesarean section were enrolled</p> <p>Exclusion criteria: abnormal lumbar spaces, coagulopathy, infection, pre-eclampsia or obesity</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Quincke group: 30 (50%) • 24 G Gertie Marx group: 30 (50%) <p>2. No patients were excluded at follow-up</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 25 G Quincke group: 31.6, 3.9; 24 G Gertie Marx group: 32.5, 3.4 • Height (mean, SD): 25 G Quincke group: 162.8, 3.5; 24 G Gertie Marx group: 161.1, 4.6 • Weight (mean, SD): 25 G Quincke group: 77.7, 9.2; 24 G Gertie Marx group: 77, 10.6 |

Imarengiaye 2002 (Continued)

| | |
|---------------|---|
| Interventions | <ol style="list-style-type: none"> 25 G Quincke Needle; the needle was introduced with the injection orifice parallel to the dural fibres 24 G Gertie Marx (IMD, Inc UT, USA, length 127 mm) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> Number of attempts at successful identification of the spinal space Intraoperative complications PDPH No - PDPH and backache |
| Notes | <ol style="list-style-type: none"> Trial registration: not stated Funder: not stated Role of funder: not stated A priori sample size estimation: yes Conducted: not stated Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Low risk | Quote: "They were randomized, pulling out of a hat method (...)" (page 379) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "All patients and the assessor of postoperative complications but not the attending anaesthetists were blinded to the needle used" (page 380) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Postoperatively, the patients were visited daily for five days by an anaesthetist not involved in the perioperative care (..)" (page 1007) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Imbelloni 1997

| | |
|---------|--|
| Methods | <ul style="list-style-type: none"> Design: parallel-group (2 arms) Country: Brazil Multisite: no Needle tip used: Atraucan versus Quincke Needle diameter used: 26 vs 27 Number of attempts (> 5): 14 versus 19 Procedure: anaesthesia Site of the puncture: L2-3 or L3-4 |
|---------|--|

Imbelloni 1997 (Continued)

- Training level of those who administered the puncture: unknown
- Median or paramedian technique: median or paramedian
- Type of anaesthetic: unclear
- Patient position: lateral or sitting

| | |
|---------------|--|
| Participants | <p>1. 693 patients under 50 years undergoing spinal anaesthesia were included</p> <p>Exclusion criteria: patients with diseases that could affect CSF pressure were excluded from the study</p> <p>Patients divided into 2 groups:</p> <ul style="list-style-type: none"> • 26 G Atraucan group: 150 (21.6%) • 27 G Quincke group: 543 (78.3%) <p>2. No patients reported as lost to follow-up</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 26 G Atraucan group: 33.8, 9.31; 27 G Quincke group: 34.1, 9.97 • Height (mean, SD): 26 G Atraucan group: 167.2, 9.06; 27 G Quincke group: 168.2, 9.31 • Weight (mean, SD): 26 G Atraucan group: 67.08, 12.09; 27 G Quincke group: 68.6, 12.2 |
| Interventions | <ol style="list-style-type: none"> 1. 26 G Atraucan (Braun Melsugen, 8.8 cm) 2. 27 G Quincke (Becton-Dickinson, 8.89 cm) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Severity of headache 3. Number of attempts to achieve satisfactory dural puncture 4. Backache 5. Failure to achieve an adequate block 6. Satisfied with puncture |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | High risk | Quote: "693 patients younger than 50 years, submitted to spinal anaesthesia, were divided into two groups corresponding to each type of disposable needle used" (page 3) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. |
| Blinding of participants (performance bias) | Low risk | Quote: "The patients did not know which type of needle to use" (page 3) |
| Blinding of outcome assessment (detection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |

Imbelloni 1997 (Continued)

All outcomes

| | | |
|--|----------|--|
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were reported as lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Kang 1992

| | |
|---------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: USA • Multisite: no • Needle tip used: 26 G Quincke vs 27 G Quincke • Needle diameter used: 26 vs 27 • Number of attempts: unknown • Procedure: anaesthesia • Site of the puncture: L3-4, L4-5 or L5-S1 • Training level of those who administered the puncture: investigators • Median or paramedian technique: midline approach • Type of anaesthetic: lidocaine 5% with glucose 7.5% or bupivacaine 0.75% in dextrose 8.25% • Patient position: unknown |
| Participants | <p>1. 730 ambulatory surgery patients, 18 years or older, ASA I or II, and electing to receive spinal anaesthesia, were enrolled</p> <p>Exclusion criteria: patients with history of migraine headache or chronic back pain</p> <p>Number of patients randomized to each group: unclear</p> <p>2. 72 patients (9.86%) were excluded at follow-up</p> <p>Patients analysed:</p> <ul style="list-style-type: none"> • 26 G Quincke group: 322 • 27 G Quincke group: 336 <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 26 G Quincke group: 38.3, 16; 27 G Quincke group: 38.6, 16.9 • Height (mean, SD): 26 G Quincke group: 170.5, 9.5; 27 G Quincke group: 170.2, 9.7 • Weight (mean, SD): 26 G Quincke group: 77.6, 15.7; 27 G Quincke group: 77, 15.8 • Gender - male (number): 26 G Quincke group: 158; 27 G Quincke group: 162 • Procedures/knee and ankle arthroscopy (number): 26 G Quincke group: 234; 27 G Quincke group: 237 |
| Interventions | <ol style="list-style-type: none"> 1. 26 G Quincke (Becton-Dickinson, Rutherford, NJ), with the bevel entering the dura parallel to the longitudinal axis of the spinal cord 2. 27 G Quincke (Becton-Dickinson, Rutherford, NJ), with the bevel entering the dura parallel to the longitudinal axis of the spinal cord |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Kang 1992 (Continued)

2. Duration of PDPH
3. Back pain
4. Satisfaction with spinal anaesthesia
5. Willingness to it again in the future for a similar surgery

- Notes
1. Trial registration: not stated
 2. Funder: Gundersen Medical Foundation
 3. Role of funder: not stated
 4. A priori sample size estimation: no
 5. Conducted: not stated
 6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "were randomly assigned (...)". (page 734) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "In operating room, while patients were blinded to the needle size used (...)". (page 380) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "One of the nurse investigators (..), who had no knowledge of the patient 's needle assignment, made (...)". (page 1007) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 9.86% of patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Severity of headache and back pain are mentioned, but results are not reported. Adverse events, additional to PDPH, were not reported. |
| Other bias | Unclear risk | The role of the funder in this research is unclear |

Kim 2011

- Methods
- Design: parallel-group (2 arms)
 - Country: Korea
 - Multisite: no
 - Needle tip used: diamond
 - Needle diameter used: 23 vs 25
 - Number of attempts: first (60% vs 40%)
 - Procedure: anaesthesia
 - Site of the puncture: L3-4 or L4-5
 - Training level of those who administered the puncture: experienced nurse
 - Median or paramedian technique: midline approach
 - Type of anaesthetic: 0.5% bupivacaine hydrochloride or 1% tetracaine with 0.1 mg to 0.2 mg epinephrine
 - Patient position: lateral position

Kim 2011 (Continued)

| | |
|---------------|---|
| Participants | <p>1. 53 patients who underwent elective orthopaedic knee or hip surgery under spinal anaesthesia were enrolled (age > 60 years, ASA classes I–II, recumbent in bed for the first 24 hours postoperatively, and administration of intravenous patient-controlled analgesia for the first 48 hours postoperatively)</p> <p>Exclusion criteria: history of migraine headache, previous history of PDPH, cardiovascular or central nervous disease, and coagulation abnormality</p> <p>Patients were randomized to:</p> <ul style="list-style-type: none"> • 23 G Quincke group: 26 (49%) • 25 G Quincke group: 27 (51%) <p>2. 3 patients (5.66%) were excluded due to severe hypotension, heart problems after operation or refusal to participate in follow-up</p> <p>Patients analysed:</p> <ul style="list-style-type: none"> • 23 G Quincke group: 25 • 25 G Quincke group: 25 <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 23 G Quincke group: 68.2, 6.3; 25 G Quincke group: 68.5, 6.9 • Height (mean, SD): 23 G Quincke group: 158.6, 7.3; 25 G Quincke group: 159.5, 7.9 • Weight (mean, SD): 23 G Quincke group: 57.7, 7.6; 25 G Quincke group: 60.8, 8.5 • Gender - male (number): 23 G Quincke group: 9; 25 G Quincke group: 10 |
| Interventions | <ol style="list-style-type: none"> 1. 23 G Quincke needles (Hakko, Chikuma, Japan). Bevel parallel to the longitudinal dural fibre. 2. 25 G Quincke needles (Hakko, Chikuma, Japan). Bevel parallel to the longitudinal dural fibre. 3. Co-intervention: recumbent in bed for the first 24 hours postoperatively. |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Severity of PDPH 3. Back pain 4. Number of attempted lumbar punctures |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: none 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: December 2006 to October 2007 6. Declared conflicts of interest: yes (none declared) |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The 53 patients were randomly allocated to either the experimental group (...)" (page 1316) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "The patients were blinded to the intervention allocations. In addition, research assistants who were working as a nurse on the orthopedic nursing |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Kim 2011 (Continued)

| | | |
|---|-----------|---|
| | | unit and measured postdural puncture headache and post-operative back pain, were blinded to the intervention allocations (...)" (page 1316) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "The patients were blinded to the intervention allocations. In addition, research assistants who were working as a nurse on the orthopedic nursing unit and measured postdural puncture headache and post-operative back pain, were blinded to the intervention allocations (...)" (page 1316) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 5.66% of patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Kleyweg 1995

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms, standard and atraumatic) • Country: The Netherlands • Multisite: no • International: no • Needle type design used: diamond vs pencil • Needle diameter used: 20 G = 0.9 mm, 22 G = 0.7 mm • Procedure: lumbar puncture |
| Participants | <ol style="list-style-type: none"> 1. 100 patients enrolled (Dutch patients, both sexes, > 18 years of age) <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 20 G standard needle (50 patients) • 22 G atraumatic needle (49 patients) <ol style="list-style-type: none"> 2. 1 randomized patient was excluded due to: <ul style="list-style-type: none"> • Already had lumbar surgery (1) 3. 0 patients lost to follow-up 4. Main characteristics of patients: <ul style="list-style-type: none"> • Age: 20 G (mean 43, range 20 to 79), 22 G (mean 47, range 15 to 78) • Gender: female 57/male 42; 20 G 31 female, 19 male; 22 G 26 female, 23 male |
| Interventions | <ol style="list-style-type: none"> 1. Atraumatic 22 G group (intervention) 2. Standard 22 G group (control) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Incidence of PDPH in standard group 2. Side effects |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated |

Kleyweg 1995 (Continued)

4. A priori sample size estimation: yes
5. Conducted: April 1992 to January 1993
6. Declared conflicts of interest: not reported

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Low risk | At random allocation a few minutes before lumbar puncture, through telephone via the trial bureau |
| Allocation concealment (selection bias) | Low risk | Allocation was controlled by a central and independent randomization unit. The allocation sequence was unknown to the investigators. |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | The outcome was assessed by a medical doctor not involved in the lumbar puncture and blinded to the intervention type |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 1 patient excluded from the study |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Kokki 1996

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Finland • Multisite: no • Needle tip used: diamond • Needle diameter used: 25 vs 29 • Number of attempts: 1.2 vs 1.4 • Procedure: anaesthesia • Site of the puncture: L3-4 or L4-5 • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline approach • Type of anaesthetic: isobaric or hyperbaric bupivacaine 0.5% at a dose of 0.3 mg/kg-l was used for children under 7 years old. Older children were given hyperbaric lignocaine 5% at a dose of 1 mg/kg-l. • Patient position: lateral position |
| Participants | <ol style="list-style-type: none"> 1. 60 ASA physical status 1 and 2 children aged one to 13 years, scheduled for day case operations of the lower abdomen, genital area or lower extremities, were enrolled <p>Patients were randomized to:</p> <ul style="list-style-type: none"> • 25 G Quincke group: 30 (50%) • 29 G Quincke group: 30 (50%) <ol style="list-style-type: none"> 2. No patients were excluded at follow-up |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Kokki 1996 (Continued)

3. Main characteristics of patients:

- Age, months (mean, SD): 25 G Quincke group: 86, 48; 29 G Quincke group: 80, 34
- Height (mean, SD): 25 G Quincke group: 121, 27; 29 G Quincke group: 120, 17
- Weight (mean, SD): 25 G Quincke group: 27, 14; 29 G Quincke group: 24, 11
- Gender - male (number): 25 G Quincke group: 21; 29 G Quincke group: 23

| | |
|---------------|---|
| Interventions | 1. 25 G Quincke 89 mm long needle (Vygon, France). Needle bevel was parallel to the longitudinal dural fibres. 2. 29 G Quincke 89 mm long needle (Vygon, France). Needle bevel was parallel to the longitudinal dural fibres. Co-intervention: at the end of the operation the children were given ibuprofen 10 mg/kg-1 as a suppository for pre-emptive pain therapy |
| Outcomes | Outcomes were not classified as primary or secondary 1. Spinal puncture time 2. Time for CSF to appear at the needle hub 3. Injection time of the local anaesthetic 4. Postoperative complaints 5. PDPH 6. Non-PDPH |
| Notes | 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The children were randomly allocated (...)" (page 116) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Kokki 1998

| | |
|---------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (4 arms), open, randomized, prospective design • Country: Finland • Multisite: no • Needle type design used: diamond vs pencil • Needle diameter used: 25 G vs 26 G vs 24 G vs 27 G • Procedure: anaesthesia • Number of attempts: unclear • Site of the puncture: L3-4 or L4-5, L5-S1 • Training level of those who administered the puncture: experienced anaesthetist • Median or paramedian technique: midline approach • Type of anaesthetic: isobaric or hyperbaric bupivacaine 5 mg ml⁻¹ • Patient position: lateral position |
| Participants | <p>1. 200 patients enrolled (ASA I-II children, aged 2 to 128 months, and scheduled for day care surgery)</p> <p>Exclusion criteria: known contraindication to spinal puncture, such as an increased intracranial pressure, haemorrhagic diathesis or infection at the puncture site. Children with neurologic disorders or allergy to bupivacaine or other local anaesthetics were also excluded.</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Quincke (50) • 26 G Atraucan (50) • 24 G Sprotte (50) • 27 G Whitacre (50) <p>2. 5 patients randomized were excluded due to:</p> <ul style="list-style-type: none"> • Needle too short for spinal puncture (5) <p>3. 1 patients lost to follow-up:</p> <ul style="list-style-type: none"> • Not returning questionnaire (1) <p>4. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Median age in months <ul style="list-style-type: none"> * 25 G Quincke (50) * 26 G Atraucan (44) * 24 G Sprotte (50) * 27 G Whitacre (38) • Number of (women/men): <ul style="list-style-type: none"> * 25 G Quincke (12/38) * 26 G Atraucan (6/44) * 24 G Sprotte (7/43) * 27 G Whitacre (12/38) |
| Interventions | <ol style="list-style-type: none"> 1. 25 G Quincke group: Vygon, France, 50 mm long 2. 26 G Atraucan group: B. Braun, Germany, 25 mm long 3. 27 G Whitacre group: Becton-Dickinson, USA, 37 mm long 4. 24 G Sprotte group: Pajunk, Germany, 35 mm long |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Incidence of PDPH |

Kokki 1998 (Continued)

2. Post-puncture complaints
3. Severity of PDPH
4. Non-PDPH subsequent to lumbar puncture

- Notes
1. Trial registration: not stated
 2. Funder: not stated
 3. Role of funder: not stated
 4. A priori sample size estimation: no
 5. Conducted: not reported
 6. Declared conflicts of interest: not reported

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The patients were randomly allocated to receive spinal anaesthesia with either (...)" (page 1077) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The parents were blinded to the needle used." (page 1077) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 6 patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Kokki 1999

- Methods
- Design: parallel-group (2 arms), open, randomized, prospective design
 - Country: Finland
 - Multisite: no
 - Needle type design used: diamond vs pencil
 - Needle diameter used: 22 G
 - Procedure: lumbar puncture
 - Number of attempts: unclear
 - Site of the puncture: L2-L3, L3-L4, L4-L5
 - Training level of those who administered the puncture: paediatricians with previous experience with spinal punctures
 - Median or paramedian technique: midline approach
 - Type of anaesthetic: fentanyl cream
 - Patient position: lateral decubitus position, sitting position

Kokki 1999 (Continued)

| | |
|---------------|--|
| Participants | <ol style="list-style-type: none"> 1. 57 patients enrolled (ASA I-II children, aged 8 months to 15 years, with cancer or neurological symptoms having a diagnostic and/or therapeutic LP) <p>Exclusion criteria: unclear</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 22 G Quincke (29) • 22 G Whitacre (28) • 48 lumbar punctures were performed with 22 G Quincke, 50 with 22 G Whitacre <ol style="list-style-type: none"> 2. No exclusions 3. No losses to follow-up: 4. Main characteristics of patients: <ul style="list-style-type: none"> • Median age in months <ul style="list-style-type: none"> * 22 G Quincke (75) * 22 G Whitacre (86) • Number of (females/males): <ul style="list-style-type: none"> * 22 G Quincke (15/14) * 22 G Whitacre (18/10) |
| Interventions | <ol style="list-style-type: none"> 1. 22 G Quincke group: Becton-Dickinson, Meylan, Spain, 50 mm long 2. 22 G Whitacre group: Becton-Dickinson, Meylan, Spain, 37 mm long |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Incidence of PDPH 2. Post-puncture complaints 3. Severity of PDPH 4. Other complaints |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not reported 6. Declared conflicts of interest: no |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The 53 patients were randomly allocated to either the experimental group (...)Those children having repeated LPs remained in the same needle group throughout the study" (page 1316) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "The patients were blinded to the intervention allocations. In addition, research assistants who were working as a nurse on the orthopedic nursing unit and measured postdural puncture headache and post-operative back pain, were blinded to the intervention allocations (...)" (page 1316) |

Kokki 1999 (Continued)

| | | |
|---|----------|---|
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "The patients were blinded to the intervention allocations. In addition, research assistants who were working as a nurse on the orthopedic nursing unit and measured postdural puncture headache and post-operative back pain, were blinded to the intervention allocations (...)" (page 1316) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 5.66% of patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Kokki 2000

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms), open, randomized • Country: Finland • Multisite: no • Needle type design used: pencil point and cutting point • Needle diameter used: a 50 mm long 25 G needle was used in children up to 7 years and a 90 mm long 27 G needle for older children • Procedure: anaesthesia • Number of attempts (1 to 2): 97% • Site of the puncture: unknown • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline approach • Type of anaesthetic: hyperbaric bupivacaine 5 mg ml⁻¹ (MarcainA, Astra, Sodertelje, Sweden) was used at a dose of 0.4 mg kg⁻¹ in children up to 7 years and at a dose of 0.3 mg kg⁻¹ in older children • Patient position: unknown |
| Participants | <ol style="list-style-type: none"> 1. 215 patients enrolled (ASA I-II children, aged 1 to 18 years, undergoing surgery below the umbilicus) <ul style="list-style-type: none"> • Patients randomized to: <ul style="list-style-type: none"> * Pencil point (106) * Cutting point (109) 2. 1 patient randomized was excluded from the complication analysis 4. Main characteristics of patients: <ul style="list-style-type: none"> • Median age in years: pencil point group: 9; cutting point group: 8 • Number of females/males: pencil point group: 36/70; cutting point group: 40/69 • Number of ASA I/II: pencil point group: 82/27; cutting point group: 84/22 |
| Interventions | <ol style="list-style-type: none"> 1. Pencil point group: Pencan, B-Braun, Melsungen, Germany, duration: 48 seconds 2. Cutting point group: Yale, Becton-Dickinson, Madrid, Spain. Duration: 40 seconds 3. Co-intervention: each child was premedicated with diazepam and fentanyl cream was used at the puncture sites |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Incidence of PDPH 2. Post-puncture complaints 3. Severity of PDPH |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Kokki 2000 (Continued)

4. Any headache

Notes

1. Trial registration: not stated
2. Funder: not stated
3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: December 1997 to January 1999
6. Declared conflicts of interest: no

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "The random allocation schedule was generated by a computer and concealed until the patient arrived in the operating theatre (...)" (page 211) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to assess this item as low or high risk |
| Blinding of participants (performance bias) | Low risk | Quote: "Patients, parents and post-anaesthesia care unit (PACU) nurses were unaware of the type of needle used. (...)" (page 211) |
| Blinding of outcome assessment (detection bias) All outcomes | High risk | Quote: "using an open-randomised, parallel-groups, and prospective design (...)" (page 211) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 1 patient was lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Kuusniemi 2013

Methods

- Design: parallel-group (2 arms)
- Country: Finland
- Multisite: no
- International: no
- Needle type design used: Quincke vs Whitacre
- Needle diameter used: 27
- Procedure: anaesthesia
- Number of attempts (first): 25 vs 24
- Site of the puncture: L2-3
- Training level of those who administered the puncture: unknown
- Median or paramedian technique: midline approach
- Type of anaesthesia: 0.5% plain bupivacaine
- Patient position: lateral position

Participants

1. 60 consecutive outpatients (ASA) physical status I–III, ages ranging between 18 and 60 years, scheduled for unilateral lower limb surgery, with spinal block being used as the sole anaesthetic without any intraoperative sedation were enrolled

Kuusniemi 2013 (Continued)

Exclusion criteria: previous history of intolerance to the study drug or related compounds and existing contraindications for spinal anaesthesia, patients with a body mass index (BMI) of 30 kg/m², those with a history of alcoholism, drug abuse, or psychological or other emotional problems, patients who were pregnant or lactating

Patients randomized to:

- Quincke group: 30 patients (50%)
- Whitacre group: 30 patients (50%)

2. No patients were excluded from analysis

3. Main characteristics of patients:

- Age (mean, SD): Quincke group: 45, 9.1; Whitacre group: 42, 11.4
- Men (number): Quincke group: 8; Whitacre group: 11
- Weight (mean, SD): Quincke group: 70, 11.6; Whitacre group: 70, 11.2

| | |
|---------------|---|
| Interventions | <ul style="list-style-type: none"> • 27 G Quincke: Yale/Becton–Dickinson • 27 G Whitacre group: Becton–Dickinson <p>In both groups a 20 G introducer was applied</p> |
| Outcomes | <p>Primary outcome:</p> <ol style="list-style-type: none"> 1. Spread of spinal anaesthesia <p>Secondary outcomes:</p> <ol style="list-style-type: none"> 1. Patient satisfaction 2. Adverse effects: headache, PDPH, backache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: not stated 6. Declared conflicts of interest: yes (page 230) |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "using a sealed envelope technique, the patients were randomized to two groups". (page 225) |
| Allocation concealment (selection bias) | Low risk | Quote: "using a sealed envelope technique, the patients were randomized to two groups" (page 225) |
| Blinding of participants (performance bias) | Low risk | Quote: "patients, nurses, and the anesthetist performing the motor and sensory block assessments were blinded for the spinal needle type used". (page 225) |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) | Low risk | No patients were lost to follow-up |

Kuusniemi 2013 (Continued)

All outcomes

| | | |
|--------------------------------------|----------|--|
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Lavi 2006

| | |
|---------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms), prospective, randomized trial • Country: Israel • Multisite: no • International: no • Needle type design used: 22 G Quincke traumatic needle, 22 G Whitacre atraumatic needle • Needle diameter used: 22 G • Procedure: lumbar puncture • Patient position: patients were lying on their side and received local anaesthesia prior to the procedure |
| Participants | <ol style="list-style-type: none"> 1. 63 patients enrolled (consecutive patients older than 18 years scheduled for a diagnostic or therapeutic lumbar puncture as a part of their routine clinical management) <ul style="list-style-type: none"> • 58 patients randomized to: <ul style="list-style-type: none"> * 22 G Quincke traumatic (N = 29) * 22 G Whitacre atraumatic (N = 29) 2. 5 patients randomized were excluded due to: <ul style="list-style-type: none"> • Low platelet count • Abnormal brain CT scan • History of recent lumbar puncture 3. 0 patients lost to follow-up 4. Main characteristics of patients: <ul style="list-style-type: none"> • Mean age <ul style="list-style-type: none"> * 22 G Quincke traumatic: 49 years * 22 G Whitacre atraumatic: 42 years • Number (%) of women: <ul style="list-style-type: none"> * 22 G Quincke traumatic: 17 (59) * 22 G Whitacre atraumatic: 16 (55) • Percentage/number of postures during the lumbar puncture: lying on side, directed parallel to patient's axis • Other characteristics: PDPH was more prevalent in patients with lower BMI (< 20, 37.5%; BMI 20 to 30, 13.5%) |
| Interventions | <ol style="list-style-type: none"> 1. Quincke traumatic group: 22 G, 90 mm, TSK Japan 2. Whitacre atraumatic group: 22 G, 0.70 mm, 103 mm, Polymedic, E.C. Japan |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <p>A. Incidence of PDPH</p> <p>B. Adverse events: not reported</p> |

Lavi 2006 (Continued)

C. Severity PDPH

D. Any headache subsequent to a lumbar puncture: not reported

| | |
|-------|---|
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: July to December 2004 6. Declared conflicts of interest: no (page 1492) |
|-------|---|

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomly assigned to undergo LP with a standard (...).Patients were randomized only once. Therefore, those who required repeated LPs had them done with the same needle type." (page 1492) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "The study was blinded to the patient. However, because the different needles have different structures, the physician knew which needle was used and could not be blinded to the needle." (page 1492) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Follow-up was performed by a physician, blinded to the randomization, on days 2 (...)" (page 1492) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Lynch 1992a

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Germany • Multisite: no • International: no • Needle type design used: Quincke vs Whitacre • Needle diameter used: 25 vs 22 • Procedure: anaesthesia • Number of attempts: unknown • Site of the puncture: L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: median approach • Type of anaesthesia: 0.5% hyperbaric bupivacaine |
|---------|---|

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Lynch 1992a (Continued)

| | |
|---------------|--|
| | <ul style="list-style-type: none"> • Patient position: lateral or sitting position |
| Participants | <p>1. 300 patients (ASA I or II) aged 15 to 40 years (196 male, 104 female) undergoing elective orthopaedic procedures were enrolled</p> <p>Exclusion criteria: migraine or chronic severe headache, infection, local anaesthetic allergy or a preference for general anaesthesia</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • Quincke group: 150 patients (50%) • Whitacre group: 150 patients (50%) <p>2. No patients were excluded from analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): Quincke group: 25, 1; Whitacre group: 27.8, 1 • Men (number): Quincke group: 95; Whitacre group: 101 • Weight (mean, SD): Quincke group: 73, 1; Whitacre group: 73.8, 1 |
| Interventions | <ul style="list-style-type: none"> • 29 G Quincke: Spinocan, Braun • 22 G Whitacre group: Becton Dickinson or Monoject <p>All punctures were done with a 20 G introducer (Braun, Germany)</p> |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Severity of PDPH 3. Backache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were allocated randomly to have (...)" (page 58) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) | Low risk | No patients were lost to follow-up |

Lynch 1992a (Continued)

All outcomes

| | | |
|--------------------------------------|-----------|---|
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported. Presence of associated symptoms is mentioned in methods, but not reported. |
| Other bias | Low risk | No other biases were identified |

Mayer 1992

| | |
|---------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Canada • Multisite: yes (2 sites) • Needle type design used: 27 G Quincke vs 24 G Sprotte • Needle diameter used: 27 vs 24 • Procedure: spinal anaesthesia • Number of attempts: 1.7 vs 1.6 • Site of the puncture: L2-3, L3-4 • Training level of those who administered the puncture: staff, fellows and residents under supervision • Median or paramedian technique: unknown • Type of anaesthetic: hyperbaric 0.75% bupivacaine with 8.25% dextrose or preservative-free morphine (0.2 mg) was added to the syringe containing bupivacaine • Patient position: sitting or lateral position |
| Participants | <ol style="list-style-type: none"> 1. 298 patients enrolled (patients consenting to spinal anaesthesia for elective and emergency caesarean section) <ul style="list-style-type: none"> • Patients randomized to: <ul style="list-style-type: none"> * 27 G Quincke group: (147, 49.3%) * 24 G Sprotte group: (151, 50.7%) 3. Losses to follow-up or exclusions: not reported 2. Main characteristics of patients: <ul style="list-style-type: none"> • Age (mean, SD): 27 G Quincke group: 30.3, 5; 24 G Sprotte group: 30.5, 4.5 • Height (mean, SD): 27 G Quincke group: 160.8, 6.1; 24 G Sprotte group: 161.9, 6.5 • Weight (mean, SD): 27 G Quincke group: 73.7, 10.7; 24 G Sprotte group: 75.1, 12.9 |
| Interventions | <ol style="list-style-type: none"> 1. Quincke group: 27 G needle, Becton-Dickinson, Rutherford, NJ 2. Sprotte group: 24 G needle, Pajunk, Geisingen, Germany 3. Co-intervention: an introducer was used in all patients |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Number of attempts at puncture 3. Adverse events (paraesthesias) 4. Severity of PDPH 5. Headache different from PDPH |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no |

Mayer 1992 (Continued)

5. Conducted: not stated
6. Declared conflicts of interest: not reported

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The needle to be used was assigned in a random manner: (...)". (page 58) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

McGann 1992

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: UK • Multisite: no • International: no • Needle type design used: unknown • Needle diameter used: 22 vs 26 • Procedure: myelography • Number of attempts: unknown • Site of the puncture: unknown • Amount of CSF removed: 7 ml • Injection: 17 ml of Iohexol • Patient position: sitting position |
| Participants | <ol style="list-style-type: none"> 1. 160 patients attending for myelography were included. Further details were not provided. Exclusion criteria: patients with marked obstruction of CSF flow Number of patients randomized by arm: unknown 2. 14 patients (8.75%) were excluded from analysis due to incomplete follow-up or death Patients analysed: <ul style="list-style-type: none"> • 22 G group: 75 patients • 26 G group: 71 patients |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

McGann 1992 (Continued)

3. Main characteristics of patients (in general):

- Males (number): 75

| | |
|---------------|---|
| Interventions | <ul style="list-style-type: none"> • 20 G group: no details were provided • 26 G group: no details were provided <p>After the study, patients rested in bed with head elevated for 24 hours and were encouraged to consume fluids</p> |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Headache (PDPH) 2. Severity of PDPH 3. Procedure tolerability 4. Other symptoms |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: unclear 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "were randomized to undergo (..)". (page 1102) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "The patients were questioned by an independent observer at 24 hours (...)". (page 1102) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 8% of patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Morros-Vinoles 2002

| | |
|---------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Spain • Multisite: no |
|---------|--|

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Morros-Vinoles 2002 (Continued)

- Needle tip used: Sprotte
- Needle diameter used: 27 G vs 29 G
- Number of attempts (1): 78.5% vs 71.2%
- Procedure: anaesthesia
- Site of the puncture: L3-4
- Training level of those who administered the puncture: experienced anaesthesiologists
- Median or paramedian technique: median
- Type of anaesthesia used: 0.5% bupivacaine
- Patient position: unclear

Participants

1. 389 patients undergoing orthopaedic surgery or general surgery were enrolled

Exclusion criteria: refusal of technique, allergy to anaesthesia, neurological comorbidities or coagulation conditions

Patients randomized to:

- Sprotte 27 G group: 189 (48.5%)
- Sprotte 29 G group: 200 (51.4%)

2. 12 patients (3%) were excluded from analysis, due to protocol deviations

Patients analysed:

- Sprotte 27 G group: 186
- Sprotte 29 G group: 191

Telephone interview was complete in (lost to follow-up: 10%):

- Sprotte 27 G group: 175
- Sprotte 29 G group: 184

3. Main characteristics of patients:

- Age (mean, SD): Sprotte 27 G group: 41, 13; Sprotte 29 G group: 43, 13
- Height (mean, SD): Sprotte 27 G group: 171, 9; Sprotte 29 G group: 168, 15
- Weight (mean, SD): Sprotte 27 G group: 76, 13; Sprotte 29 G group: 75, 12
- Gender - male (number): Sprotte 27 G group: 155; Sprotte 29 G group: 163

Interventions

1. Grupo Sprotte G 27 (Sp27): 0.4 mm G 27 (Sprotte®, Pajunk®)
2. Grupo Sprotte G 29 (Sp29): 0.33 mm G 29 (Sprotte®, Pajunk®)
3. Co-intervention: bed rest for 8 h and analgesia with metamizol 2 g (Nolotil®) IM/8h

Outcomes

Outcomes were not classified as primary or secondary

1. Technical difficulties
2. PDPH
3. Severity of PDPH
4. Back pain

Notes

1. Trial registration: not stated
2. Funder: not stated
3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: not stated
6. Declared conflicts of interest: not stated

Morros-Vinoles 2002 (Continued)

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomized into two groups (..)" (page 449) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "patients were interviewed by telephone to the second and seventh day after surgery, by an anesthesiologist unaware of who and who and how the puncture was made, and following a specific and as a template for all patients (..)" (page 450) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 10% of patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Muller 1994

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Germany • Multisite: no • Needle tip used: 22 G Sprotte vs 20 G Quincke • Needle diameter used: 22 vs 20 • Number of attempts (2 or more): 32 patients • Procedure: diagnostic LP • Site of the puncture: unknown • Training level of those who administered the puncture: resident • Median or paramedian technique: unknown • Amount of CSF extracted: 10 ml to 20 ml • Amount of injected volume: unclear • Patient position: sitting |
| Participants | <p>1. 100 consecutive patients undergoing diagnostic LP were enrolled</p> <p>Exclusion criteria: contraindications against any type of LP</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 22 G Sprotte group: 50 (50%) • 20 G Quincke group: 50 (50%) <p>2. 10 patients (10%) were excluded from analysis, due to protocol deviations</p> <p>Patients analysed:</p> |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Muller 1994 (Continued)

- 22 G Sprotte group: 48
 - 20 G Quincke group: 42
3. Main characteristics of patients (only analysed patients):
- Age (mean, SD): 22 G Sprotte group: 46, 16; 20 G Quincke group: 44, 16
 - Height (mean, SD): 22 G Sprotte group: 167, 8; 20 G Quincke group: 170, 9
 - Weight (mean, SD): 22 G Sprotte group: 69, 13; 20 G Quincke group: 73, 14
 - Gender - male (number): 22 G Sprotte Group: 21; 20 G Quincke Group: 25

| | |
|---------------|---|
| Interventions | <ol style="list-style-type: none"> 1. Sprotte G 22: (Pajunk GmbH, Feinwerk-Medizintechnologie, Geisingen, Germany). The atraumatic cannula was used by an introducer 18 G. 2. Quincke 20 G. Unclear if an introducer was used. 3. Co-intervention: after LP all patients were told to lie flat in bed for 6 hours, the first 30 minutes in the abdominal position, and to drink amply (1 L mineral water or tea) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Post-puncture complaints 2. PDPH 3. Severity of PDPH |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The study was carried out as a prospective randomized blind study on a general neurological ward (..)" (page 376) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "The LP was carried out by a resident who was asked not to disclose the type of needle to the patient or to the masked examiner." (page 377) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "All examinations were carried out by an examiner who was unaware of the puncture technique and observations were recorded on standardised check-lists (...)" (page 377) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 10% of patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Oberoi 2009

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: India • Multisite: no • Needle type design used: 25 G Quincke, 25 G Whitacre • Needle diameter used: 25 G • Procedure: anaesthesia • Number of attempts: unknown • Procedure: anaesthesia • Site of the puncture: unknown • Training level of those who administered the puncture: experienced anaesthesiologists • Median or paramedian technique: unknown • Type of anaesthetic: not reported • Patient position: unknown |
| Participants | <p>1. 200 patients enrolled (obstetric female patients aged 20 to 35 belonging to ASA I undergoing elective or emergency lower segment caesarean section)</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Quincke (Q) (100) • 25 G Whitacre (W) (100) <p>2. Losses to follow-up and exclusions were not reported</p> <p>2. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 25 G Quincke: 26.97, 3.8; 25 G Whitacre: 27.1, 4.22 • Height (mean, SD): 25 G Quincke: 156.7, 4.31; 25 G Whitacre: 158.6, 3.94 • Weight (mean, SD): 25 G Quincke: 63, 3.65; 25 G Whitacre: 65.1, 3.61 |
| Interventions | <ol style="list-style-type: none"> 1. 25 G Quincke spinal needle group 2. 25 G Whitacre spinal needle group |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Side effects 3. Severity of PDPH: assessed with Corbey severity grading and VAS |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not reported 6. Declared conflicts of interest: no |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "The patients were randomly allocated to one of the two groups Q or W according to computer generated numbers". (page 420) |

Oberoi 2009 (Continued)

| | | |
|---|--------------|--|
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Post-operatively, follow up was done up to 7 days after the surgery or till the time of discharge by an anaesthesiologist who had no knowledge of the spinal needle." (page 421) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Severity of post-dural puncture headache was assessed according to Corbey severity grading and visual analogue scale (VAS). This information is not reported. |
| Other bias | Low risk | No other biases were identified |

Pan 2004

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: USA • Multisite: no • Needle tip used: 26 G Atraucan vs 25 G Whitacre • Needle diameter used: 26 vs 25 • Number of attempts: 1.5 vs 1.6 • Procedure: anaesthesia • Site of the puncture: L2-3, L 3-4 or L4-5 • Training level of those who administered the puncture: anaesthesiology residents or senior nurse anaesthetist students, with close supervision of attending anaesthesiologists, performed the spinal anaesthetic procedures • Median or paramedian technique: midline • Type of anaesthetic: 75 mg of 5% lidocaine in 7.5% dextrose injected intrathecal • Patient position: sitting position |
| Participants | <p>1. 215 American Society of Anesthesiology Class I to II postpartum patients presenting for elective postpartum bilateral tubal ligations under spinal anaesthesia were enrolled</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 26 G Atraucan group: 109 • 25 G Whitacre group: 106 <p>2. 11 patients (5.1%) were excluded from analysis, because of loss to follow-up, cancellation of surgery or inability to identify the sub-arachnoid space</p> <p>Patients analysed:</p> <ul style="list-style-type: none"> • 26 G Atraucan group: 104 • 25 G Whitacre group: 100 <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 26 G Atraucan group: 28.5; 25 G Whitacre: 28.5 |

Pan 2004 (Continued)

- Weight (mean, SD): 26 G Atraucan group: 76, 14; 25 G Whitacre: 78, 18
- Height (mean, SD): 26 G Atraucan group: 164, 6; 25 G Whitacre: 162, 8

| | |
|---------------|--|
| Interventions | <ol style="list-style-type: none"> 1. 26 G Atraucan spinal needles (B. Braun Medical, Bethlehem, PA) (outside diameter 0.45 mm; length 8.89 cm) were used with the bevel of the needles turned parallel to the longitudinal axis of the patient's vertebral column 2. 25 G Whitacre spinal needles (Becton-Dickinson, Rutherford, NJ) (outside diameter 0.5 mm; length 8.89 cm) were used with the terminal orifice of the needle facing cephalad to the patient |
|---------------|--|

| | |
|----------|--|
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Number of attempts 2. Final sensory level of the spinal blockade 3. Failure to obtain CSF 4. Time for placement of spinal anaesthesia 5. Amount of intraoperative analgesic supplement required 6. PDPH 7. Severity of PDPH 8. Any headache 9. Number of days of PDPH |
|----------|--|

| | |
|-------|--|
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: this study was supported in part by an unrestricted education grant from B. Braun Medical, Inc. Medical Devices Company 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: not stated 6. Declared conflicts of interest: not stated |
|-------|--|

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "The patients were randomized by means of a computer-generated random number table into either" (page 360) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Postoperatively, an investigator who was blinded to the group assignment interviewed the patients daily while in the hospital" (page 360) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 5% of patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Unclear risk | The role of funder is unclear |

Pedersen 1996

| | |
|---------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Norway • Multisite: no • Needle tip used: 22 G Quincke vs 22 G Whitacre • Needle diameter used: 22 G • Number of attempts: unknown • Procedure: myelography • Site of the puncture: L2-3 • Training level of those who administered the puncture: unknown • Median or paramedian technique: unknown • Amount of CSF extracted: unknown • Amount of injected volume: Iohexol 15 ml • Patient position: unknown |
| Participants | <p>1. 107 consecutive patients (inpatient and outpatient) referred to the Department of Radiology for lumbar myelography were enrolled</p> <p>Number of patients randomized per arm: unclear</p> <p>2. 7 patients (6.5%) were excluded from analysis because they were operated within the first 7 days or they did not return the questionnaire</p> <p>146 patients were analysed:</p> <ul style="list-style-type: none"> • 22 G Quincke group: 53 patients • 22 G Whitacre group: 47 patients <p>3. Main characteristics of patients: 58 men, 42 women, age range: 20 to 82 years, mean: 50.5 years)</p> |
| Interventions | <ol style="list-style-type: none"> 1. 22 G (0.7 mm) Quincke needle (Spinocan, B Braun Melsungen, Germany) 2. 22 G Whitacre (Becton- Dickinson). Puncture was done first with a 19 G needle through the skin and subcutis |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Headache/PDPH 2. Low back pain 3. Nausea, dizziness 4. Severity of PDPH |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "were randomized into two groups (..)" (page 184) |

Pedersen 1996 (Continued)

| | | |
|---|--------------|---|
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 6.5% of patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Peterman 1996

| | |
|--------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: USA • Multisite: no • Needle tip used: 22 G Quincke vs 22 G Whitacre • Needle diameter used: 22 G • Number of attempts: 1.36 vs 1.19 • Procedure: myelography • Site of the puncture: unknown • Training level of those who administered the puncture: mix • Median or paramedian technique: mix • Amount of CSF extracted: unknown • Amount of injected volume: 10.56 vs 10.45 • Patient position: unknown |
| Participants | <p>1. 778 patients undergoing myelography from 26 April 1993 to 7 September 1994, at a large, tertiary care, academic hospital were eligible for this study</p> <p>Of the 778 eligible patients, 340 consented to participate in the study</p> <p>340 patients were randomized to:</p> <ul style="list-style-type: none"> • 22 G Quincke: 173 patients (50.8%) • 22 G Whitacre: 167 patients (49.2%) <p>2. 26 patients received another needle than the randomized needle; additionally, 49 patients were not followed up. Authors include all data (as randomized) in the final analysis.</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 22 G Quincke group: 55.6, 13.9; 22 G Whitacre group: 52.4, 13.7 • BMI (mean, SD): 22 G Quincke group: 26.6, 4.7; 22 G Whitacre group: 27.4, 5.5 • Gender - male (number): 22 G Quincke group: 77; 22 G Whitacre group: 88 |

Peterman 1996 (Continued)

| | |
|---------------|---|
| Interventions | <ol style="list-style-type: none"> 22 G Whitacre spinal needle. Needle was passed through a short, 18G introducer needle to penetrate the skin and subcutaneous tissues. 22 G Quincke spinal needle (Becton Dickinson, Franklin Lakes, NJ) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> PDPH Headache severity |
| Notes | <ol style="list-style-type: none"> Trial registration: not stated Funder: supported in part by Becton Dickinson, the Association of University Radiologists-General Electric Radiology Research Academic Fellowship, and the National Institute of Neurologic Disorders and Stroke grant ROI NS 30928 Role of funder: not stated A priori sample size estimation: no Conducted: April 1993 to September 1994 Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Low risk | Quote: "The sequential order of Whitacre and Quincke needle assignments was randomly assigned by computer in blocks of 10 to ensure an equal number of patients in each needle group." (page 772) |
| Allocation concealment (selection bias) | Low risk | Quote: "When a patient consented to enter the study, the fluoroscopy technologist received the needle assignment from the chief radiologic technologist, who kept the randomization list." (page 772) |
| Blinding of participants (performance bias) | Low risk | Quote: "There was no formal masking of the research nurses or patients; however, there was probable masking in effect. At follow-up, most patients did not seem to know their needle group assignment." (page 772) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "The principal investigator (S.B.P.), who was masked to the needle group assignment, coded the patient diagnosis by chart review." (page 772) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 14.4% of patients were lost to follow-up. However, all randomized patients were included in the analysis. |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Unclear risk | The role of the funder in this research is unclear |

Pippa 1995

| | |
|---------|--|
| Methods | <ul style="list-style-type: none"> Design: parallel-group (2 arms) Country: Italy Multisite: no Needle tip used: Quincke Needle diameter used: 21 vs 25 |
|---------|--|

Pippa 1995 (Continued)

- Number of attempts: unknown
- Procedure: anaesthesia
- Site of the puncture: L5-S1
- Training level of those who administered the puncture: unknown
- Median or paramedian technique: paramedian approach
- Type of anaesthetic: 5 ml 0.5% plain bupivacaine + fentanyl 50 µg
- Patient position: lateral

| | |
|---------------|---|
| Participants | <p>1. 160 ASA grade I or II patients undergoing orthopaedic surgery or manipulations to reduce lower limb fractures were included</p> <p>Exclusion criteria: patients with a history of migraine or frequent headaches and neurological problems</p> <p>Patients divided into 2 groups:</p> <ul style="list-style-type: none"> • 21 G Quincke group: 80 (50%) • 25 G Quincke group: 80 (50%) <p>2. No patients reported as lost to follow-up</p> <p>3. Main characteristics of patients: not fully reported</p> |
| Interventions | <p>1. 21 G Quincke: no further details reported</p> <p>2. 25 G Quincke: no further details reported</p> |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Severity of headache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | High risk | Quote: "Patients were randomly allocated, on the basis of date (but not the year) of their birth, to receive spinal anaesthesia with either (...)" (page 560) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Two of the authors, who were unaware of the needle gauge employed, examined each patient on the first, second and third postoperative days and inquired about the occurrence of headache" (page 561) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were reported as lost to follow-up |

Pippa 1995 (Continued)

| | | |
|--------------------------------------|-----------|---|
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Pittoni 1995

| | |
|---------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Italy • Multisite: no • Needle tip used: 22 G Sprotte vs 25 G Sprotte • Needle diameter used: 22 vs 25 • Number of attempts: 1 to 5 attempts • Procedure: anaesthesia • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: experienced anaesthesiologist • Median or paramedian technique: median • Type of anaesthesia: bupivacaine 1% in glucose 8% • Patient position: lateral position |
| Participants | <ol style="list-style-type: none"> 1. 234 ASA I-II outpatients undergoing elective arthroscopy of the knee joint <p>Exclusion criteria: contraindication to regional anaesthesia</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 22 G Sprotte group: 117 patients (50%) • 25 G Sprotte group: 117 patients (50%) <ol style="list-style-type: none"> 2. No patients were excluded from analysis 3. Main characteristics of patients: <ul style="list-style-type: none"> • Age (mean, SD): 22 G Sprotte group: 39, 15; 25 G Sprotte group: 37, 15 • Height (mean, SD): 22 G Sprotte group: 171, 7; 25 G Sprotte group: 171, 9 • Weight (mean, SD): 22 G Sprotte group: 75, 13; 25 G Sprotte group: 73, 12 • Gender - male (number): 22 G Sprotte group: 86; 25 G Sprotte group: 78 |
| Interventions | <ol style="list-style-type: none"> 1. 22 G (0.7 mm) Sprotte needle (Pajunk, Geisingen, Germany) 2. 25 G (0.7 mm) Sprotte needle (Pajunk, Geisingen, Germany). A 21 G introducer was used. |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Headache/PDPH - backache 2. Duration of PDPH 3. Presence of associated symptoms 4. Severity of PDPH 5. Number of attempts 6. Failed spinal anaesthesia |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no |

Pittoni 1995 (Continued)

5. Conducted: not stated
6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were allocated randomly to receive (...)" (page 73) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "and were interviewed by one of the authors (blind with respect to needle size(...))" (page 74) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Prager 1996

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms + 1 in separated patients) • Country: USA • Multisite: no • Needle type design used: diamond vs pencil • Number of attempts: unknown • Procedure: myelography • Site of the puncture: L2-3 • Training level of those who administered the puncture: senior neuroradiologists • Median or paramedian technique: slightly off midline for most patients • Amount of CSF extracted: not collected • Amount of injected volume: iohexol (Omnipaque: Nycomed, New York, NY) (10 ml to 15 ml of 180 concentration for the lumbar spine and 10 ml of 300 concentration for the cervical spine) • Patient position: prone and slightly oblique on a fluoroscopy table with a pillow under the abdomen |
| Participants | <ol style="list-style-type: none"> 1. 108 patients enrolled (patients referred for myelograms) <p>Exclusion criteria: inability to sit or stand, inability to reliably communicate, a situation that would tend to decrease the presence and reporting of spinal headache</p> <p>108 patients randomized to:</p> <ul style="list-style-type: none"> • Quincke group: 56 patients (51.85%) • Sprotte group: 52 patients (48.14%) |

Prager 1996 (Continued)

2. Main characteristics of patients:

- Mean age:
 - * Quincke: 57
 - * Sprotte: 56
 - * Gertie Marx: 57
- Number of females/males: Gertie Marx: 13/17. Numbers not reported for the other groups.

| | |
|---------------|---|
| Interventions | 1. Quincke group: 22 G bevel tip needle (Becton-Dickinson, Franklin Lakes, NJ) 2. Sprotte group: 22 G, pencil point (Pajunk, Geisingen, Germany) 3. Co-interventions: after myelogram bed rest with head of bed elevated 45 degrees for 6 hours after the procedure |
| Outcomes | Outcomes were not classified as primary or secondary 1. Incidence of PDPH 2. Severity of PDPH (1 to 10 scale) 3. Blood patches required: Quincke 2, Sprotte 2 4. Non-spinal headache 5. Extraarachnoid contrast material |
| Notes | 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not reported 6. Declared conflicts of interest: not reported |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "108 were randomized to a 22-gauge" (page 1290) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "An observer contacted each subject by telephone 5-14 days after the myelogram. The observer did not know which type of needle had been used on the subjects." (page 1290) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Rafique 2014

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Pakistan • Needle tip used: diamond • Needle diameter used: 25 G vs 27 G • Number of attempts: 1 • Procedure: anaesthesia • Site of the puncture: site/unclear • Training level of those who administered the puncture: attending anaesthesiologist • Median or paramedian technique: unclear • Type of anaesthetic: unclear • Patient position: sitting or lateral supine position |
| Participants | <p>1. 90 patients enrolled (female patients of 20 to 38 years old, undergoing caesarian sections)</p> <p>Exclusion criteria: ASA above III</p> <p>Number of patients randomized per arm: unclear</p> <p>2. Number of patients excluded (who required more than one prick): unclear. 3 patients were excluded from analysis for unknown reasons.</p> <p>Number of analysed patients:</p> <ul style="list-style-type: none"> • Group I (25 G Quincke spinal needle): 44 (48%) • Group II (27 G Quincke spinal needle): 43 (47%) <p>3. No patients lost to follow-up</p> <p>4. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): group 1: 28 ± 4.5/group 2: 27 ± 3.1 |
| Interventions | <ol style="list-style-type: none"> 1. Group 1: spinal anaesthesia with 25 G Quincke spinal needle 2. Group 2: spinal anaesthesia with 27 G Quincke spinal needle |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Patient satisfaction 3. Severity of headache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not reported |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "ninety female patients of 20 to 38 years of age, undergoing caesarian sections were randomly distributed to either 25 or 27 gauge Quincke needle groups" (page 1) |

Rafique 2014 (Continued)

| | | |
|---|--------------|--|
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The patients were interviewed first through third post-operative days about the occurrence of headache and their satisfaction regarding spinal anaesthesia." (page 1) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Rasmussen 1989a

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Denmark • Multisite: no • Needle tip used: unclear vs pencil • Needle diameter used: 20 vs 25 • Number of attempts: unknown • Procedure: anaesthesia • Site of the puncture: L3-4 • Training level of those who administered the puncture: anaesthetists • Median or paramedian technique: midline approach • Type of anaesthetic: 0.5% bupivacaine • Patient position: lateral position |
| Participants | <p>1. 200 admitted for elective total unilateral hip replacement were enrolled</p> <p>Number of patients randomized per arm: unclear</p> <p>2. 17 patients (8.5%) were excluded from analysis, in the pre and postoperative period. It was impossible to perform the spinal procedure with the prescribed 25 G needle in 4 patients; 7 had an incomplete block, of whom 5 had a supplementary general anaesthetic and 2 another spinal injection; 4 had major cardiovascular complications, 1 had a classical migraine first noticed postoperatively and another needed a further spinal anaesthetic on the second postoperative day because the artificial hip dislocated.</p> <p>183 patients were analysed:</p> <ul style="list-style-type: none"> • 20 G Mediplast group: 93 patients • 25 G Vygon group: 90 patients <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, range): 20 G Mediplast group: 68.8, 45 to 88; 25 G Vygon group: 69.1, 21 to 82 • Gender - male (number): 20 G Mediplast group: 43; 25 G Vygon group: 44 |

Rasmussen 1989a (Continued)

| | |
|---------------|--|
| Interventions | <ol style="list-style-type: none"> 20 G Mediplast. No further details are provided. 25 G Vygon. No further details are provided. |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> Headache/PDPH - no PDPH |
| Notes | <ol style="list-style-type: none"> Trial registration: not stated Funder: not stated Role of funder: not stated A priori sample size estimation: no Conducted: not stated Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The patients were randomly allocated in a double blind manner (..)" (page 184) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | <p>Quote: "The authors as well as the patients were blinded with respect to needle size" (page 571)</p> <p>"Spinal anaesthesia was performed by the department anaesthetists, but did not include the authors." (page 571)</p> |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | <p>Quote: "The authors as well as the patients were blinded with respect to needle size" (page 571)</p> <p>"The patients in study 1 were interviewed by one of the authors on the fourth day after surgery (...)" (page 571)</p> |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 8.5% of patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Rasmussen 1989b

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> Design: parallel-group (2 arms) Country: Denmark Multisite: no Needle tip used: unclear vs pencil Needle diameter used: 20 vs 25 Number of attempts: unknown Procedure: anaesthesia |
|---------|---|

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Rasmussen 1989b (Continued)

- Site of the puncture: L3-4
- Training level of those who administered the puncture: anaesthetists
- Median or paramedian technique: midline approach
- Type of anaesthetic: 0.5% bupivacaine
- Patient position: lateral position

| | |
|---------------|--|
| Participants | <p>1. 200 patients aged between 20 and 40 years and admitted for either elective or acute orthopaedic, lower abdominal or urogenital surgery were enrolled</p> <p>Number of patients randomized per arm: unclear</p> <p>2. 7 patients (3.5%) were excluded. It was impossible to perform the spinal procedure with a 25 G needle in 1 patient; 2 needed a supplementary general anaesthetic, 1 another spinal anaesthetic, while 3 had a history of migraine first noticed postoperatively</p> <p>193 patients were analysed:</p> <ul style="list-style-type: none"> • 20 G Mediplast group: 98 patients • 25 G Vygon group: 95 patients <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, range): 20 G Mediplast group: 29.2, 20 to 40; 25 G Vygon group: 29.7, 20 to 40 • Gender - male (number): 20 G Mediplast group: 80; 25 G Vygon group: 68 |
| Interventions | <p>1. 20 G Mediplast. No further details are provided.</p> <p>2. 25 G Vygon. No further details are provided.</p> |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <p>1. Headache/PDPH - no PDPH</p> |
| Notes | <p>1. Trial registration: not stated</p> <p>2. Funder: not stated</p> <p>3. Role of funder: not stated</p> <p>4. A priori sample size estimation: no</p> <p>5. Conducted: not stated</p> <p>6. Declared conflicts of interest: not stated</p> |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The patients were randomly allocated in a double blind manner (..)" (page 184) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "The authors as well as the patients were blinded with respect to needle size" (page 571) "Spinal anaesthesia was performed by the department anaesthetists, but did not include the authors." (page 571) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "The authors as well as the patients were blinded with respect to needle size" (page 571) |

Rasmussen 1989b (Continued)

"The patients in study 1 were interviewed by one of the authors on the fourth day after surgery (..)" (page 571)

| | | |
|--|-----------|---|
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 8.5% of patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Riley 2002

| | |
|---------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms), randomized • Country: USA • Multisite: no • Needle type design used: pencil • Needle diameter used: 24 G • Number of attempts: unknown • Procedure: anaesthesia • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline approach • Type of anaesthetic: 10 µg sufentanil • Patient position: sitting position |
| Participants | <p>1. 73 patients enrolled (women in active labour who requested labour analgesia and accepted a combined spinal-epidural technique)</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • Gertie Marx group: 37, 50.6% • Sprotte group: 36, 49.4% <p>2. 6 (8.21%) patients lost to follow-up because no cerebrospinal fluid was obtained with the Sprotte needle</p> <p>Patients analysed:</p> <ul style="list-style-type: none"> • Gertie Marx group: 37 patients • Sprotte group: 30 patients <p>3. Main characteristics of patients were not provided. Quote: "The two groups were similar with regard to cervical dilation, parity, height, weight, and initial pain score." (page 575)</p> |
| Interventions | <ol style="list-style-type: none"> 1. Gertie Marx group: 24 G, 127 mm spinal needle (International Medical Development, Park City, Utah) 2. Sprotte group: 24 G, 120 mm spinal needle (Pencan, B. Braun, Melsungen, Germany) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Incidence of PDPH 2. Severity of PDPH: verbal 0 to 10 scale 3. Epidural blood patch required |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Riley 2002 (Continued)

2. Funder: donation of the spinal needles from International Medical Devices, Park City, Utah
3. Role of funder: not stated
4. A priori sample size estimation: yes
5. Conducted: not reported
6. Declared conflicts of interest: not reported

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomized to have the spinal component (..)" (page 574) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 8.21% of patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Saenghirunvattana 2008

| | |
|--------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Thailand • Multisite: no • Needle tip used: diamond vs pencil • Needle diameter used: 27 vs 25 • Number of attempts (1): 47 vs 15 • Procedure: anaesthesia • Site of the puncture: unknown • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline or paramedian at the anaesthesiologist's discretion • Type of anaesthesia: hyperbaric 0.5% bupivacaine 2.5 ml to 3.5 ml • Patient position: lateral position |
| Participants | <p>1. 91 patients undergoing spinal anaesthesia for operations in the departments of orthopaedics, general surgery and urology from August 2006 to October 2007 were enrolled</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 27 G Quincke: 59 patients (64.83%) • 25 G Pajunk group: 32 patients (35.16%) |

Saenghirunvattana 2008 (Continued)

| | |
|---------------|---|
| | <ol style="list-style-type: none"> 2. No patients were excluded from analysis 3. Main characteristics of patients: <ul style="list-style-type: none"> • Age (mean, SD): 27 G Quincke group: 59.03, 18.8; 25 G Pajunk group: 58.34, 14.24 • Height (mean, SD): 27 G Quincke group: 162.3, 6.92; 25 G Pajunk group: 163.06, 5.48 • Weight (mean, SD): 27 G Quincke group: 61.9, 13.6; 25 G Pajunk group: 60.54, 10.61 |
| Interventions | <ol style="list-style-type: none"> 1. 27 G Quincke (Becton-Dickinson, Rutherford, NJ, USA or Dr. Japan Co, Tokyo, Japan) 2. 25 G Pajunk (Pajunk, GmbH Medizin Technik, West Germany) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Number of attempts 2. Surgeon rating 3. Postoperative complication: headache, blurred vision 4. Patient's comments |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: August 2006 to -October 2007 6. Declared conflicts of interest: yes. Quote: "This study was carried out without any conflict of interest." (page S157) |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The patients were randomly allocated into (...)" (page S157) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Santanen 2004

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) |
|---------|---|

Santanen 2004 (Continued)

- Country: Finland
- Multisite: no
- Needle tip used: 27 G Quincke vs 27 G Whitacre
- Needle diameter used: 27
- Number of attempts: unknown
- Procedure: anaesthesia
- Site of the puncture: L2-3 or L3-4
- Training level of those who administered the puncture: unknown
- Median or paramedian technique: unknown
- Type of anaesthesia: hyperbaric bupivacaine 5 mg/ml-1 (Bicain pond1, Orion Pharma Ltd, Espoo, Finland) 1.5 ml to 2.5ml
- Patient position: lateral position

Participants

1. 676 outpatients (ASA physical status I-II, aged 18 to 60 years) given spinal anaesthesia for elective day-case surgery were enrolled

Exclusion criteria: use of oral opioids or regular use of nonsteroidal anti-inflammatory drugs, history of allergy to any study medication, patient refusal, contraindication for spinal anaesthesia, abuse of drugs or alcohol, headache preoperatively on the morning of surgery and body mass index not within normal limits (17 to 28)

Number of patients randomized per arm: unclear

2. 54 patients (33 in the Quincke group and 21 in the Whitacre group) were excluded from the study for various reasons such as if they received midazolam for sedation (15/10), general anaesthesia was required because of insufficient spinal block (12/6), pethidine was required for postoperative shivering (2/2), or pain medication different from the study protocol had been given to the patient in the ward or at home (2/1)

Of the remaining 622 patients, 529 patients returned the questionnaire (85.1%) and were available for the final analysis

Total of exclusions: 147 (21.74%)

3. Patients analysed:

- Group I: 27 G Quincke group: 259
- Group II: 27 G Whitacre group: 270

4. Main characteristics of patients:

- Age (mean, SD): 27 G Quincke group: 46, 34; 27 G Whitacre group: 42, 12
- Height (mean, SD): 27 G Quincke group: 173, 9; 27 G Whitacre group: 172, 9
- Weight (mean, SD): 27 G Quincke group: 74, 12; 27 G Whitacre group: 73, 13
- Gender - male (number): 27 G Quincke group: 127; 27 G Whitacre group: 122

Interventions

1. 27 G (0.41 mm) Whitacre (Whitacre1, Becton Dickinson Ltd, Madrid, Spain)
2. 27 G (0.41 mm) Quincke spinal needle (Yale1, Becton Dickinson Ltd). The bevel of the Quincke spinal needle was kept parallel to the dural fibres.

The choice of whether to use an introducer needle (22 G (0.7 mm) 30 mm long, Yale1 needle, Becton Dickinson Ltd) was left to the individual anaesthesiologist performing the spinal block.

Outcomes

Outcomes were not classified as primary or secondary

1. Any headache
2. PDPH

Notes

1. Trial registration: not stated

Santanen 2004 (Continued)

2. Funder: Novartis
3. Role of funder: supply of Voltaren tablets given to the study patients for postoperative pain relief
4. A priori sample size estimation: yes
5. Conducted: not stated
6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "The randomization was computer-generated and double-blind except for the anaesthetist performing (...)" (page 475) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "The patients, surgeons, as well as the postoperative ward personnel did not know which spinal needle had been used." (page 475) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "The anaesthesiologist who analyzed patient outcome was unaware of the spinal needle type used." (page 475) |
| Incomplete outcome data (attrition bias) All outcomes | High risk | 21% patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Schmittner 2010

| | |
|--------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Germany • Multisite: no • International: no • Needle type design used: Quincke • Needle diameter used: 25 vs 29 • Procedure: subarachnoid anaesthesia • Number of attempts (1 attempt): 87.3% vs 84.9% • Site of the puncture: L3-4 • Training level of those who administered the puncture: experienced anaesthesiologists • Median or paramedian technique: midline approach • Type of anaesthesia: 1 mL of 0.5% bupivacaine • Patient position: sitting position |
| Participants | <p>1. 216 patients ASA I to III, undergoing in-house and ambulatory anorectal surgery, performed in lithotomy position, were enrolled</p> <p>Exclusion criteria: contraindications against spinal anaesthesia, patients considered to be ASA status IV–I, operation techniques other than in lithotomy position and prior participation in the study.</p> |

Schmittner 2010 (Continued)

After inclusion of 216 patients, the study was terminated when interim analysis showed unexpected high rates of PDPH in both study groups.

Patients randomized to:

- 25 G Quincke group: 106 patients (49.07%)
- 29 G Quincke group: 110 patients (50.93%)

2. No patients were excluded from further analysis

3. Main characteristics of patients:

- Age (mean, SD): 25 G Quincke group: 51.6, 12.6; 29 G Quincke group: 45.5, 12.3
- Weight (mean, SD): 25 G Quincke group: 82.7, 16.9; 29 G Quincke group: 79.3, 19.4
- Height (mean, SD): 25 G Quincke group: 171.5, 8.5; 29 G Quincke group: 172.2, 10

| | |
|---------------|---|
| Interventions | <ul style="list-style-type: none"> • 25 G Quincke needle with introducer (Spinocan 0.53 × 88 mm – G 25 × 3 1/2, B. Braun, Melsungen, Germany) • 29 G Quincke needle with introducer (Spinocan 0.35 × 88 mm – G 29 × 3 1/2, B. Braun, Melsungen, Germany) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Time to onset 3. Duration of PDPH |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: ISRCTN: 11431649 2. Funder: B. Braun, Melsungen, Germany 3. Role of funder: provision of needles 4. A priori sample size estimation: yes 5. Conducted: March to August 2008 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Low risk | Quote: "Upon arrival in the operating theatre the patients were randomly allocated 1:1 using sealed envelopes in blocks of 20 to receive a spinal saddle block with either a 25-G or a 29-G Quincke type spinal needle" (page 776) |
| Allocation concealment (selection bias) | Low risk | Quote: "Upon arrival in the operating theatre the patients were randomly allocated 1:1 using sealed envelopes in blocks of 20 to receive a spinal saddle block with either a 25-G or a 29-G Quincke type spinal needle" (page 776) |
| Blinding of participants (performance bias) | Low risk | Quote: "Study participants were blinded to the type of needle used." (page 776) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "A consultant anaesthesiologist who was blinded towards the needles used and who was not involved in the study assessed the incidence of PDPH" (page 776) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |

Schmittner 2010 (Continued)

| | | |
|--------------------------------------|-----------|---|
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Schmittner 2011

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (4 arms) (we only extracted and analysed needle interventions) • Country: Germany • Multisite: no • Needle tip used: 27 G pencil-point vs 27 G Quincke • Needle diameter used: 27 • Number of attempts: mean: 1 • Procedure: anaesthesia • Site of the puncture: L3-4 • Training level of those who administered the puncture: experienced anaesthesiologists • Median or paramedian technique: midline • Type of anaesthesia: 1.0 mL of hyperbaric bupivacaine 0.5% (Bucaïn 0.5% hyperbaric[®], Delta Select, Dreieich, Germany) for in-house patients or 1.0 mL of hyperbaric mepivacaine 4% (Mecain 4% hyperbar[®], Delta Select, Dreieich, Germany) • Patient position: sitting position |
| Participants | <p>1. 363 patients (male/female, 18 to 80 years; American Society of Anesthesiologists (ASA) physical grade I–III) undergoing in-house and ambulatory anorectal surgery, performed in lithotomy position, were enrolled and randomized</p> <p>Exclusion criteria: general contraindications against spinal anaesthesia, patients' history of recurrent headaches or a previous PDPH, patients considered to be ASA grade IV–VI, operation techniques other than in lithotomy position and prior participation in the study.</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • Group A: 27 G PP needle, 10 min pre-operative time in upright sitting position: 90 patients (24.8%) • Group B: 27 G Q needle, 10 min pre-operative time in upright sitting position: 90 patients (24.8%) • Group C: 27 G PP needle, 30 min pre-operative time in upright sitting position: 90 patients (24.8%) • Group D: 27 G Q needle, 30 min pre-operative time in upright sitting position: 93 patients (25.6%) <p>2. No patients were excluded from further analysis</p> <p>3. Main characteristics of patients (in general):</p> <ul style="list-style-type: none"> • Sex ratio male/female: 219/144 • Age (years): 46.61 (12.6) • Height: 173.09, 9.54 • Weight: 80.46, 18.4 <p>Quote: "The groups did not differ in their demographic data" (page 99)</p> |
| Interventions | <p>1. Group A: 27 G PP needle, 10 minutes pre-operative time in upright sitting position. 27 G PP needle with introducer (Pencan[®] 0.42 × 88 mm– G27 × 3½, B. Braun, Melsungen, Germany)</p> <p>2. Group B: 27 G Q needle, 10 minutes pre-operative time in upright sitting position. 27 G Q needle with introducer (Spinocan[®] 0.42 × 88 mm–G27 × 3½, B-Braun, Melsungen, Germany)</p> <p>1. Group C: 27 G PP needle, 30 minutes pre-operative time in upright sitting position. 27 G PP needle with introducer (Pencan[®] 0.42 × 88 mm– G27 × 3½, B. Braun, Melsungen, Germany)</p> |

Schmittner 2011 (Continued)

1. Group D: 27 G Q needle, 30 minutes pre-operative time in upright sitting position. 27 G Q needle with introducer (Spinocan® 0.42 × 88 mm–G27 × 3½, B-Braun, Melsungen, Germany)

A vertical bevel direction was used.

| | |
|----------|--|
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Performance of spinal anaesthesia 3. Duration of PDPH 4. Severity of PDPH |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: ISRCTN 12262174 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: August 2008 until April 2009 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "upon arrival in the operating theatre, the patients were randomised via sealed envelopes in order to assign each patient into one of four study groups" (page 98) |
| Allocation concealment (selection bias) | Low risk | Quote: "upon arrival in the operating theatre, the patients were randomised via sealed envelopes in order to assign each patient into one of four study groups" (page 98) |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "A consultant anaesthesiologist who was blinded towards the needles used and who was not involved in the study assessed the incidence of PDPH" (page 99) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Schultz 1996

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Austria • Multisite: no • International: no • Needle type design used: Quincke vs Atraucan • Needle diameter used: 27 vs 26 |
|---------|---|

Schultz 1996 (Continued)

- Procedure: subarachnoid anaesthesia
- Number of attempts (1 attempt): 87% vs 86%
- Site of the puncture: L2-3
- Training level of those who administered the puncture: unknown
- Median or paramedian technique: median approach
- Type of anaesthesia: 0.5% bupivacaine, 4% mepivacaine or lidocaine 5%
- Patient position: sitting position

| | |
|---------------|--|
| Participants | <p>1. 388 ASA I-III patients, aged 15 to 80 years, who were scheduled for subumbilical surgery, were enrolled</p> <p>Exclusion criteria: obstetric patients</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 27 G Quincke group: 202 patients (52.06%) • 26 G Atraucan group: 186 patients (47.94%) <p>2. No patients were excluded from further analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Males (number): 27 G Quincke group: 85; 26 G Atraucan group: 86 |
| Interventions | <ul style="list-style-type: none"> • 27 G Quincke: Becton Dickinson, Rutherford, NJ • 26 G Atraucan needle: Braun, Melsungen, Germany <p>Both needles were used with a 20 G introducer to facilitate puncture</p> |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Headache (PDPH) 2. Severity of headache 3. Back pain |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "the patients were randomly assigned" (page 462) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |

Schultz 1996 (Continued)

| | | |
|--|----------|--|
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Sears 1994

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: USA • Multisite: no • Needle tip used: 24 G Sprotte vs 22 G Sprotte • Needle diameter used: 24 vs 22 25 vs 27 • Number of attempts (first attempt): unknown • Procedure: spinal anaesthesia • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: experienced anaesthesiologists • Median or paramedian technique: midline • Type of anaesthesia: hyperbaric bupivacaine 0.75% or hyperbaric 5% lidocaine, with or without fentanyl and/or morphine 12.5 mg to 17.5 mg • Patient position: lateral position |
| Participants | <p>1. 375 ASA physical status I and II caesarean section and postpartum tubal ligation patients at 4 hospitals participated in the study</p> <p>Exclusion criteria: unclear</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 24 G Sprotte group: 186 patients (49.6%). • 22 G Sprotte group: 189 patients (50.4%) <p>2. No patients were excluded from further analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 24 G Sprotte group: 29.5, 5; 22 G Sprotte group: 27.5, 4.8 • Height (mean, SD): 24 G Sprotte group: 163.1, 6.5; 22 G Sprotte group: 160.8, 6.3 • Weight (mean, SD): 24 G Sprotte group: 79.3, 11.9; 22 G Sprotte group: 79.7, 10.9 |
| Interventions | <p>1. 22 G Sprotte needle</p> <p>2. 24 G Sprotte needle</p> <p>All patients received an infusion of at least 1000 mL of lactated Ringer's solution over 30 minutes prior to the block</p> |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <p>1. Complication: headache</p> <p>2. PDPH</p> |

Sears 1994 (Continued)

3. Severity of PDPH

| | |
|-------|--|
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: January 2008 and December 2009 6. Declared conflicts of interest: not stated |
|-------|--|

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomly assigned to receive" (page 43) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Patients were visited at least once by the anesthesiologist during the postoperative period, and nurses on the obstetrics floor were instructed to notify the anesthesiologist of any complication, including headache. In addition, patients were contacted by telephone 1 week or more after discharge by an investigator who was blinded to the type of needle used." (page 43) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Shah 2010

| | |
|---------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: India • Multisite: no • International: no • Needle type design used: Quincke vs Whitacre • Needle diameter used: 25 vs 27 • Procedure: subarachnoid anaesthesia • Number of attempts (1 attempt): 92% to 61% • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: experienced anaesthesiologists • Median or paramedian technique: midline approach • Type of anaesthesia: 12.5 mg to 17.5 mg bupivacaine • Patient position: lateral position |
|---------|--|

Shah 2010 (Continued)

| | |
|---------------|---|
| Participants | <p>1. 800 young patients (16 to 40 years old) with ASA risk I/II scheduled for endoscopic urological procedures under spinal anaesthesia between January 2008 and December 2009 were enrolled in this study</p> <p>Exclusion criteria: history of headache, use of oral opioids or non-steroidal anti-inflammatory drugs, or contraindications to spinal anaesthesia</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Quincke group: 200 patients (25%) • 27 G Quincke group: 200 patients (25%) • 25 G Whitacre group: 200 patients (25%) • 27 G Whitacre group: 200 patients (25%) <p>2. No patients were excluded from further analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 25 G Quincke group: 30, 8.2; 27 G Quincke group: 27.8, 9.4; 25 G Whitacre group: 29, 7.7; 27 G Whitacre group: 28.31, 8.8 • Weight (mean, SD): 25 G Quincke group: 59.3, 14.8; 27 G Quincke group: 57.3, 11.6; 25 G Whitacre group: 56.5, 13.3; 27 G Whitacre group: 59.5, 11.8 |
| Interventions | <ul style="list-style-type: none"> • Quincke 25 G (0.50 x 90 mm) Becton Dickinson (Madrid, Spain) • Quincke 27 G (0.40 x 90 mm) Becton Dickinson (Madrid, Spain) • Whitacre pencil point 25 G (0.50 x 90 mm) Becton Dickinson (Madrid, Spain) • Whitacre 27 G (0.40 x 90 mm) Becton Dickinson (Madrid, Spain) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Headache (PDPH) 2. Severity of headache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: January 2008 and December 2009 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "Patients were randomly divided by computer-generated random numbers into four groups of 200 patients each." (page 25) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Postoperatively, all patients were visited successively for three days by a staff member, who was unaware of the type of needle used, to inquire about headache." (page 25) |
| Incomplete outcome data (attrition bias) | Low risk | No patients were lost to follow-up |

Shah 2010 (Continued)

All outcomes

| | | |
|--------------------------------------|-----------|---|
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Shaikh 2008

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group(3 arms) • Country: India • Multisite: no • Needle tip used: 25 G Quincke vs 27 G Quincke vs 27 G Whitacre • Needle diameter used: 25 vs 27 • Number of attempts: 1 • Procedure: anaesthesia • Site of the puncture: L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: unknown • Type of anaesthesia: 1.5 ml to 2.0 ml 0.75% hyperbaric bupivacaine • Patient position: sitting position |
| Participants | <p>1. 480 American Society of Anesthesiologists physical status classification (ASA) I-II women, aged 18 to 45 years, undergoing elective caesarean section, were enrolled</p> <p>Exclusion criteria: patient refusal, contraindication to spinal anaesthesia for infectious haemodynamic, haemostatic or neurological reasons, emergency caesarean section, severe pre-eclampsia or failure of the spinal anaesthesia. Patients with more than one attempt were excluded from the study.</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Quincke group: 168 patients (35%) • 27 G Quincke group: 160 patients (33%) • 27 G Whitacre group: 152 patients (32%) <p>2. No patients were excluded from further analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 25 G Quincke group: 25.8, 5.6; 27 G Quincke group: 26.4, 5.86; 27 G Whitacre group: 26.7, 4.45 • Weight (mean, SD): 25 G Quincke group: 59.9, 8.37; 27 G Quincke group: 61.7, 8.45; 27 G Whitacre group: 63, 9.10 |
| Interventions | <ol style="list-style-type: none"> 1. 25 G Quincke (group I). No further information was provided. The bevel of the Quincke spinal needles (group I and II) was kept parallel to the sagittal plane to prevent cutting of the dural fibres. 2. 27 G Quincke (group II). No further information was provided. The bevel of the Quincke spinal needles (group I and II) was kept parallel to the sagittal plane to prevent cutting of the dural fibres. 3. 27 G Whitacre (group III). No further information was provided. |
| Outcomes | <p>Outcomes were not classified as primary or secondary.</p> <ol style="list-style-type: none"> 1. PDPH 2. Non-specific headaches 3. Severity of PDPH |

Shaikh 2008 (Continued)

- Notes
1. Trial registration: not stated
 2. Funder: not stated
 3. Role of funder: not stated
 4. A priori sample size estimation: no
 5. Conducted: October 2005 to December 2006
 6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "The patients were selected randomly by balloting." (page 10) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "Patient, surgeon and the assessor in the ward did not know which spinal needle was used." (page 10) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Postoperatively, all patients were assessed daily for 4-days by an investigator, blinded to the type and size of the needle used.." (page 11) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Sharma 1995

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: USA • Multisite: no • Needle tip used: 25 G Whitacre vs 26 G Atraucan • Needle diameter used: 25 vs 27 • Number of attempts: 1 • Procedure: anaesthesia • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: experienced • Median or paramedian technique: midline • Type of anaesthesia: 70 mg to 80 mg lidocaine 5% with glucose 7.5% (Astra Pharmaceutical, Westborough, PA) • Patient position: sitting position |
| Participants | <p>1. 96 women (ASA I and II) scheduled for elective post-partum tubal ligation under spinal anaesthesia were enrolled</p> <p>Exclusion criteria: abnormal lumbar spaces due to deformities of the spine or obesity</p> |

Sharma 1995 (Continued)

Exclusion criteria: patient refusal, contraindication to spinal anaesthesia for infectious haemodynamic, haemostatic or neurological reasons, emergency caesarean section, severe pre-eclampsia or failure of the spinal anaesthesia. Patients with more than one attempt were excluded from the study.

Patients randomized to:

- 25 G Whitacre group: 46 patients (47.9%)
- 26 G Atraucan group: 50 patients (52.1%)

2. No patients were excluded from further analysis

3. Main characteristics of patients:

- Age (mean, SD): 25 G Whitacre group: 27, 5; 26 G Atraucan group: 28, 5
- Weight (mean, SD): 25 G Whitacre group: 62, 4; 26 G Atraucan group: 61, 5
- Height (mean, SD): 25 G Whitacre group: 154, 6; 26 G Atraucan group: 156, 8

| | |
|---------------|---|
| Interventions | <ol style="list-style-type: none"> 1. 25 G Whitacre (Beeton-Dickinson, Rutherford, NJ. OD - 0.5 mm, length - 8.89 cm) 2. 26 G Atraucan (B. Braun Medical, Bethlehem, PA. OD - 0.45 mm, length - 8.89 cm) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Non-specific headaches 3. Backache 4. Severity of PDPH 5. Technical issues: ease of needle insertion through the spinal ligaments, number of attempts at dural puncture, presence or absence of dural click, incidence of paraesthesia, and time for 2 CSF drops after the appearance of CSF at the end of the hub of the needle |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: B. Braun Medical, Inc 3. Role of funder: supply of Atraucan spinal needles 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "Patients were assigned randomly, using computer generated numbers." (page 707) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "All patients were evaluated daily throughout their hospital course by an observer blinded to group assignment and then interviewed by telephone one week after discharge from hospital for the presence of headache, backache, or any other complication". (page 707) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |

Sharma 1995 (Continued)

| | | |
|---|----------|--|
| Selective reporting (re-reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Shutt 1992

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (3 arms) • Country: UK • Multisite: yes • Needle tip used: 22 G Whitacre vs 25 G Whitacre vs 26 G Quincke • Needle diameter used: 22 vs 25 vs 26 • Number of attempts (= 1): 105 patients • Procedure: anaesthesia • Site of the puncture: L3-4 • Training level of those who administered the puncture: mix • Median or paramedian technique: midline • Type of anaesthesia: 0.5% bupivacaine in 8% glucose 2 ml to 2.5 ml • Patient position: lateral position |
| Participants | <ol style="list-style-type: none"> 1. 150 women of ASA grade I undergoing spinal anaesthesia for elective caesarean section were enrolled <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 22 G Whitacre group: 50 patients (33.3%) • 25 G Whitacre group: 50 patients (33.3%) • 26 G Quincke group: 50 patients (33.3%) <ol style="list-style-type: none"> 2. 6 patients (4%) were excluded from further analysis because of a failure to identify the subarachnoid space with the trial needle 3. Main characteristics of patients: <ul style="list-style-type: none"> • Age (mean): 22 G Whitacre group: 29.9; 25 G Whitacre group: 29.8; 26 G Quincke group: 28.8 • Weight (mean, SD): 22 G Whitacre group: 62.7, 11.1; 25 G Whitacre group: 63.9, 11.2; 26 G Quincke group: 61.5, 11 • Height (mean, SD): 22 G Whitacre group: 1.62, 0.8; 25 G Whitacre group: 1.62, 0.07; 26 G Quincke group: 1.61, 0.07 |
| Interventions | <ol style="list-style-type: none"> 1. 22 G Whitacre. No additional details provided. 2. 25 G Whitacre group: 25 G and 26 G needles were inserted through an introducer 3. 26 G Quincke group: 25 G and 26 G needles were inserted through an introducer |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Non-specific headaches 3. Backache 4. Dysuria 5. Severity of PDPH |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: Vygon UK Ltd |

Shutt 1992 (Continued)

3. Role of funder: supply of Whitacre and Quincke spinal needles
4. A priori sample size estimation: no
5. Conducted: not stated
6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "Each woman was allocated by random number selection to one of." (page 589) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "At 24 h also, the second "blind " anaesthetist visited the patient. His duty was to check that the questionnaire had been completed and to record the patient's temperature. If a headache had been reported, he completed a second questionnaire ascertaining the onset and distribution of the headache, the effect of posture and if there was any visual or auditory disturbance." (page 590) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 4% of patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Smith 1994

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: UK • Multisite: no • Needle tip used: atraumatic needles • Needle diameter used: 25 G Whitacre vs 27 G Whitacre • Number of attempts: unclear • Procedure: anaesthesia • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: unknown • Type of anaesthesia: 0.5% bupivacaine • Patient position: lateral position |
| Participants | <ol style="list-style-type: none"> 1. 212 women of ASA grade I undergoing spinal anaesthesia for elective caesarean section were enrolled <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Whitacre group: 104 patients (49.1%) |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Smith 1994 (Continued)

- 27 G Whitacre group: 108 patients (50.9%)
- 2. No patients were excluded from further analysis
- 3. Main characteristics of patients:
 - Weight (mean, SD): 25 G Whitacre group: 66.4, 14.4; 27 G Whitacre group: 66.7, 14.9
 - Height (mean, SD): 25 G Whitacre group: 1.74, 0.15; 27 G Whitacre group: 1.60, 0.08

| | |
|---------------|--|
| Interventions | <ol style="list-style-type: none"> 1. 25 G Whitacre group: no additional details provided 2. 27 G Whitacre group: no additional details provided |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Backache 3. Severity of PDPH 4. Factors affecting easy of use |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomly allocated to receive a subarachnoid block using either a 25G or a 27G Whitacre (...)" (page 859) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Patients were interviewed daily on the 1st to 5th postoperative days, by an anaesthetist unaware of the needle size used (..)". (page 860) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 8 patients (3.7%) were excluded from analysis |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Srivastava 2010a

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (4 arms), randomized |
|---------|---|

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Srivastava 2010a (Continued)

- Country: India
- Multisite: no
- International: no
- Needle type design used: 27 G Quincke, 27 G Whitacre
- Needle diameter used: not reported
- Procedure: spinal anaesthesia
- Random unit: patients
- Analysis unit: patients
- Definition PDPH: location of pain in the occipital/frontal areas of the head – exacerbation of symptoms while sitting or standing

| | |
|---------------|--|
| Participants | <ol style="list-style-type: none"> 1. 100 patients enrolled (either sex, age group 14 to 75, ASA I and II, admitted for elective or emergency lower segment caesarian section and other surgical procedures) <p>Losses at follow-up and reasons for exclusions not reported</p> <ol style="list-style-type: none"> 2. Patients randomized to: <ul style="list-style-type: none"> • 27 G Whitacre non-obstetric (50) • 27 G Quincke non-obstetric (50) 3. Main characteristics of patients: <ul style="list-style-type: none"> • Mean age (SD): 27 G Whitacre no 38.43 (14.15); 27 G Quincke no 42.5 (14.11) • Numbers of males/females were not reported • Percentage of postures during the lumbar puncture: left lateral or sitting position (91% in sitting position) |
| Interventions | <ol style="list-style-type: none"> 1. 27 G Whitacre non-obstetric group 2. 27 G Quincke non-obstetric group |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Incidence of PDPH 2. Onset of PDPH 3. Intraoperative complications 4. Severity of PDPH 5. Any headache subsequent to lumbar puncture: not reported |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not reported 6. Declared conflicts of interest: no |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomly allocated into four groups" (page 711) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |

Srivastava 2010a (Continued)

| | | |
|---|--------------|--|
| Blinding of participants (performance bias) | Low risk | Quote: "All the patients were blinded to the needle utilized. The anaesthetist conducting the procedure was not blinded as the two needles have different appearance making blinding impossible". (page 711) |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Srivastava 2010b

| | |
|---------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (4 arms), randomized • Country: India • Multisite: no • International: no • Needle type design used: 27 G Quincke, 27 G Whitacre • Needle diameter used: not reported • Procedure: spinal anaesthesia |
| Participants | <p>1. 100 patients enrolled (either sex, age group 14 to 75, ASA I and II, admitted for elective or emergency lower segment caesarian section and other surgical procedures)</p> <p>Losses at follow-up and reasons for exclusions not reported</p> <p>2. Patients randomized to:</p> <ul style="list-style-type: none"> • 27 G Whitacre obstetric (50) • 27 G Quincke obstetric (50) <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Mean age (SD): 27 G Whitacre 38.43 (14.15); 27 G Quincke 42.5 (14.11) • Percentage of postures during the lumbar puncture: left lateral or sitting position (91% in sitting position) |
| Interventions | <ol style="list-style-type: none"> 1. 27 G Whitacre obstetric group 2. 27 G Quincke obstetric group |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Incidence of PDPH 2. Onset of PDPH 3. Intraoperative complications 4. Severity of PDPH 5. Any headache subsequent to lumbar puncture: not reported |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated |

Srivastava 2010b (Continued)

2. Funder: not stated
3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: not reported
6. Declared conflicts of interest: no

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomly allocated into four groups" (page 711) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "All the patients were blinded to the needle utilized. The anaesthetist conducting the procedure was not blinded as the two needles have different appearance making blinding impossible". (page 711) |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Standl 2004

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms), randomized • Country: Germany • Multisite: yes (4 hospitals) • International: no • Needle type design used: hybrid vs pencil • Needle diameter used: 25 G • Procedure: spinal anaesthesia |
| Participants | <ol style="list-style-type: none"> 1. 700 patients enrolled (ASA I/II/III patients were scheduled for lower abdominal or extremity surgery (orthopaedic, trauma, urology, visceral, gynaecology) and underwent the same protocol) <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Ballpen (339) • 25 G Sprotte (338) <p>23 randomized patients (15 group B, 18 group S) were excluded due to:</p> <ul style="list-style-type: none"> • Missing data (23) <ol style="list-style-type: none"> 2. 0 patients lost to follow-up |

Standl 2004 (Continued)

3. Main characteristics of patients:

- Mean age (SD):
 - * 25 G Ballpen 54 (18)
 - * 25 G Sprotte 56 (17)
- Number of females/males:
 - * 25 G Ballpen 130/209
 - * 25 G Sprotte 131/207
- Number of postures during the lumbar puncture: lateral position (25 G Ballpen N = 3, 25 G Sprotte N = 4), sitting position (25 G Ballpen N = 336, 25 G Sprotte N = 334)

| | |
|---------------|---|
| Interventions | 1. 25 G Ballpen needle group): Rüschi, Kernen, Germany 2. 25 G Sprotte needle group: Pajunk, Geisingen, Germany |
| Outcomes | Outcomes were not classified as primary or secondary 1. Incidence of PDPH 2. Side effects |
| Notes | 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: yes 5. Conducted: not reported 6. Declared conflicts of interest: no |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: "according to a randomization protocol that was created by a computerized program for each study site". (page 513) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "During postoperative Day 2 and 4, all patients were visited by an anesthesiologist who was blinded to the type of spinal needle" (page 514) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 23 patients (3.2%) were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Strupp 2001

| | |
|---------|---|
| Methods | <ul style="list-style-type: none"> • Design: prospective, randomized, double-blind study, 2 arms |
|---------|---|

Strupp 2001 (Continued)

- Country: Germany
- Multisite: no
- Needle type design used: diamond vs pencil
- Needle diameter used: 22 G (0.80 mm)
- Number of attempts: not reported
- Procedure: lumbar puncture
- Site of the puncture: not reported
- Training level of those who administered the puncture: experienced neurologists
- Median or paramedian technique: not reported
- Type of anaesthetic: not reported
- Patient position: sitting

| | |
|---------------|--|
| Participants | <p>1. 230 patients enrolled (who had a neurologic indication for an LP (e.g. MS, neuroborreliosis or other CNS infections), between 18 and 59 years, no recent headache (at least up to 1 week before LP, years; 2) no recent headache, i.e. at least up to 1 week), no evidence of increased intracranial pressure, no LP in the last 4 weeks, ability to be mobilized and no previous headache or other pain medication.</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 22 G Sprotte (115) • 22 G Quincke (115) <p>2. No exclusions or losses to follow-up were reported</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • 22 G Sprotte: mean age 39.8 (SD 12.8), 64 females • 22 G Quincke: mean age 40.7 (SD 11.5), 63 females |
| Interventions | <ol style="list-style-type: none"> 1. "atraumatic" Sprotte needle (22 G, 0.80 mm, 90 mm; Pajunk, Geisingen, Germany) 2. "traumatic" Quincke needle (22 G, 0.80 mm, 90 mm; Braun, Melsungen, Germany) |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. PDPH intensity (mean pain score) 3. PDPH severity |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: November 2000 to March 2001 6. Declared conflicts of interest: not reported |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were allocated randomly to one or the other group according to Efron." (page 2311) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |

Strupp 2001 (Continued)

| | | |
|---|--------------|---|
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Unclear if patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Tabedar 2003

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: prospective, randomized, double-blind study, 2 arms • Country: Nepal • Multisite: no • Needle type design used: diamond vs pencil • Needle diameter used: 25 G and 26 G • Number of attempts: 1, 2 or more than 2 • Procedure: midline approach • Site of the puncture: L2-L3 or L3-L4 • Training level of those who administered the puncture: unclear • Median or paramedian technique: unclear • Type of anaesthetic: 2.9 ml 0.5% heavy bupivacaine • Patient position: sitting |
| Participants | <p>1. 60 ASA I and II primi and multipara parturient undergoing elective caesarean section aged 19 to 40 years. Exclusion criteria: parturient refusal, weight more than 75 kg, eclampsia/pre-eclampsia, bleeding disorders</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • Quincke (30) • Eldor (30) <p>2. 6 (8.21%) patients lost to follow-up because no cerebrospinal fluid was obtained with the Sprotte needle</p> <p>3. Main characteristics:</p> <ul style="list-style-type: none"> • Quincke: age 19 to 33 • Eldor: age 19 to 35 |
| Interventions | <ol style="list-style-type: none"> 1. 25 G Quincke: no further details were provided 2. 26 G Eldor: no further details were provided |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Headache 2. PDPH |

Tabedar 2003 (Continued)

3. Attempts

| | |
|-------|--|
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: not stated 5. Conducted: not reported 6. Declared conflicts of interest: not reported |
|-------|--|

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "60 ASA I and II primi and multipara parturient undergoing elective caesarean section aged 19-40 years were randomly divided (...)" (page 264) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Tarkkila 1992

| | |
|--------------|---|
| Methods | <ul style="list-style-type: none"> • Design: randomized, prospective study, 2 arms • Country: Finland • Multisite: yes • Needle type design used: diamond vs pencil • Needle diameter used: 24 G, 25 G • Number of attempts: not reported • Procedure: spinal anaesthesia • Site of the puncture: not reported • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline lumbar puncture • Type of anaesthetic: lidocaine, hyperbaric bupivacaine, isobaric bupivacaine • Patient position: not reported |
| Participants | <ol style="list-style-type: none"> 1. 300 co-operative ASA I and II who had spinal anaesthesia for minor orthopaedic or urologic operations, and who were not expected to need a blood transfusion |

Tarkkila 1992 (Continued)

Patients randomized to:

- 25 G Quincke with bevel parallel (100)
- 25 G Quincke with bevel perpendicular (100)
- 24 G Sprotte (100)

2. 256 patients (86.5%) returned the second questionnaire and were included in the study

- 12 patients were excluded due to failure
- Patients analysed: 256

1. Main characteristics:

- 25 G Quincke with bevel parallel, mean age: 43.5, 46 female
- 25 G Quincke with bevel perpendicular, mean age 44.7, 44 female
- 24 G Sprotte, mean age 40.3, 43 female

| | |
|---------------|--|
| Interventions | 1. 25 G Quincke: no further details were provided 2. 24 G Sprotte: no further details were provided |
| Outcomes | Outcomes were not classified as primary or secondary 1. PDPH 2. Non-PDPH 3. Other complications |
| Notes | 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: not stated 5. Conducted: not reported 6. Declared conflicts of interest: not reported |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The patients were randomized into three groups of equal size" (page 284) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | 13.5% of patients lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |

Tarkkila 1992 (Continued)

| | | |
|------------|----------|---------------------------------|
| Other bias | Low risk | No other biases were identified |
|------------|----------|---------------------------------|

Tarkkila 1994

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: randomized, prospective study • Country: Finland • Multisite: no • Needle type design used: diamond • Needle diameter used: 25 G, 27 G, 29 G • Number of attempts: unknown • Procedure: spinal anaesthesia • Site of the puncture: unclear • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline • Type of anaesthetic: 0.5% hyperbaric bupivacaine or 5% hyperbaric lignocaine • Patient position: lateral |
| Participants | <p>1. 300 patients undergoing surgery under spinal anaesthesia</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Quincke (100) • 27 G Quincke (100) • 29 G Quincke (100) <p>2. Patients analysed: 2% failure rate, thus 6 patients were excluded from analysis. 94% were interviewed postoperatively.</p> <p>3. Main characteristics:</p> <ul style="list-style-type: none"> • 25 G Quincke mean age 46, 44 female • 27 G Quincke mean age 44, 47 female • 29 G Quincke mean age 43, 46 female |
| Interventions | <ol style="list-style-type: none"> 1. 25 G Quincke (Becton Dickinson): no further details were provided 2. 27 G Quincke (Becton Dickinson): no further details were provided 3. 29 G Quincke (Becton Dickinson): no further details were provided |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. PDPH 2. Backache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: not stated 5. Conducted: not reported 6. Declared conflicts of interest: not reported |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|------|--------------------|-----------------------|
|------|--------------------|-----------------------|

Tarkkila 1994 (Continued)

| | | |
|---|--------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Three hundred patients undergoing surgery under spinal anaesthesia were randomly allocated (...)". (page 723) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | High risk | Quote: "All the spinal anaesthetics were performed by the authors"... "The patients were contacted by one of the authors one week after the surgery." (page 723) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 18 patients (6%) were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Thomas 2000

| | |
|--------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: UK • Multisite: no • International: no • Needle tip used: diamond vs pencil • Needle diameter used: 20 G • Number of attempts: mean 4 • Procedure: diagnostic lumbar puncture • Site of the puncture: unclear • Training level of those who administered the puncture: senior physician • Median or paramedian technique: unclear • Amount of CSF extracted: unclear • Amount of injected volume: unclear • Patient position: lateral position |
| Participants | <p>1. 116 patients enrolled (patients attending the investigation ward on a regional neurology unit for elective diagnostic lumbar puncture)</p> <p>Not randomized (n = 15)</p> <p>Consent refused (n = 8)</p> <p>Incomplete training for senior house officers (n = 7)</p> <p>99 patients randomized to:</p> <ul style="list-style-type: none"> • Standard needle (49, 48.51%) • Atraumatic needle (50, 49.5%) |

Thomas 2000 (Continued)

2. 2 patients (2%) did not receive the allocated intervention in each arm and they were excluded. 97 patients randomized to: standard needle (48, 46.56%); atraumatic needle (49, 47.53%)

6. Main characteristics of patients:

- Age: atraumatic needle group: 39.6 (SD 11.5)
- Standard needle group: 40 (SD 10.6)
- Gender: atraumatic needle group: 65%/39 female and 35%/17 male; standard needle group: 77%/37 female and 23%/11 male

| | |
|---------------|---|
| Interventions | <ol style="list-style-type: none"> 1. Standard needle group: 20 G Quincke needle 2. Atraumatic needle group: Sprotte or Pajunk needle 3. Co-intervention: all patients rested in bed for at least 4 hours after the procedure and fluid intake was encouraged |
| Outcomes | <p>Outcomes were classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Primary: incidence of moderate or severe headache at 1 week according to needle type (intention-to-treat) 2. Secondary: incidence of moderate or severe headache at 1 week by successful needle type, incidence of headache at 24 hours and 1 week, incidence of backache at 24 hours and 1 week, and ease of use by operator |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: Glasgow Neurosciences Foundation 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: September 1998 and February 1999 6. Declared conflicts of interest: yes, not reported (page 989) |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Low risk | Quote: "Randomisation was done by a computer generated code stored in opaque envelopes that were serially numbered and sealed" (page 987) |
| Allocation concealment (selection bias) | Low risk | Quote: "Randomisation was done by a computer generated code stored in opaque envelopes that were serially numbered and sealed" (page 987) |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "One week after lumbar puncture, the patients were telephoned by a single observer who was blinded to needle allocation" (page 987) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 2 patients were lost to follow-up (2%) |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Unclear risk | The role of funder is unclear |

Tourtellotte 1972

| | |
|---------------|---|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: USA • Multisite: no • International: no • Needle tip used: 22 G vs 26 G needles • Needle diameter used: 22 G vs 26 G needles • Number of attempts: unclear • Procedure: diagnostic lumbar puncture • Site of the puncture: unclear • Training level of those who administered the puncture: unclear • Median or paramedian technique: unclear • Amount of CSF extracted: 20 ml • Amount of injected volume: unclear • Type of anaesthetic: unclear • Patient position: left lateral position |
| Participants | <ol style="list-style-type: none"> 1. 100 patients enrolled (healthy volunteers rated normal on physical and neurological examinations) <ul style="list-style-type: none"> • 100 patients randomized to: <ul style="list-style-type: none"> * 22 G needle group (50, 50%) * 26 G needle group (50, 50%) 2. No randomized patients were excluded from the study <ul style="list-style-type: none"> • No patients lost to follow-up 3. Main characteristics of patients: <ul style="list-style-type: none"> • Age: 22 G needle group and 26 G needle group: 23.2 years with a range of 20 to 41 • Gender: 22 G needle group: 46% female/54% male • 26 G needle group: 34% female/66% male |
| Interventions | <ol style="list-style-type: none"> 1. 22 G needle group 2. 26 G needle group |
| Outcomes | <p>Outcomes were not classified as primary or secondary</p> <ol style="list-style-type: none"> 1. Post-lumbar puncture complaints 2. Post-lumbar puncture complaints: minor complaints: headaches for only a short period immediately after the LP, minimal to mild, non-postural headaches, unusual tiredness on the day of the LP, slight numbness and insomnia 3. Post-lumbar puncture complaints: major complaints: mild to severe postural headaches that were often incapacitating and accompanied by other complaints such as backaches, unusual tiredness, anorexia, nausea and vomiting, and weight loss 4. Presence of postural headaches |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: not stated 3. Role of funder: not stated 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: no |

Risk of bias

Tourtellotte 1972 (Continued)

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Members of each successive pair of incoming volunteers were randomly" (page 1) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "The subjects were blinded with respect to size of needle used. They were all interviewed by the same neurologist (W.W.T.), who was also blinded as to needle size" (page 2) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "They were all interviewed by the same neurologist (W.W.T.), who was also blinded as to needle size" (page 2) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Wiesel 1993

| | |
|--------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Canada • Multisite: no • International: no • Needle type design used: Sprotte vs Quincke • Needle diameter used: 24 vs 27 • Procedure: spinal anaesthesia • Number of attempts (1 attempt): 73.9% vs 66% • Site of the puncture: unknown • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline approach • Type of anaesthesia: unclear • Patient position: unknown |
| Participants | <p>1. 96 patients less than 45 years of age undergoing elective or emergency surgery were enrolled</p> <p>Exclusion criteria: obstetric patients</p> <p>Number of patients randomized to each group: unclear</p> <p>2. 3 patients were excluded from further analysis due to incomplete interviews</p> <p>Patients analysed:</p> <ul style="list-style-type: none"> • 24 G Sprotte group: 46 patients • 27 G Quincke group: 47 patients <p>3. Main characteristics of patients:</p> |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Wiesel 1993 (Continued)

- Age (mean, SD): 24 G Sprotte group: 32.4, 7.3; 27 G Quincke group: 34.2, 8
- Males (number): 24 G Sprotte group: 27; 27 G Quincke group: 23

Interventions

- 24 G Sprotte needle (8.89 cm; Pajunk, Germany)
- 27 G Quincke needle (8.89 cm; Becton Dickinson, Franklin Lake, New Jersey)

Outcomes

Outcomes were not classified as primary or secondary

1. Headache (PDPH)
2. Severity of headache
3. Satisfaction of patient

Notes

1. Trial registration: not stated
2. Funder: not stated
3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: not stated
6. Declared conflicts of interest: not stated

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were randomized to receive spinal anesthesia with either the 24 gauge Sprotte needle or the 27 G Quincke needle." (page 608) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Low risk | Quote: "Patients were interviewed in person or by telephone (if discharged from the hospital) by an anesthetist not involved with the case or by a research nurse. Both were blinded to the spinal needle used" (page 608) |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Patients were interviewed in person or by telephone (if discharged from the hospital) by an anesthetist not involved with the case or by a research nurse. Both were blinded to the spinal needle used" (page 608) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Wilkinson 1991

Methods

- Design: parallel-group (2 arms)
- Country: UK
- Multisite: no
- International: no
- Needle tip used: 26 G versus 22 G

Wilkinson 1991 (Continued)

- Needle diameter used: 26 G versus 22 G
- Number of attempts: unclear
- Procedure: myelography
- Site of the puncture: unclear
- Training level of those who administered the puncture: unclear
- Median or paramedian technique: unclear
- (For dx lumbar puncture or myelography only)
- Amount of CSF extracted: unclear
- Amount of injected volume: 10 ml iopamidol 300 (3.0 g iodine) were used for lumbar myelography and 15 ml (4.5 g iodine) for thoracic and cervical myelography
- All lumbar punctures were performed with the patient in the left lateral decubitus position

Participants

1. 284 patients enrolled (patients referred for myelography)
 - Patients randomized to:
 - * 22 G needle group (147, 51.7%)
 - * 26 G needle group (137, 48.2%)
 - No patients were lost to follow-up
 - No randomized patients were excluded from this study
2. 6 patients were excluded following failed lumbar puncture with 26 G needles
3. Main characteristics of patients:
 - Average age: 46.9 (range 13 to 86 years)
 - Percentage/number of females/males by group:
 - * 26 G: female 118 (41.5%); male 166 (58.4%)
 - * 22 G: female 59; male 78

Interventions

1. Up to 2 ml of 1% lignocaine was injected intradermally using a 25 G needle and into the subcutaneous tissues using a 21 G needle
2. The 26 G spinal needles were inserted coaxially through a 4 cm long 21 G needle used for local anaesthesia

All lumbar punctures were performed with the patient in the left lateral decubitus position

Patients were routinely ambulatory following the examination

Outcomes

Outcomes were not classified as primary or secondary

1. Incidence of headaches: postural headaches as well as mild, moderate or severe headaches
2. Incidence of adverse events: nausea, vomiting, dizziness and visual disturbance
3. Type of myelogram
4. Experience of radiologist

Notes

1. Trial registration: not stated
2. Funder: not stated
3. Role of funder: not stated
4. A priori sample size estimation: no
5. Conducted: not reported
6. Declared conflicts of interest: not reported

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|------|--------------------|-----------------------|
|------|--------------------|-----------------------|

Wilkinson 1991 (Continued)

| | | |
|---|--------------|--|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "The patients were randomly assigned to the 22 G or the 26 G needle group." (page 338) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "Patients were given a questionnaire to complete on discharge from hospital 24h after the myelogram. Late complications were obtained by telephone" (page 338) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | Low risk | All patient-important outcomes were reported |
| Other bias | Low risk | No other biases were identified |

Zela 1994

| | |
|--------------|--|
| Methods | <ul style="list-style-type: none"> • Design: parallel-group (2 arms) • Country: Mexico • Multisite: no • International: no • Needle type design used: Whitacre vs Quincke • Needle diameter used: 25 • Procedure: spinal anaesthesia • Number of attempts (1 attempt): unknown • Site of the puncture: L2-3 or L3-4 • Training level of those who administered the puncture: unknown • Median or paramedian technique: midline approach • Type of anaesthesia: unclear • Patient position: unknown |
| Participants | <p>1. 40 patients ASA I-II, aged from 18 to 50 years, undergoing subumbilical surgery were enrolled</p> <p>Exclusion criteria: history of headache, refusal of method, hypertension</p> <p>Patients randomized to:</p> <ul style="list-style-type: none"> • 25 G Whitacre Group: 20 patients (50%) • 25 G Quincke Group: 20 patients (50%) <p>2. No patients were excluded from further analysis</p> <p>3. Main characteristics of patients:</p> <ul style="list-style-type: none"> • Age (mean, SD): 25 G Whitacre group: 27, 18; 25 G Quincke group: 29, 17 • Men (number): 24 G Sprotte group: 10; 27 G Quincke group: 10 |

Zela 1994 (Continued)

| | |
|---------------|--|
| Interventions | <ul style="list-style-type: none"> • 25 G Whitacre needle: no details were provided • 25 G Quincke needle: no details were provided |
| Outcomes | Outcomes were not classified as primary or secondary <ol style="list-style-type: none"> 1. Headache (PDPH) 2. Severity of headache |
| Notes | <ol style="list-style-type: none"> 1. Trial registration: not stated 2. Funder: Becton Dickinson and Company 3. Role of funder: provision of needles 4. A priori sample size estimation: no 5. Conducted: not stated 6. Declared conflicts of interest: not stated |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias. Quote: "(we) developed a clinical trial with 40 patients" (page 1) |
| Allocation concealment (selection bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of participants (performance bias) | Unclear risk | Insufficient information to score this item as low or high risk of bias |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Quote: "Follow-up to detect patients who developed PDPH was realized by an anesthesiologist different from the one who performed the procedure" (page 67) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | No patients were lost to follow-up |
| Selective reporting (reporting bias) | High risk | Adverse events, additional to PDPH, were not reported |
| Other bias | Low risk | No other biases were identified |

Acronyms and abbreviations used in this table

ASA: American Society of Anesthesiologists; ASN: Atraucan spinal needle; BMI: body mass index; CI: confidence interval; c-section: caesarean section; CSF: cerebrospinal fluid; G: gauge; IQR: interquartile range; L2-3 to L3-4: lumbar vertebrae 2-3 to 3-4; LP: lumbar puncture; NRS: numerical rating scale; NYHA: New York Heart Association; PDPH: post-dural puncture headache; RCT: randomized controlled trial; SD: standard deviation; SEM: standard error of the mean; VAS: visual analogue scale; vs: versus; WSN: Whitacre spinal needle

Characteristics of excluded studies [ordered by study ID]

| Study | Reason for exclusion |
|-------------------------------|---|
| Ansaloni 2000 | In this study, the authors did not evaluate the use of a specific type of needle or its gauge for the evaluation of PDPH. |

| Study | Reason for exclusion |
|-------------------------------------|---|
| Benedetti 1992 | This study was excluded because it was performed without any random allocation process. |
| Braune 1992 | This study is not a randomized controlled trial. |
| Browne 2005 | This study was excluded because an intervention to treat PDPH is included. |
| Carrada 1997 | This study was excluded because it was performed without any random allocation process. |
| Charuluxananan 2005 | In this study, the units of randomization were anaesthesiologists in training (learning curve) and not a specific type of needle. |
| Das-Neves 2001 | This study was excluded because it was performed without any random allocation process. |
| Eldor 2003 | This study was excluded because it was a letter to the editor. |
| Eshuis 1995 | This study was excluded because it was a comment. |
| Flaatten 1998 | This study was excluded because the unit of randomization was the procedure and not the patient. |
| Ginosar 2012 | In this study, the authors used a pulsatile cerebrospinal fluid model to test a spinal needle. |
| Guclu 2006 | This study was excluded because it was a letter to the editor. |
| Herbstman 1998 | This study was excluded because an intervention to treat PDPH is included. |
| Huffnagle 1998 | This study was excluded because the intervention assessed in this review was not addressed. |
| Jones 1994 | This study was excluded because it did not use an adequate method of randomization (odd and even hospital record numbers). |
| Landau 2001 | This study was excluded because it was performed without any random allocation process. |
| Lynch 1992 | This study was excluded because it was performed without any random allocation process. |
| Malhotra 2007 | This study was excluded because it was performed without any random allocation process. |
| Mardirosoff 2001 | This study was excluded because it evaluated the duration of time sitting and spinal needle type on the maximal spread of local anaesthetics and not the presence of PDPH. |
| Mazze 1993 | This study was excluded because the unit of randomization was the procedure and not the patient. |
| Merlo 1989 | This study was excluded because it was performed without any random allocation process. |
| Nunes 1999 | This study was excluded because it was performed without any random allocation process. |
| Pjevic 1993 | This study is not a randomized controlled trial. |
| Quinn 2013 | This study was excluded because it was a narrative review. |
| Russell 2002 | This study was excluded because it evaluated different positions (oxford position, lateral and sitting positions) during spinal-epidural anaesthesia and not the use of different types of needles. |
| Samayoa 2004 | This study was excluded because it was performed without any random allocation process. |
| Shah 2002 | This study is not a randomized controlled trial. |

| Study | Reason for exclusion |
|-----------------------------------|--|
| Sinikoglu 2013a | This study was excluded because it evaluated the effects of reinsertion of the stylet after a spinal anaesthesia procedure on PDPH and not the type or size of the needle. |
| Strupp 1998 | This study was excluded because it evaluated the effects of reinsertion of the stylet after a spinal anaesthesia procedure on PDPH and not the type or size of the needle. |
| Strupp 2009 | This study was excluded because it was a narrative review. |
| Thoren 1994 | This study was excluded because it evaluated different types of anaesthesia techniques (sequential combined spinal epidural block versus spinal block) and not different types of needles. |
| Vallejo 2000 | This study was excluded because the authors randomized the days on which each different needle would be used and not the patients. |
| Van Den Berg 2011 | This study was excluded because it was performed without any random allocation process. |
| Vilming 2001 | This study was excluded because it was performed without any random allocation process. |
| Wilhelm 1997 | This study was excluded because it was not focused on the prevention of PDPH. |

PDPH: post-dural puncture headache

Characteristics of studies awaiting assessment [ordered by study ID]

[Bano 2004](#)

| | |
|---------------|---|
| Methods | Single blinded, interventional, experimental study |
| Participants | A total of 100 females, aged 18 to 35 years, ASA physical status I and II, with singleton pregnancy undergoing elective or emergency caesarean section under spinal anaesthesia |
| Interventions | Participants were randomly allocated to receive spinal anaesthesia either by using 25 G Quincke or 25 G Whitacre needles. Patients were followed for 3 days postoperatively |
| Outcomes | The primary outcome was the assessment of headache and the relation to posture. Secondary outcomes were onset of headache, its duration, severity and response to the treatment |
| Notes | — |

[Buttner 1990](#)

| | |
|---------------|--|
| Methods | Prospective, randomized, double-blind study |
| Participants | A total of 400 patients who received spinal anaesthesia for operation of the lower extremities |
| Interventions | Patients were randomly assigned to 2 groups (25 G Whitacre and a 25 G Quincke needles) and were interviewed postoperatively on days 1, 3, 5 and 7 to assess PDPH |
| Outcomes | The primary outcome was PDPH. Secondary outcomes were: duration of PDPH, non-postural headache and the duration of non-postural headache. |
| Notes | — |

Castrillo 2015

| | |
|---------------|---|
| Methods | Prospective, randomized and single-blinded clinical trial |
| Participants | Patients older than 14 years were scheduled for a diagnostic or therapeutic lumbar puncture |
| Interventions | 2 kinds of spinal needle: atraumatic or S-type or traumatic or Q-type |
| Outcomes | Development of PDPH according to the International Headache Association criteria |
| Notes | — |

De Andres 1994

| | |
|---------------|--|
| Methods | Prospective, randomized, double-blind study |
| Participants | A total of 158 patients, ASA I and II, ranging in age from 20 to 40 years undergoing lower limb orthopaedic surgery |
| Interventions | Patients were randomly assigned to 2 groups (26 G Atraucan and 27 G Whitacre needles) for the realization of spinal anaesthesia |
| Outcomes | The primary outcome was: frequency and degree of PDPH. Secondary outcomes were: performance of the subarachnoid technique and intraoperative side effects. |
| Notes | — |

Fama 2015

| | |
|---------------|--|
| Methods | Prospective, randomized, experimental study in healthy participants |
| Participants | 330 parturients scheduled for caesarean section |
| Interventions | 25, 26 or 27 G pencil point, Whitacre type (with introducer) needles |
| Outcomes | Puncture failure rates, post-dural puncture headache |
| Notes | — |

Fyneface-Ogan 2006

| | |
|---------------|---|
| Methods | Prospective, single-blind, randomized study |
| Participants | A total of 100 women undergoing elective and emergency caesarean delivery under spinal anaesthesia were recruited |
| Interventions | Patients were randomly allocated to receive spinal anaesthesia either by using 2 spinal needles (Becton Dickinson Whitacre sizes 25 G and 26 G needles) |
| Outcomes | Incidence of PDPH |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Fyneface-Ogan 2006 *(Continued)*

Notes —

Harrison 1994

| | |
|---------------|--|
| Methods | Randomized, prospective study |
| Participants | A total of 113 patients referred for lumbar, thoracic, cervical or total column myelography |
| Interventions | Participants were numbered sequentially; in even-numbered patients a 22 G needle was used and for odd-numbered patients, a 25 G needle |
| Outcomes | The primary outcome was the incidence of headache following myelography. Secondary outcomes were: the influence of needle type, sex, myelogram type and operators. |
| Notes | — |

Hong 2015

| | |
|---------------|--|
| Methods | Prospective, randomized trial |
| Participants | 149 patients undergoing lumbar transforaminal epidural steroid injection for radicular leg pain |
| Interventions | Whitacre and Quincke type needles |
| Outcomes | After final confirmation of intravascular injection with digital subtraction angiography, total procedure time and amount of radiation exposure during the procedure were measured |
| Notes | — |

Jager 1995

| | |
|---------------|-------------------------|
| Methods | Only title is available |
| Participants | Not known |
| Interventions | Not known |
| Outcomes | Not known |
| Notes | — |

Jensen 1999

| | |
|--------------|---|
| Methods | Prospective, randomized study |
| Participants | A total of 197 patients aged below 40 years were included in this study |

Jensen 1999 *(Continued)*

| | |
|---------------|--|
| Interventions | Participants were randomized to receive spinal analgesia using one of the following needles: Sprotte G24, Spinocan G27 or Atraucan G26 |
| Outcomes | The primary outcome of this study was the incidence of postoperative complications including post-dural puncture headache (PDPH) |
| Notes | — |

Kaul 1996

| | |
|---------------|--|
| Methods | Prospective, randomized study |
| Participants | A total of 90 adult patients who underwent elective surgical operations under spinal anaesthesia were evaluated |
| Interventions | Patients were randomly allocated to 3 groups of 30 each to receive spinal anaesthesia using 20- G, 22 G or 24-gauge spinal needles |
| Outcomes | The primary outcome was: incidence of headache and frequency of hearing loss |
| Notes | — |

Knudsen 1998

| | |
|---------------|---|
| Methods | Prospective, randomized study |
| Participants | A total of 106 patients, aged below 40 years, scheduled for surgery in the lower part of the body were chosen for this study |
| Interventions | Patients were allocated randomly to have spinal analgesia with either a Sprotte 24 G or an Atraucan 26 G spinal needle |
| Outcomes | The primary outcome was: incidence of PDPH. Secondary outcomes were: ease of needle insertion and number of puncture attempts |
| Notes | — |

Lim 1992

| | |
|---------------|--|
| Methods | Prospective, randomized study |
| Participants | A total of 56 patients were recruited in this study |
| Interventions | Patients underwent spinal anaesthesia for extra-corporeal shockwave lithotripsy using either a Sprotte 24 G (n = 28) or Vygon 29 G or Quincke type needle (n = 28) |
| Outcomes | Frequency of PDPH |
| Notes | — |

Maclean 1994

| | |
|---------------|---|
| Methods | Prospective, randomized, double-blind study |
| Participants | A total of 60 nulliparous women |
| Interventions | Participants were randomized to receive an epidural infusion of either 0.125% plain bupivacaine or 0.0625% bupivacaine with 2.5µg/ml fentanyl |
| Outcomes | The primary outcome was pain and motor block. Secondary outcomes were maternal side effects and cardio-tocograph abnormalities |
| Notes | — |

Mignonsin 1991

| | |
|---------------|--|
| Methods | Prospective, controlled study |
| Participants | 30 ASA I or II patients |
| Interventions | Lumbar puncture was carried out with 26 G in group I and 18 G in group II |
| Outcomes | Complications during spinal anaesthesia included: vomiting, nausea, allergy and low blood pressure. Postspinal headache. |
| Notes | — |

Palmieri 1993

| | |
|---------------|--|
| Methods | Prospective, randomized study |
| Participants | A total of 92 pregnant patients undergoing elective caesarean section |
| Interventions | Patients undergoing lumbar puncture were randomized to 2 groups (Group I: 22 G Quincke disposable needle and group II: 22 G Quincke reusable needle) |
| Outcomes | The primary outcome was the assessment of PDPH. There were no secondary outcomes. |
| Notes | — |

Puolakka 1997

| | |
|---------------|--|
| Methods | Prospective follow-up study |
| Participants | A total of 400 patients were included in this study |
| Interventions | Patients were randomly selected to have a spinal anaesthesia using either a 27 G Quincke-type needle or a 27 G pencil point needle |

Puolakka 1997 *(Continued)*

| | |
|----------|--|
| Outcomes | The primary outcome was the severity of needle damage according to the type and number of attempts |
| Notes | — |

Vandana 2004

| | |
|---------------|---|
| Methods | Prospective study |
| Participants | 200 patients between 18 and 45 years of age belonging to ASA grade I and II of either sex |
| Interventions | Spinal anaesthesia with 25 G or 29 G Quincke type spinal needle |
| Outcomes | Incidence, type, severity, duration, day of onset and site of post-dural puncture headache were recorded for the first 5 postoperative days |
| Notes | — |

ASA: American Society of Anesthesiologists; G: gauge; PDPH: post-dural puncture headache

Characteristics of ongoing studies *[ordered by study ID]*
Ahmed 2012

| | |
|---------------------|--|
| Trial name or title | 'Incidence and severity of post dural puncture headache after spinal anaesthesia for caesarean section; a comparison between 25G Quincke cutting and 25G Pencan pencil point spinal needles' |
| Methods | Study design: double-blind randomized controlled trial |
| Participants | Patients and methods: 200 adult female patients aged 20 to 40 years, ASA I and II, presenting for elective or emergency caesarean deliveries under spinal anaesthesia were randomly divided into 2 groups of 100 patients each |
| Interventions | In group P, spinal anaesthesia was performed by Pencan needle while in group Q spinal anaesthesia was performed by Quincke cutting needle using a standardized technique |
| Outcomes | Level of block (sympathetic, sensory, motor) was assessed intraoperatively. Patients were followed for 3 consecutive days postoperatively for headache, its onset, severity and associated symptoms |
| Starting date | August 2009 to August 2010 |
| Contact information | Ahmed J |
| Notes | — |

Akdemir 2011

| | |
|---------------------|---|
| Trial name or title | 'The association between needle types and headache' |
| Methods | Not known |

Akdemir 2011 (Continued)

| | |
|---------------------|---|
| Participants | 664 ASA I-II group elective caesarean patients who had no contraindications for spinal anaesthesia were included to this study. The thickness of the needle and the shape of tip of the spinal needle were recorded after anaesthesia. The education period of the anaesthesia performer, number of attempts, the space used for anaesthesia (L3-4, LL4-5) and movement of patient during anaesthesia were recorded |
| Interventions | Patients were randomly divided into 2 groups: group I (Atraucan 26G n = 323) and group II (Quincke 26G n = 342) |
| Outcomes | Patients were questioned about headache for 72 hours. Chi ² and comparison of proportions were used for statistical evaluations |
| Starting date | Not known |
| Contact information | AkdemirMS |
| Notes | — |

Bertolotto 2014

| | |
|---------------------|---|
| Trial name or title | 'Post-dural puncture headache is markedly reduced when 25 Sprotte needles are used' |
| Methods | To evaluate the frequency of post-dural puncture headache (PDPH) using 4 types of needles with a prospective, rater-blind study |
| Participants | 365 lumbar punctures were performed using 4 different types of needles as follows: 39 with 20 G Quincke traumatic needle, 62 with 22G Sprotte needle, 133 with 25G Whitacre needle, 131 with 25G Sprotte needle |
| Interventions | 25 G Whitacre needle, 25 G Sprotte needle |
| Outcomes | The patient was blinded to the needle used; a neurologist, blinded to the type of the needle, interviewed the patient for PDPH. Safety and time consumption were evaluated. |
| Starting date | Not known |
| Contact information | Bertolotto A |
| Notes | — |

Bertolotto 2014a

| | |
|---------------------|--|
| Trial name or title | '25G Sprotte needle strongly reduces the risk of post-lumbar puncture headache in clinical practice' |
| Methods | To evaluate the frequency of post-lumbar puncture headache (PLPH) using 5 types of needles |
| Participants | 363 lumbar punctures were performed using 5 different types of needles as follows: 39 with 20 G Quincke traumatic needle, 11 with 22 G Quincke needle, 53 with 22 G Whitacre needle, 134 with 25 G Whitacre needle, 126 with 25 G Sprotte needle |
| Interventions | 25 G Whitacre needle, 25 G Sprotte needle |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

Bertolotto 2014a *(Continued)*

| | |
|---------------------|---|
| Outcomes | The patient was blinded to the needle used; a neurologist, blinded to the type of the needle, interviewed the patient for PLPH. Safety and time consumption were evaluated. |
| Starting date | Unclear |
| Contact information | Bertolotto A |
| Notes | — |

Bham 2010

| | |
|---------------------|--|
| Trial name or title | 'Comparison of 22/27g Microtip vs 25g Pencan spinal needle; insertion characteristic and complications' |
| Methods | Single-blind, randomized study |
| Participants | A total of 101 parturients admitted for elective lower segment caesarian sections under spinal anaesthesia were admitted in the study |
| Interventions | Patients were randomly assigned to have Pencan (n = 50) or Microtip (n = 51) needle |
| Outcomes | The outcomes of this study were: ease of needle insertion, first attempt success rate and CSF flow rate as well as incidence of paraesthesia, post-dural puncture headache (PDPH) and backache (PDPB), transient neurological symptoms (TNS) |
| Starting date | Not known |
| Contact information | Not known |
| Notes | — |

IRCT201009292080N4

| | |
|---------------------|---|
| Trial name or title | 'Comparison of Sprotte and Quincke needles with respect to post dural puncture headache' |
| Methods | Randomization: randomized Blinding: double-blind Placebo: not used Assignment: parallel Purpose: others. |
| Participants | Inclusion criteria: age 16 to 65, patients with major surgery of the lower limb or lower abdominal segment under spinal anaesthesia Exclusion criteria: patients with chronic headache and drug-induced headache Age minimum: 16 Age maximum: 65 Gender: both male and female |
| Interventions | Intervention 1: Sprotte spinal needle. Intervention 2: Quincke spinal needle |
| Outcomes | Headache |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

IRCT201009292080N4 (Continued)

| | |
|---------------------|---|
| | Hypotension |
| | Nausea & vomiting |
| | Nuchal rigidity |
| | Time point (all outcomes): every 4 hours until 24 hours after surgery. Method of measurement (all outcomes): checklist and physical exam. |
| Starting date | 21 April 2010 |
| Contact information | Afsane Norouzi |
| Notes | — |

Lorthe 2014

| | |
|---------------------|---|
| Trial name or title | 'CSE for caesarean section: Gertie Marx versus Pencan spinal needles' |
| Methods | Compared Gertie Marx spinal needle with PENCAN needle to determine which one is preferred by obstetric patients |
| Participants | Following IRB approval and informed consent, 124 ASA I-II parturients, who requested neuraxial block for C/S, were included. The epidural space was located with ESPOCAN 18 gauge epidural 'Braun' needle (B. Braun Medical Inc.) at L3-4 or L4-5 interspace with loss of resistance to air technique using a midline approach in the lateral or sitting flexed position |
| Interventions | Patients were then randomized to 1 of 2 groups. Group I: 59 patients had a 25 G PENCAN spinal needle placed in the subarachnoid space. Group II: 65 had a 26 G Gertie Marx spinal needle (IMD Inc. USA) placed in the subarachnoid space. |
| Outcomes | An investigator recorded patients' height, weight, parity, position, the distance of the epidural space from the skin, technical problems, paraesthesia and pain upon insertion of the spinal needle, time to incision, difficulty with catheter insertion, post-dural puncture headache, transient radicular irritability, duration of procedure and overall satisfaction with the technique use |
| Starting date | Not known |
| Contact information | Lorthe J |
| Notes | — |

NCT00370604

| | |
|---------------------|---|
| Trial name or title | 'Effect of small versus large epidural needles on postdural puncture headache study' |
| Methods | Allocation: randomized Endpoint classification: safety/efficacy study Intervention model: parallel assignment Masking: single-blind (outcomes assessor) Primary purpose: prevention |
| Participants | Inclusion criteria: - American Society of Anesthesiologists status 1 to 2 - Must have provided written informed consent = or < 6 cm cervical dilation |

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

NCT00370604 (Continued)

- Fetus 37 to 42 weeks gestation
 - Must be able to read and write English well enough to provide written informed consent
- Exclusion criteria:
- BMI = or > 40
 - Multiple gestation pregnancy
 - Known contraindications to use of epidural analgesia
 - Pregnancy-induced hypertension
 - Investigator concern for maternal or neonatal welfare
 - Receipt of spinal or epidural anaesthesia within 14 days of labour epidural request
 - Women with chronic headaches (defined as headaches that occur 15 or more days per month for more than 3 months)
 - Already participated in study
 - History of narcotic abuse

Age minimum: 18 years

Age maximum: N/A

Gender: female

| | |
|---------------------|---|
| Interventions | Device: => 18 G Tuohy-type needle Device: 19 G Tuohy-type epidural needle, 23 G catheter |
| Outcomes | Incidence of post-dural puncture headache (time frame: within the first 14 days of epidural placement) Anaesthesiologist satisfaction with the 19 G Tuohy epidural needle and 23 G catheter compared with traditional Tuohy-type epidural needles and traditional catheters (time frame: during labour and delivery) Degree of dysfunction and disability related to PDPH symptoms (time frame: within first 14 days post-epidural placement and, if necessary, up to 1 year post-epidural placement) |
| Starting date | June 2007 |
| Contact information | Pamela J Angle |
| Notes | — |

NCT01821807

| | |
|---------------------|---|
| Trial name or title | 'Comparison of two spinal needles regarding postdural puncture headache' |
| Methods | Time perspective: prospective |
| Participants | Inclusion Criteria: - Pregnant female patients between 18-40 years old undergoing caesarean section - Patient accepting spinal anaesthesia Exclusion Criteria: - Infection at the spinal needle insertion cite - Coagulability disorder - Patient not accepting the procedure Age minimum: 18 Years Age maximum: 40 Years Gender: Female |
| Interventions | Two kind of spinal anaesthesia needles will be used: |

NCT01821807 (Continued)

| | |
|---------------------|---|
| | <ol style="list-style-type: none"> 1. 26 Gauge Quincke (cutting-tip needle) 2. 26 Gauge Atraucan (atraumatic needle) |
| Outcomes | <p>Post-dural puncture headache in patients receiving spinal anaesthesia for caesarean section (time frame: 1 week)</p> <p>Backache in patients receiving spinal anaesthesia for caesarean section (time frame: 1 week)</p> |
| Starting date | June 2013 |
| Contact information | Ruslan Abdullayev |
| Notes | — |

NCT02384031

| | |
|---------------------|---|
| Trial name or title | 'Post-dural puncture headache - needles and biomarkers in CSF' |
| Methods | <p>Allocation: randomized</p> <p>Intervention model: parallel assignment</p> <p>Masking: double-blind (subject, investigator)</p> <p>Primary purpose: prevention</p> |
| Participants | <p>Inclusion criteria:</p> <ol style="list-style-type: none"> 1. Patients at Department of Neurology, Nordland Hospital Trust in Bodø, scheduled for diagnostic LP <p>Exclusion criteria:</p> <ol style="list-style-type: none"> 1. Dementia 2. Non-compliance or coma 3. Local skin infections over proposed puncture site 4. Suspicion of raised intracranial pressure due to neurological or radiological findings 5. Bleeding diathesis (thrombocytopenia < 50 x 10⁹/L) or ongoing anticoagulant therapy 6. Major spinal column deformities 7. Procedural complications whereby needle type or size change is a requisite 8. Recent LP (< 7 days) <p>Age minimum: 18 years</p> <p>Age maximum: 60 years</p> <p>Gender: both</p> |
| Interventions | <p>Device: atraumatic needle</p> <p>Device: traumatic needle</p> |
| Outcomes | <p>Post-dural puncture headache (PDPH) (time frame: at day 7 post LP)</p> <p>Levels of inflammatory mediators in CSF (time frame: during lumbar puncture)</p> <p>Levels of metabolites in CSF (time frame: during lumbar puncture)</p> <p>Levels of neuropeptides in CSF (time frame: during lumbar puncture)</p> |
| Starting date | February 2012 |
| Contact information | Francis Odeh, MD, PhD |

NCT02384031 (Continued)

Notes —

Shah 2011

| | |
|---------------------|--|
| Trial name or title | 'Combined spinal epidural (CSE) for cesarean section: Gertie Marx versus Pencan spinal needles' |
| Methods | Prospective, randomized study |
| Participants | A total of 124 ASA I-II parturients who requested neuraxial block for caesarean section were included in this study |
| Interventions | Patients were randomized into 2 groups (Group I: n = 59 has a 25 G PENCAN spinal needle placed in the subarachnoid space and Group II: n = 65 had a 26 G Gertie Marx spinal needle in the subarachnoid space |
| Outcomes | Need to rotate or reinsert the epidural needle, the efficacy of the block, side effects from the block, difficulty with catheter insertion and the sensory level overall satisfaction |
| Starting date | Not known |
| Contact information | Not known |
| Notes | — |

Shaikh 2013

| | |
|---------------------|--|
| Trial name or title | 'Post dural puncture headache after spinal anaesthesia for caesarean section: a comparison of 25G Quincke, 27G Quincke and 27G Whitacre spinal needles' |
| Methods | Comparative, randomized, double-blind, interventional study |
| Participants | A total of 480 ASA I-II full-term pregnant women, 18 to 45 years of age, scheduled for elective caesarean section, under spinal anaesthesia |
| Interventions | Participants were randomized into 3 groups: Group I (25 G Quincke spinal needle: n = 168), Group II (27 G Quincke spinal needle: n = 160) and Group III (27 G Whitacre spinal needle: n = 152) |
| Outcomes | The primary outcome was the frequency of PDPH. Secondary outcomes were the severity and onset of PDPH. |
| Starting date | From October 2005 to December 2006 |
| Contact information | Not known |
| Notes | — |

Acronyms and abbreviations used in this table

ASA: American Society of Anesthesiologists; ASN: Atraucan spinal needle; BMI: body mass index; CI: confidence interval; c-section: caesarean section; CSF: cerebrospinal fluid; G: gauge; IQR: interquartile range; L2-3 to L3-4: lumbar vertebrae 2-3 to 3-4; LP: lumbar puncture; NRS: numerical rating scale; NYHA: New York Heart Association; PDPH: post-dural puncture headache; RCT: randomized controlled trial; SD: standard deviation; SEM: standard error of the mean; VAS: visual analogue scale; WSN: Whitacre spinal needle

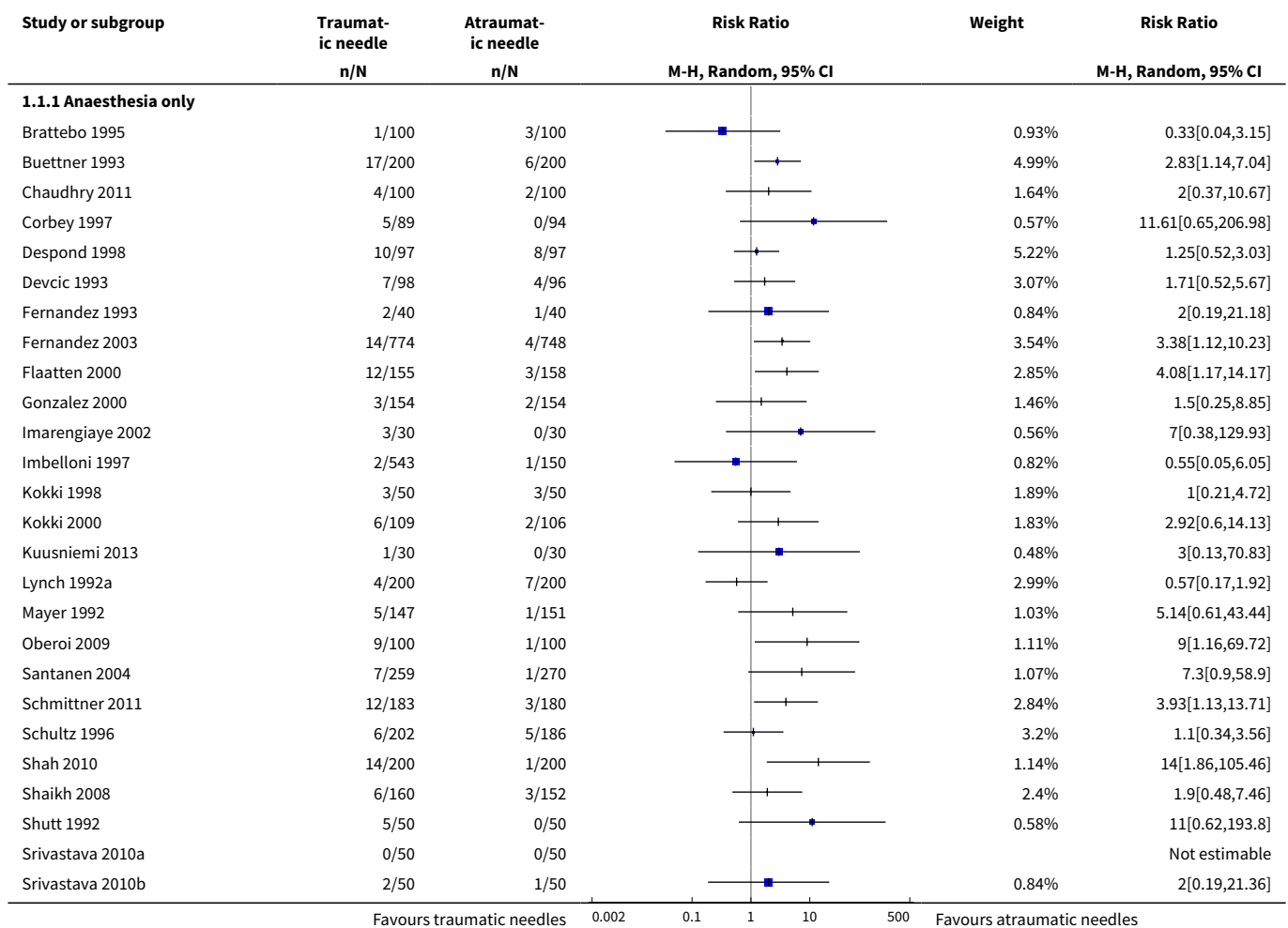
DATA AND ANALYSES

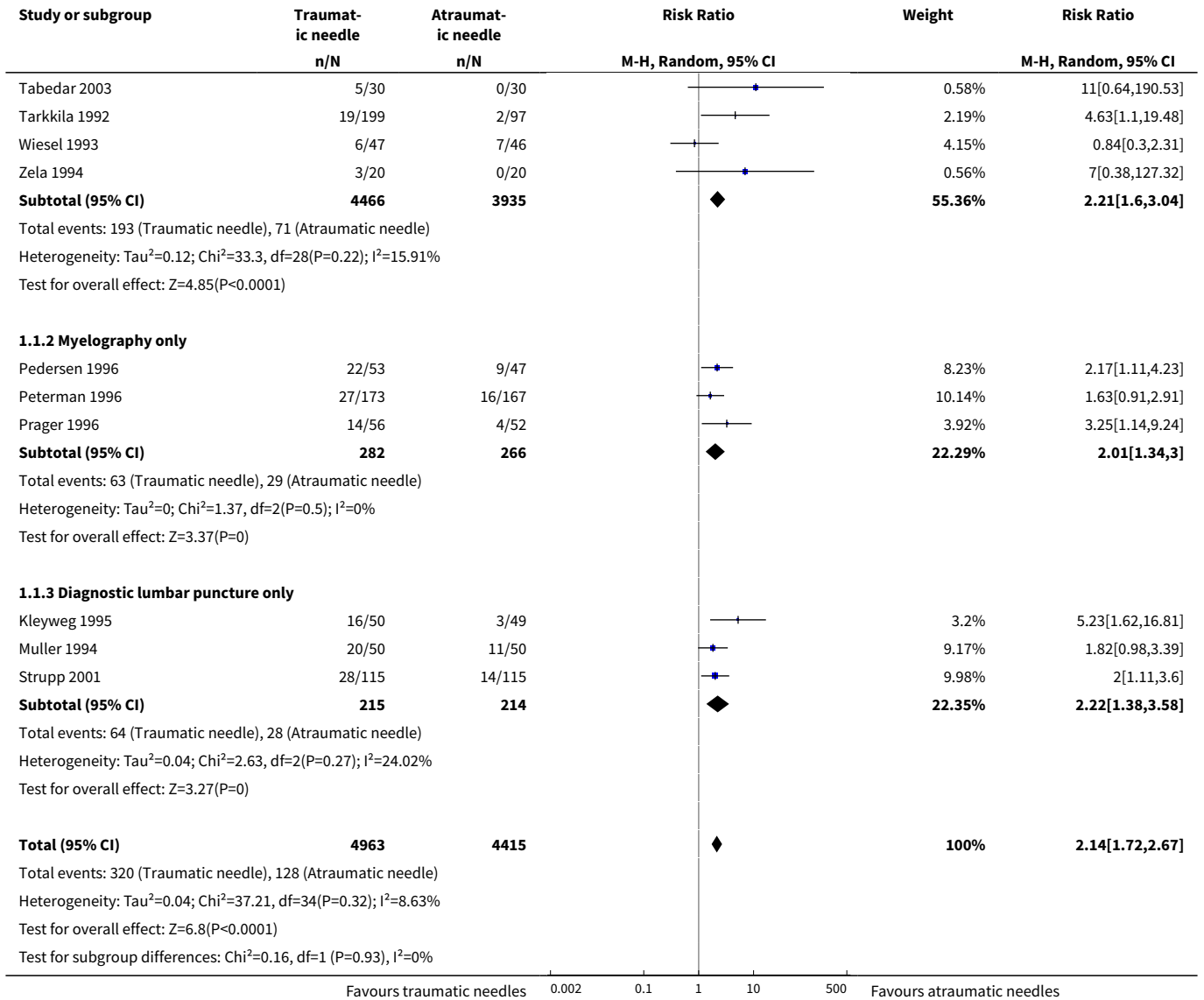
Comparison 1. Traumatic needle versus atraumatic needle

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--|----------------|---------------------|----------------------------------|-------------------|
| 1 PDPH by indication | 36 | 9378 | Risk Ratio (M-H, Random, 95% CI) | 2.14 [1.72, 2.67] |
| 1.1 Anaesthesia only | 30 | 8401 | Risk Ratio (M-H, Random, 95% CI) | 2.21 [1.60, 3.04] |
| 1.2 Myelography only | 3 | 548 | Risk Ratio (M-H, Random, 95% CI) | 2.01 [1.34, 3.00] |
| 1.3 Diagnostic lumbar puncture only | 3 | 429 | Risk Ratio (M-H, Random, 95% CI) | 2.22 [1.38, 3.58] |
| 2 PDPH by gauge | 20 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 2.1 22 gauge | 5 | 877 | Risk Ratio (M-H, Random, 95% CI) | 2.15 [1.56, 2.97] |
| 2.2 25 gauge | 5 | 1260 | Risk Ratio (M-H, Random, 95% CI) | 2.48 [1.56, 3.95] |
| 2.3 27 gauge | 11 | 4076 | Risk Ratio (M-H, Random, 95% CI) | 2.87 [1.81, 4.53] |
| 3 PDPH by gender | 9 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 3.1 Only women | 9 | 1424 | Risk Ratio (M-H, Random, 95% CI) | 2.60 [1.62, 4.17] |
| 4 PDPH/anaesthesia: type of surgery | 30 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 4.1 Caesarean section | 8 | 1324 | Risk Ratio (M-H, Random, 95% CI) | 3.12 [1.60, 6.10] |
| 4.2 Orthopaedic procedures | 3 | 994 | Risk Ratio (M-H, Random, 95% CI) | 1.35 [0.58, 3.19] |
| 4.3 Other surgeries | 19 | 6083 | Risk Ratio (M-H, Random, 95% CI) | 2.30 [1.50, 3.51] |
| 5 PDPH by position | 20 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 5.1 Lateral position | 9 | 3242 | Risk Ratio (M-H, Random, 95% CI) | 4.70 [2.39, 9.24] |
| 5.2 Sitting position | 11 | 2193 | Risk Ratio (M-H, Random, 95% CI) | 2.11 [1.52, 2.94] |
| 6 PDPH by age | 36 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 6.1 No distinctions by age | 34 | 9063 | Risk Ratio (M-H, Random, 95% CI) | 2.17 [1.73, 2.73] |
| 6.2 Only < 18 years | 2 | 315 | Risk Ratio (M-H, Random, 95% CI) | 1.69 [0.56, 5.12] |
| 7 AE: paraesthesia | 3 | 573 | Risk Ratio (M-H, Random, 95% CI) | 0.96 [0.47, 1.96] |
| 8 AE: backache | 12 | 3027 | Risk Ratio (M-H, Random, 95% CI) | 0.94 [0.78, 1.13] |
| 9 Severe PDPH by indication | 24 | 6420 | Risk Ratio (M-H, Random, 95% CI) | 1.88 [1.20, 2.94] |

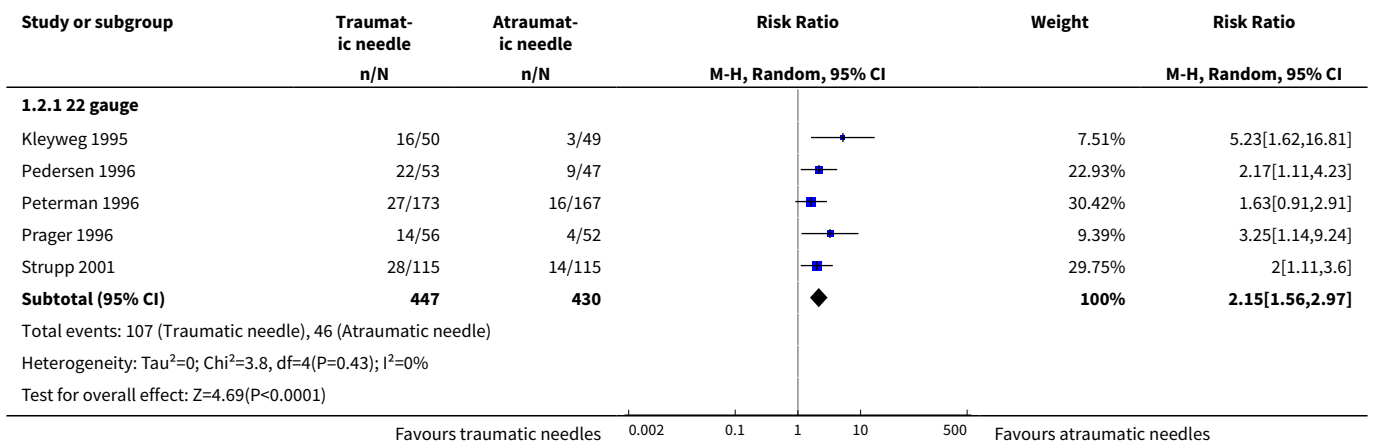
| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--------------------------------------|----------------|---------------------|----------------------------------|-------------------|
| 9.1 Anesthesia | 19 | 5542 | Risk Ratio (M-H, Random, 95% CI) | 1.77 [0.88, 3.53] |
| 9.2 Myelography | 4 | 778 | Risk Ratio (M-H, Random, 95% CI) | 1.70 [0.68, 4.28] |
| 9.3 Diagnostic lumbar puncture | 1 | 100 | Risk Ratio (M-H, Random, 95% CI) | 3.0 [1.18, 7.63] |
| 10 Any headache by indication | 18 | 4104 | Risk Ratio (M-H, Random, 95% CI) | 1.35 [1.17, 1.57] |
| 10.1 Anaesthesia | 16 | 3656 | Risk Ratio (M-H, Random, 95% CI) | 1.38 [1.17, 1.63] |
| 10.2 Myelography | 2 | 448 | Risk Ratio (M-H, Random, 95% CI) | 1.34 [0.81, 2.21] |
| 11 PDPH sensitivity analysis | 3 | 802 | Risk Ratio (M-H, Random, 95% CI) | 2.78 [1.26, 6.15] |

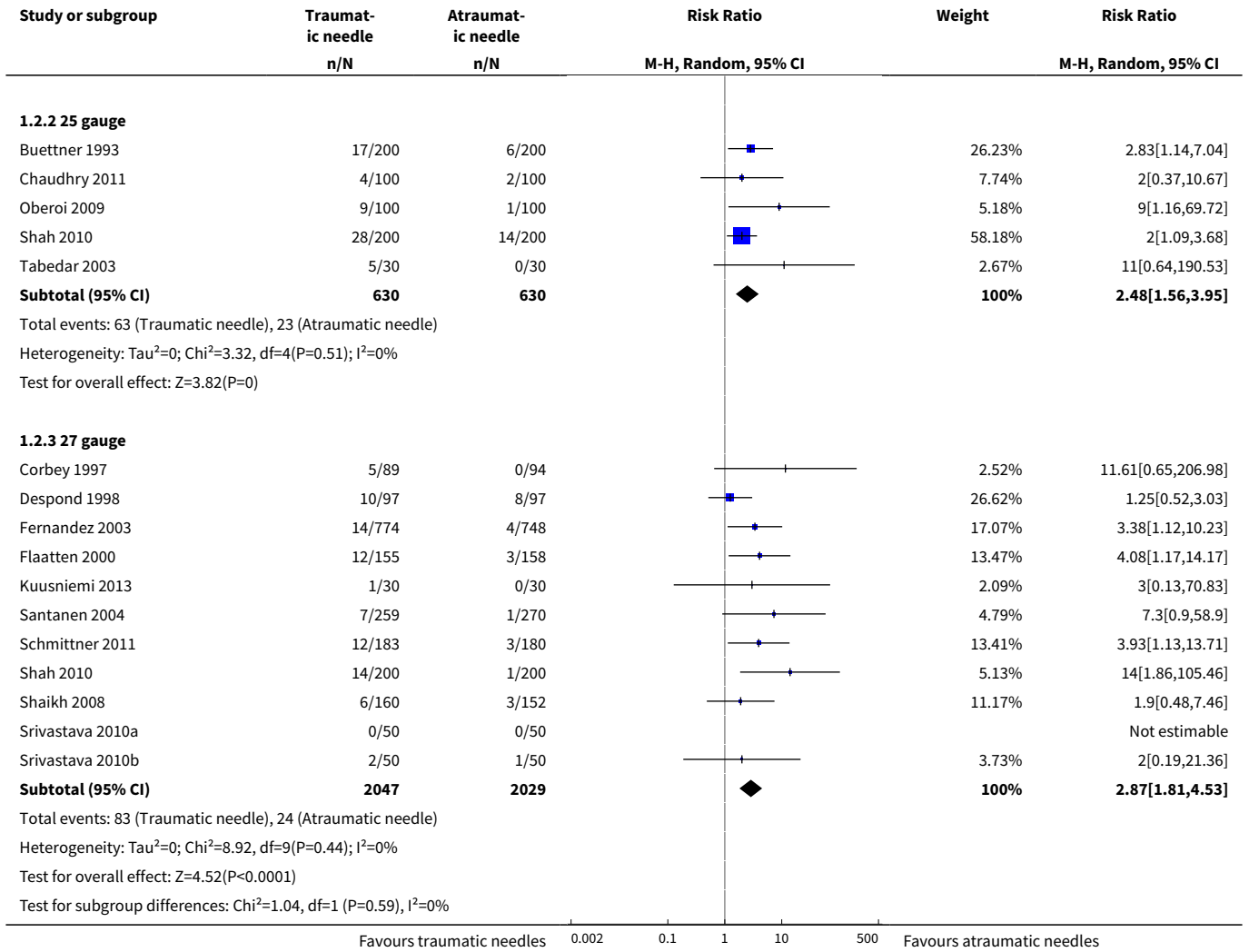
Analysis 1.1. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 1 PDPH by indication.



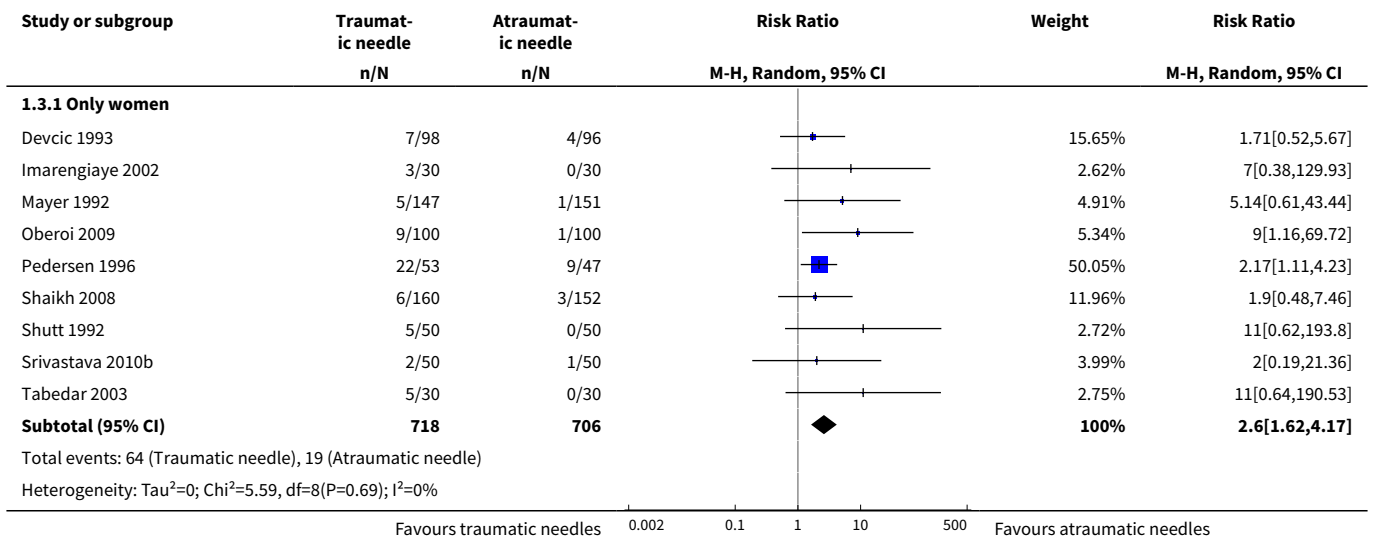


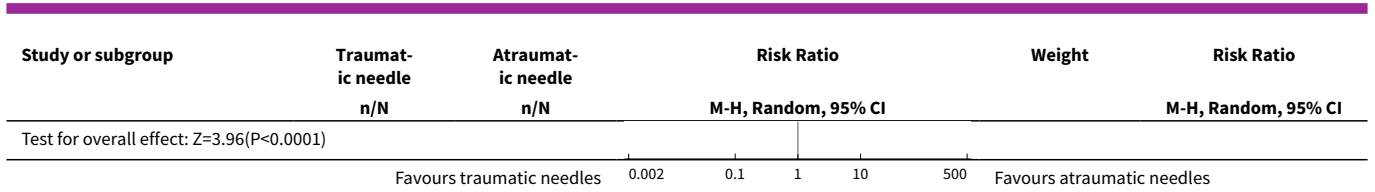
Analysis 1.2. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 2 PDPH by gauge.



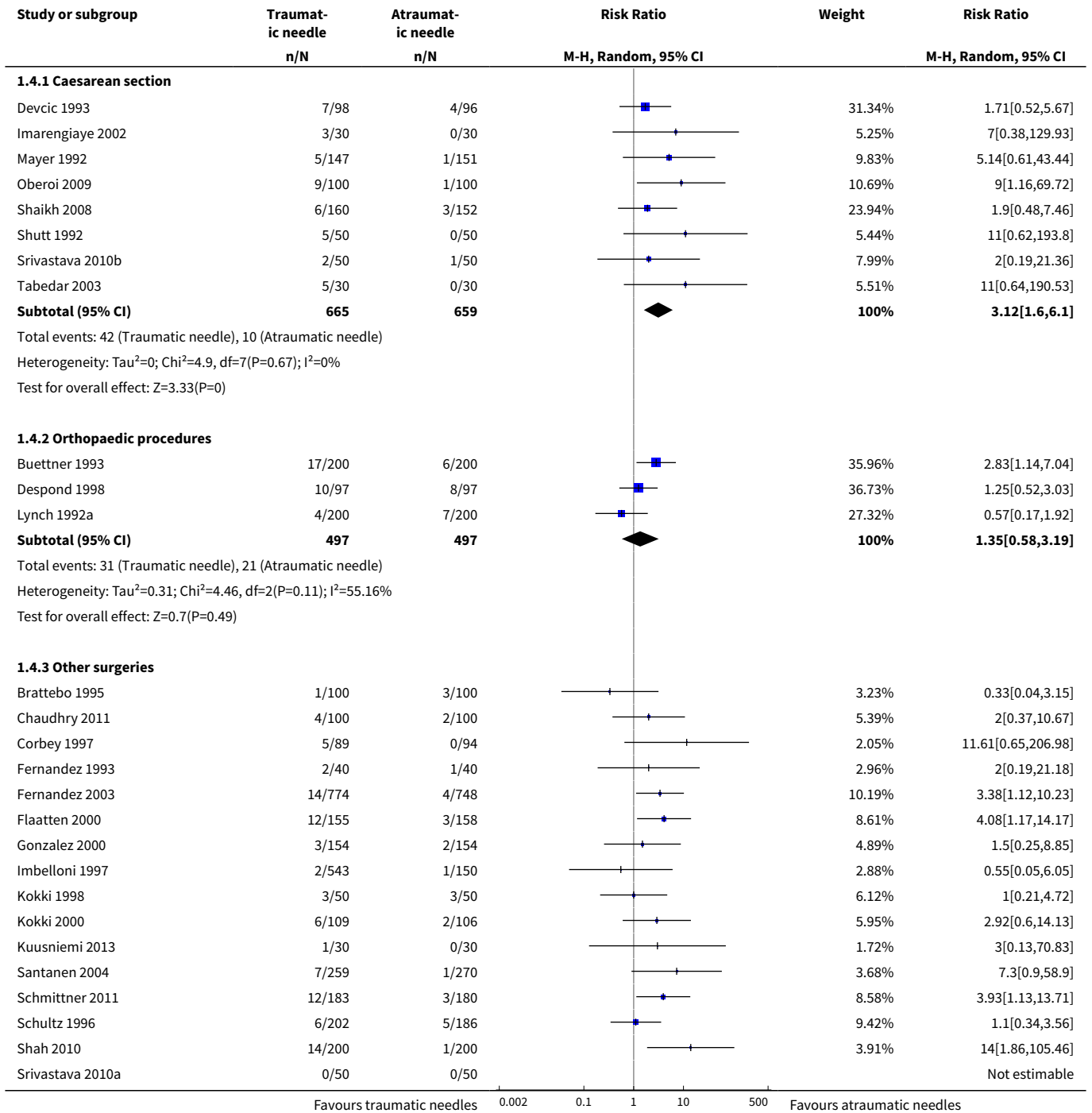


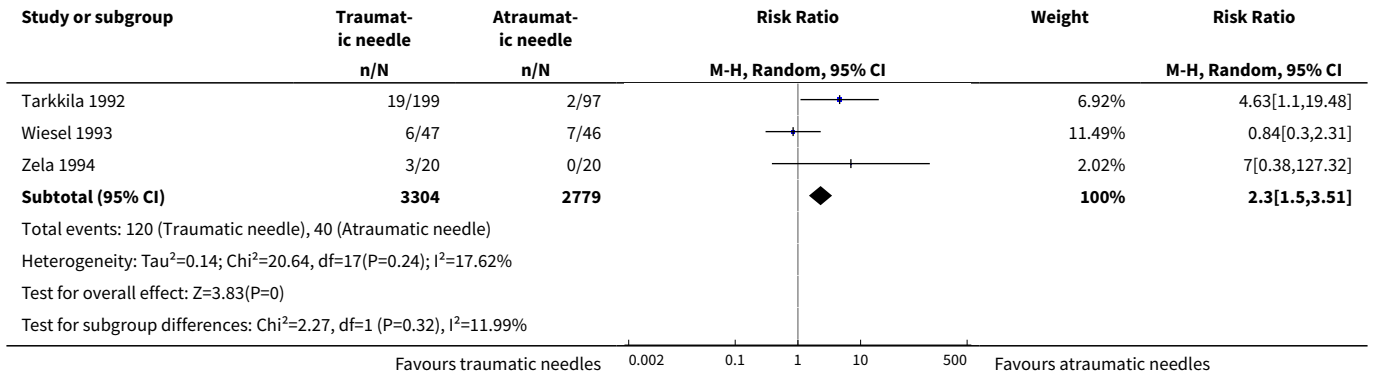
Analysis 1.3. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 3 PDPH by gender.



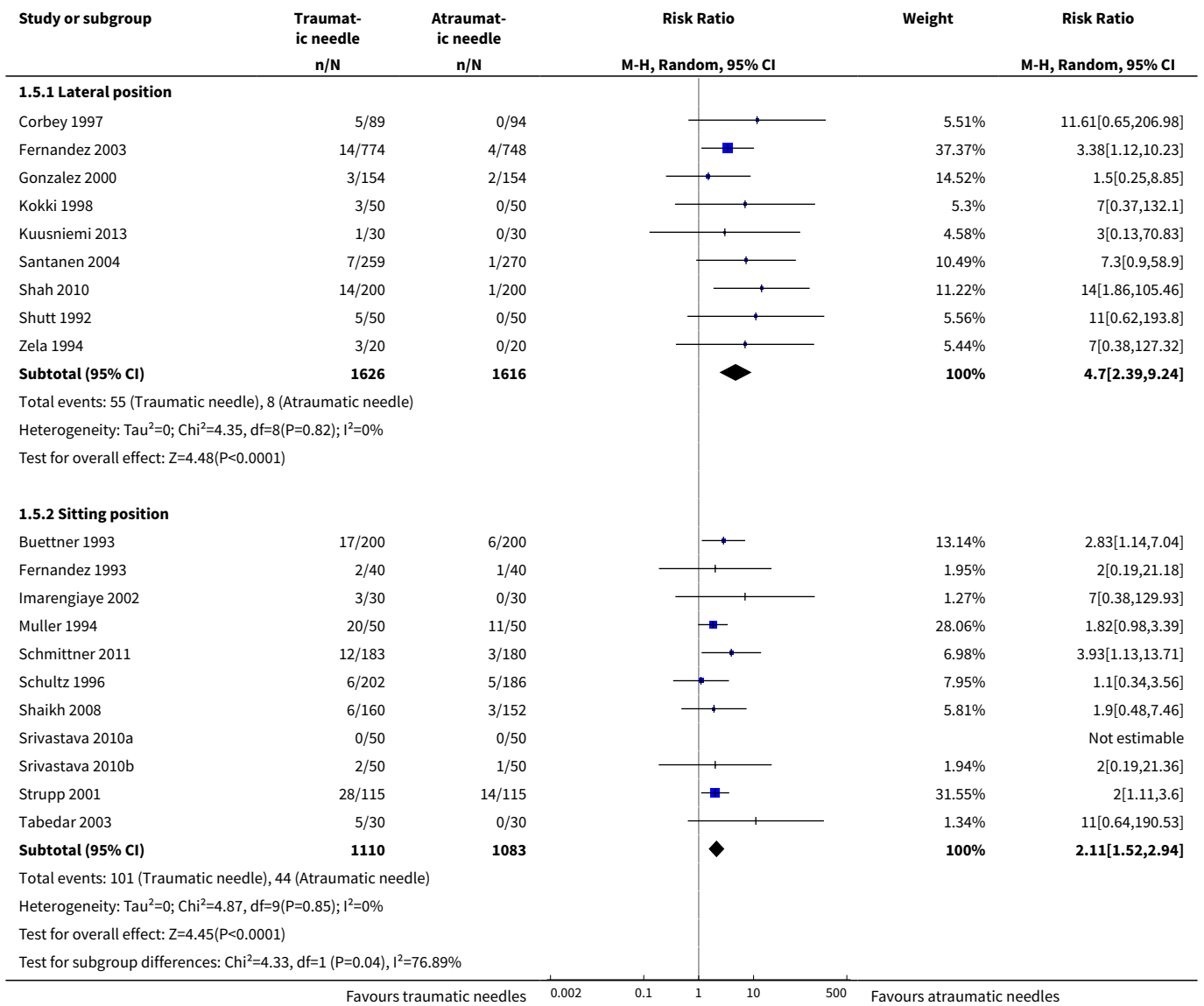


Analysis 1.4. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 4 PDPH/anaesthesia: type of surgery.

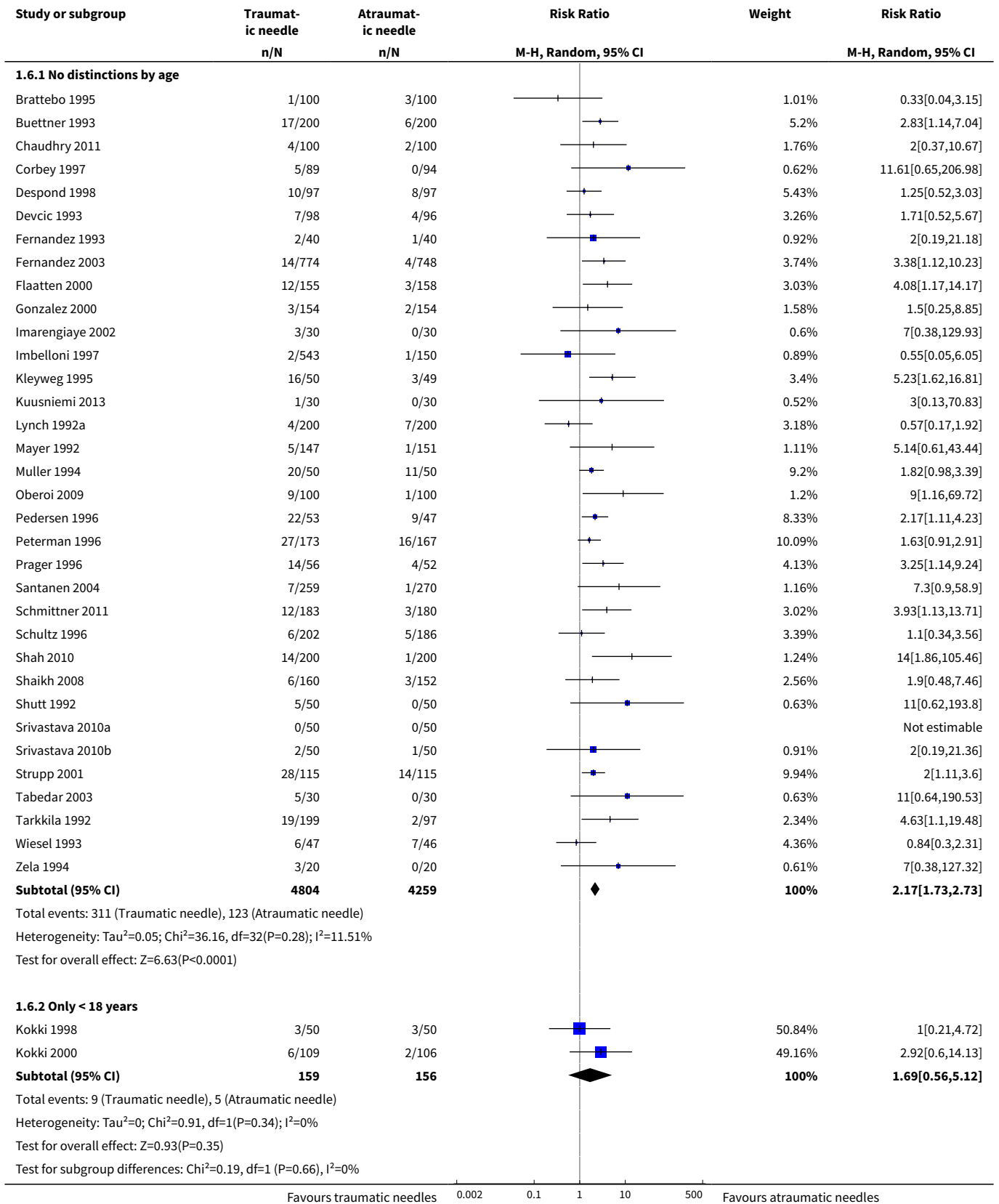




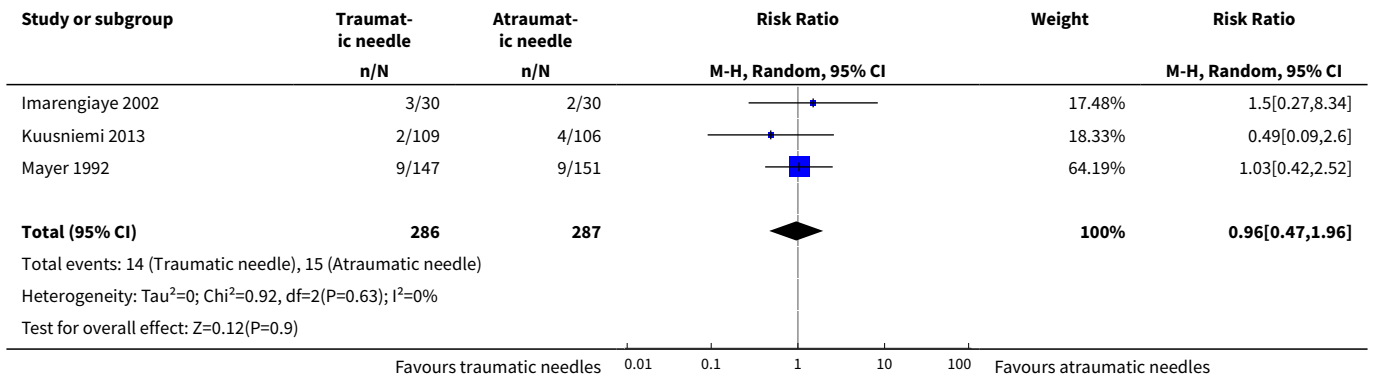
Analysis 1.5. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 5 PDPH by position.



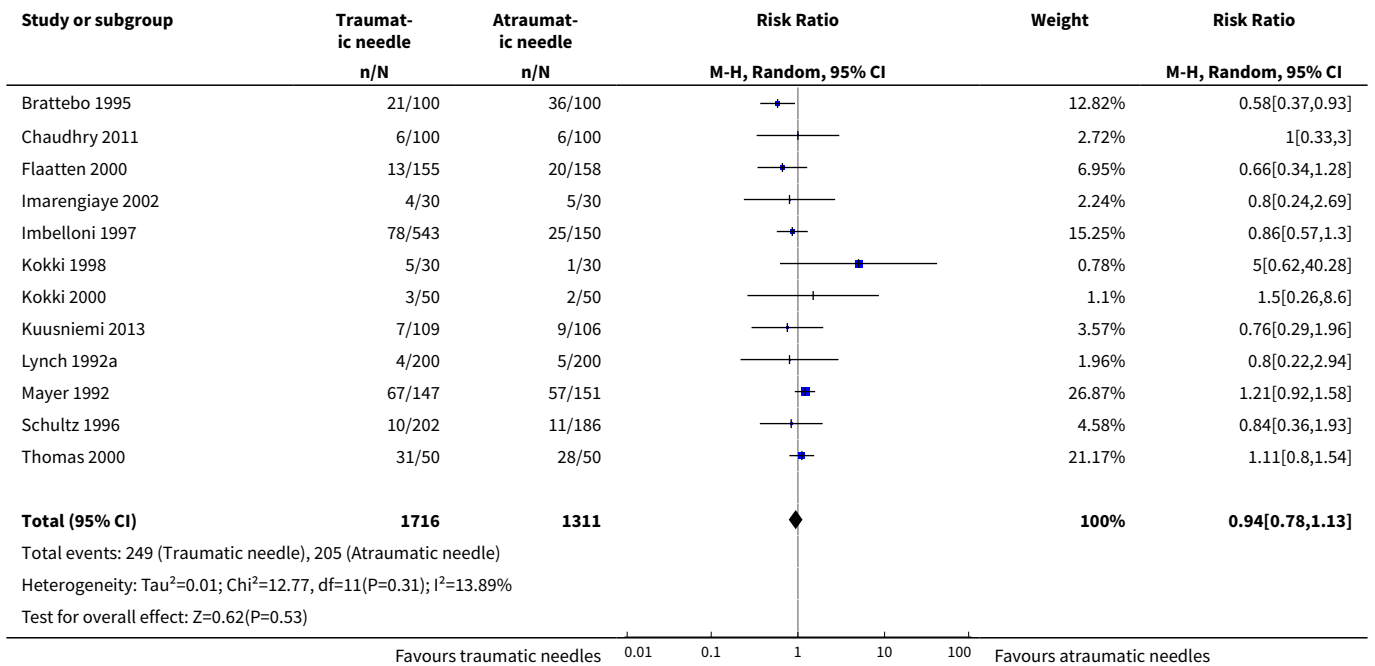
Analysis 1.6. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 6 PDPH by age.



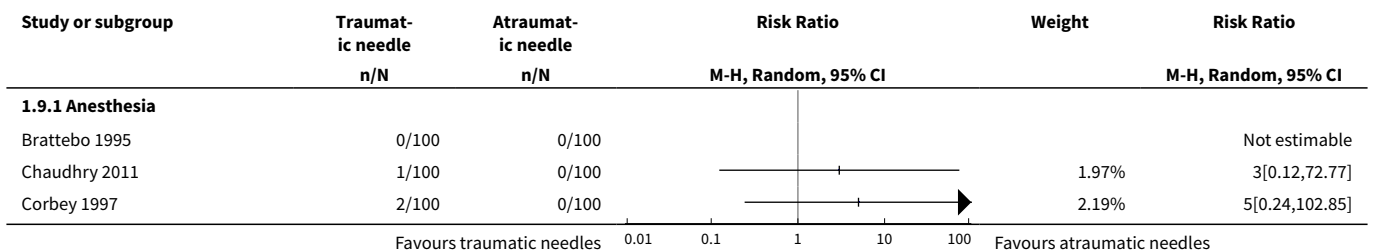
Analysis 1.7. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 7 AE: paraesthesia.

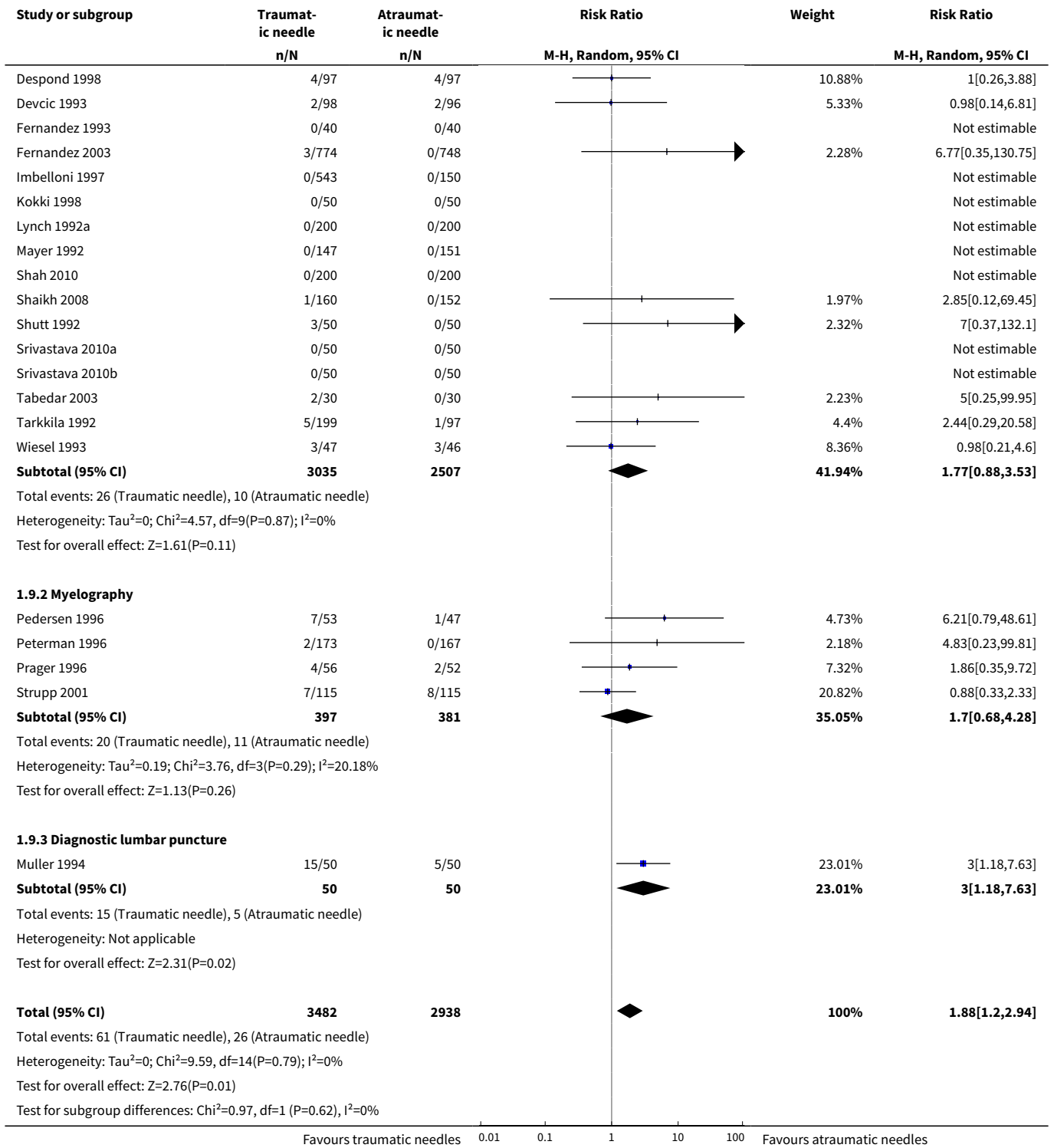


Analysis 1.8. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 8 AE: backache.

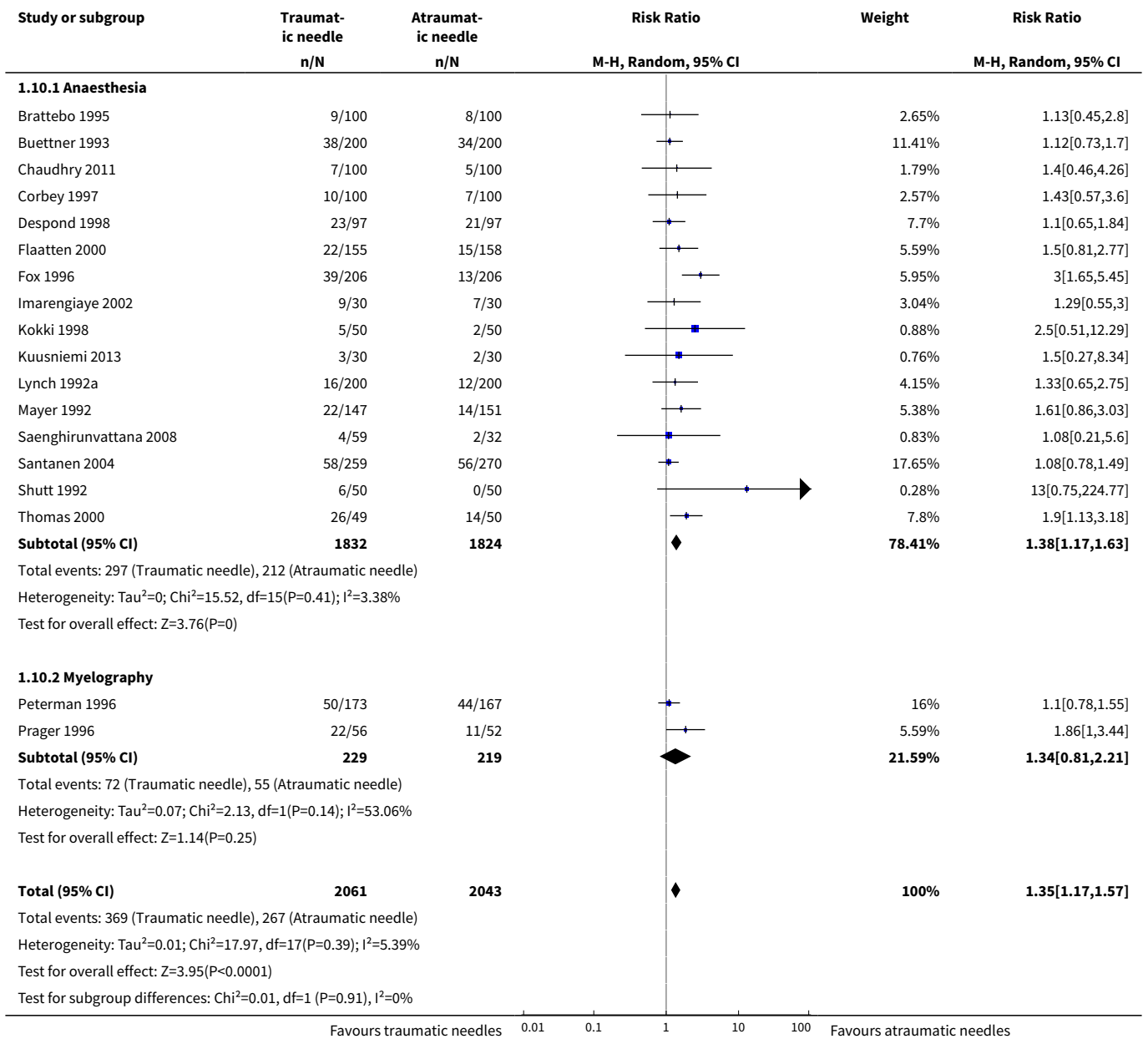


Analysis 1.9. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 9 Severe PDPH by indication.

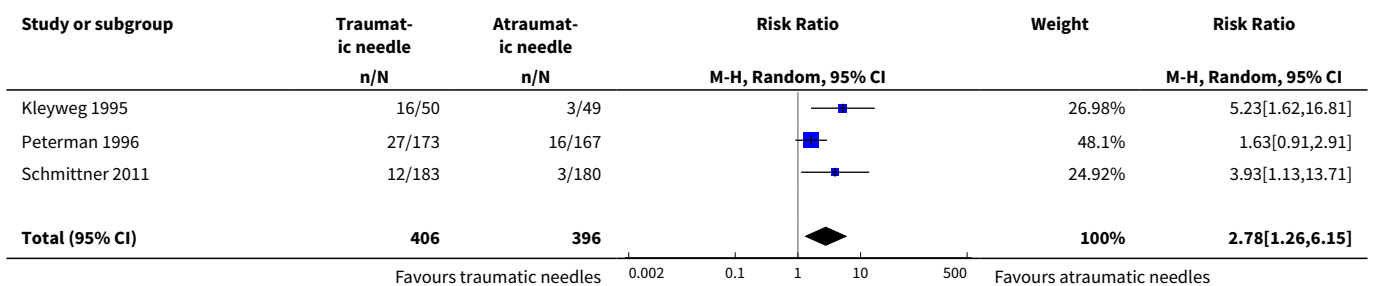


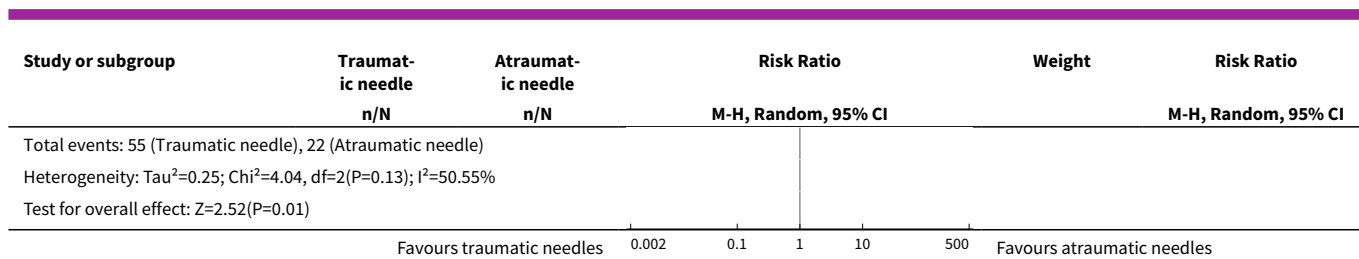


Analysis 1.10. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 10 Any headache by indication.



Analysis 1.11. Comparison 1 Traumatic needle versus atraumatic needle, Outcome 11 PDPH sensitivity analysis.



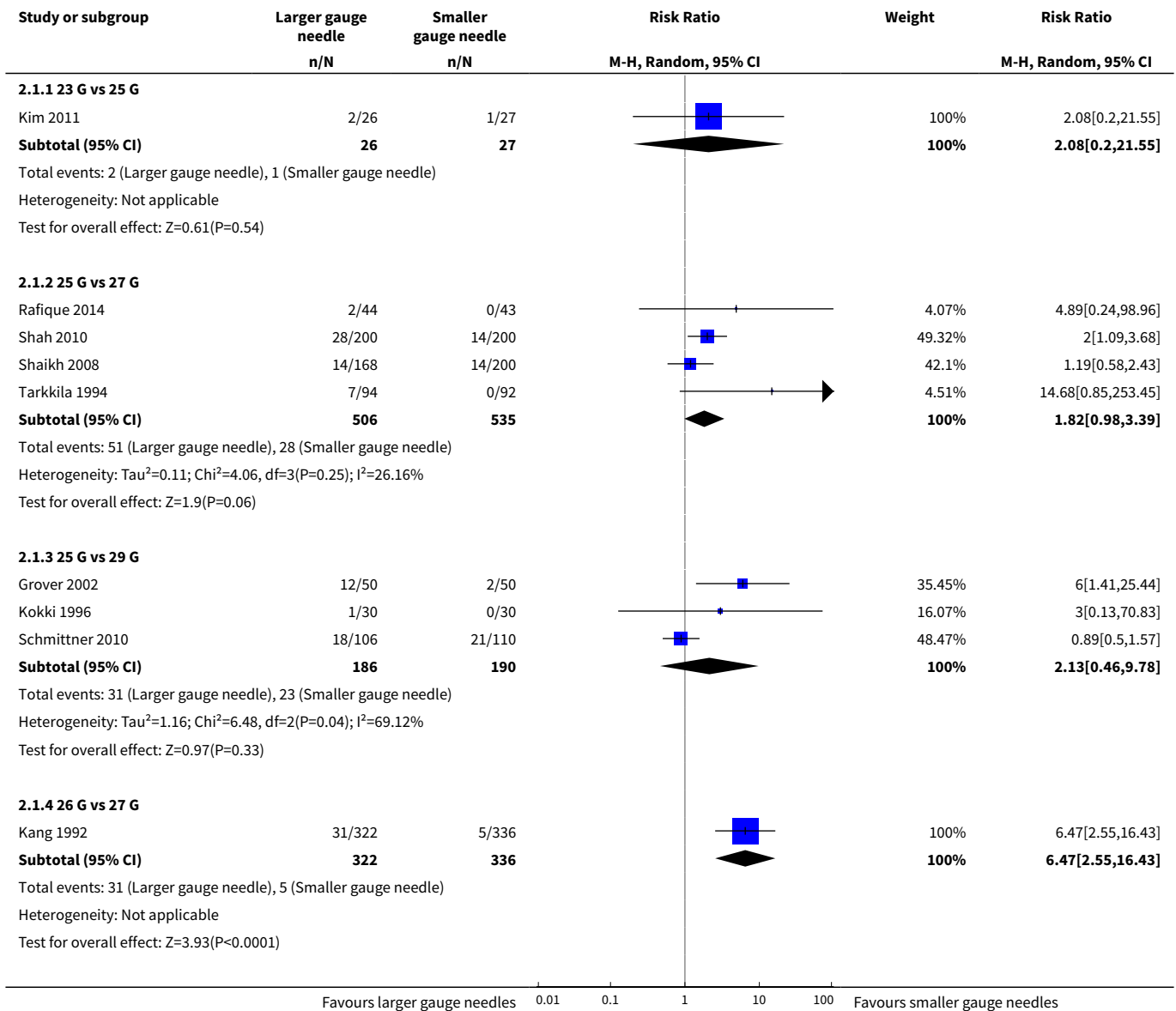


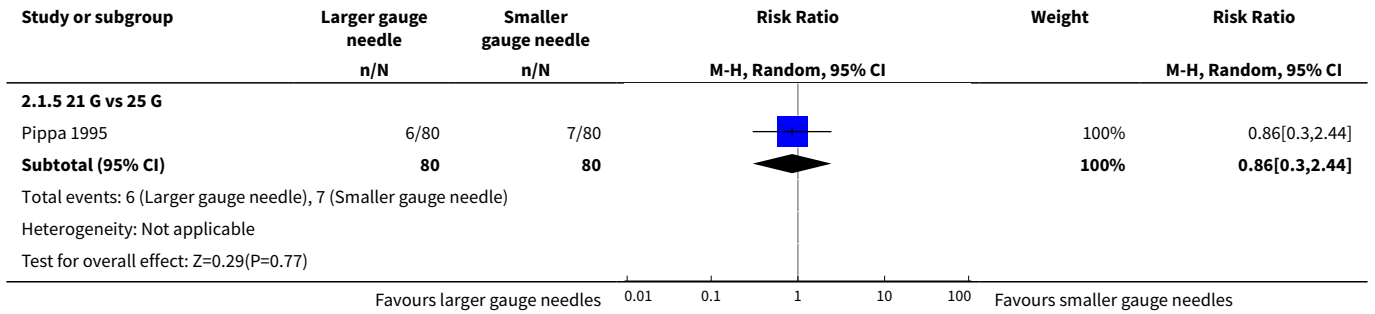
Comparison 2. Larger gauge traumatic needles versus smaller gauge traumatic needles

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|---------------------------------------|--------------------|
| 1 PDPH larger gauge vs smaller gauge | 10 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 1.1 23 G vs 25 G | 1 | 53 | Risk Ratio (M-H, Random, 95% CI) | 2.08 [0.20, 21.55] |
| 1.2 25 G vs 27 G | 4 | 1041 | Risk Ratio (M-H, Random, 95% CI) | 1.82 [0.98, 3.39] |
| 1.3 25 G vs 29 G | 3 | 376 | Risk Ratio (M-H, Random, 95% CI) | 2.13 [0.46, 9.78] |
| 1.4 26 G vs 27 G | 1 | 658 | Risk Ratio (M-H, Random, 95% CI) | 6.47 [2.55, 16.43] |
| 1.5 21 G vs 25 G | 1 | 160 | Risk Ratio (M-H, Random, 95% CI) | 0.86 [0.30, 2.44] |
| 2 PDPH by type of surgery | 10 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 2.1 Caesarean section | 2 | 455 | Risk Ratio (M-H, Random, 95% CI) | 1.28 [0.64, 2.57] |
| 2.2 Orthopaedic surgeries | 2 | 213 | Risk Ratio (M-H, Random, 95% CI) | 0.99 [0.38, 2.58] |
| 2.3 Other surgeries | 6 | 1620 | Risk Ratio (M-H, Random, 95% CI) | 2.94 [1.23, 7.03] |
| 3 PDPH by age | 10 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 3.1 No distinctions about age | 8 | 2175 | Risk Ratio (M-H, Random, 95% CI) | 2.09 [1.11, 3.95] |
| 3.2 Only children | 1 | 60 | Risk Ratio (M-H, Random, 95% CI) | 3.0 [0.13, 70.83] |
| 3.3 Only > 60 years | 1 | 53 | Risk Ratio (M-H, Random, 95% CI) | 2.08 [0.20, 21.55] |
| 4 PDPH by position | 7 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 4.1 Lateral position | 5 | 859 | Risk Ratio (M-H, Random, 95% CI) | 1.76 [0.98, 3.16] |
| 4.2 Sitting position | 2 | 584 | Risk Ratio (M-H, Random, 95% CI) | 1.00 [0.64, 1.56] |
| 5 AE: backache | 3 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 6 Severe PDPH by gauge | 6 | | Risk Difference (M-H, Random, 95% CI) | Subtotals only |

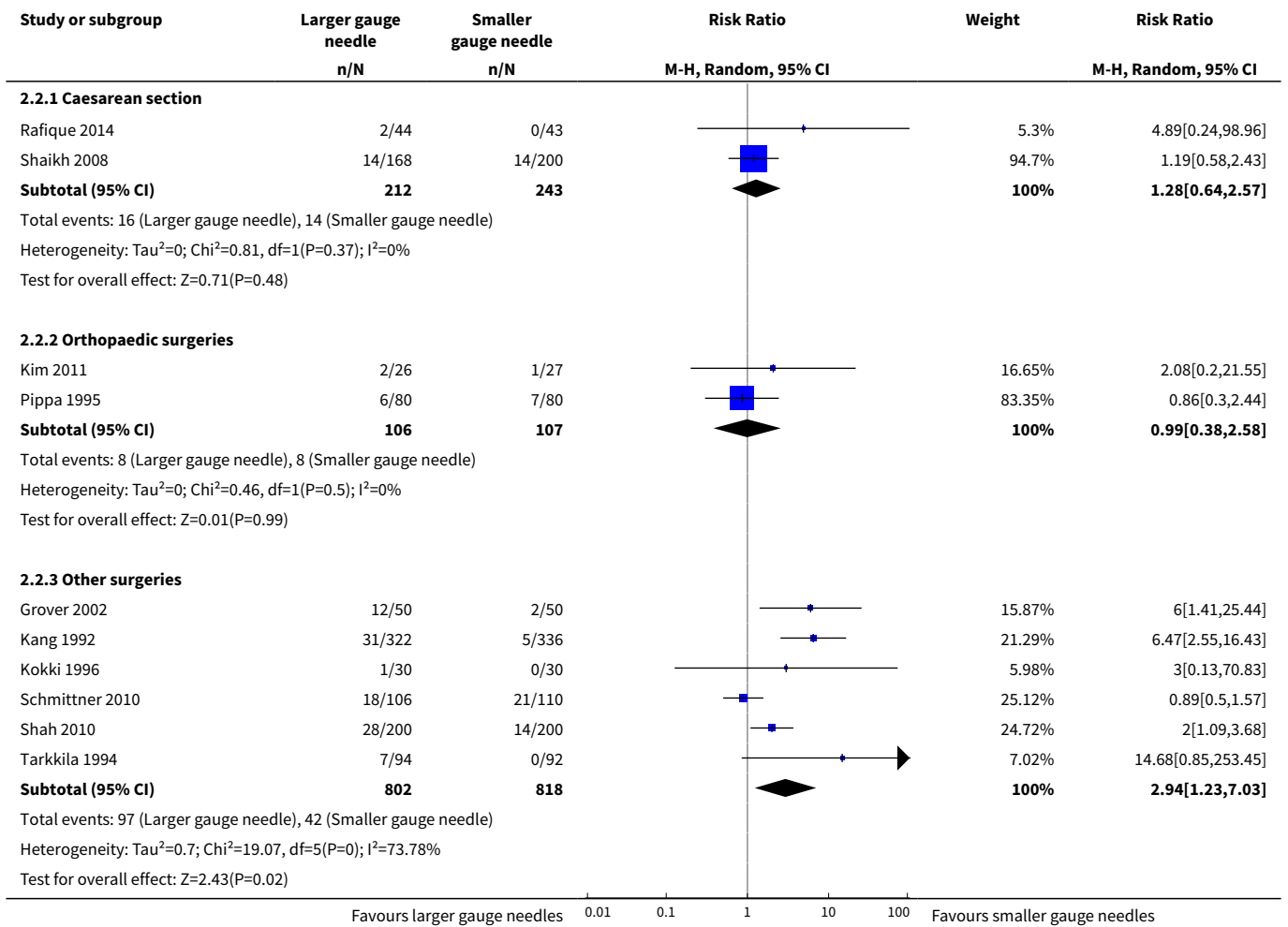
| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---------------------------|----------------|---------------------|---|-----------------------|
| 6.1 23 G vs 25 G | 1 | 53 | Risk Difference (M-H, Random, 95% CI) | 0.0 [-0.07, 0.07] |
| 6.2 25 G vs 27 G | 3 | 815 | Risk Difference (M-H, Random, 95% CI) | 0.00 [-0.01, 0.01] |
| 6.3 25 G vs 29 G | 1 | 100 | Risk Difference (M-H, Random, 95% CI) | 0.0 [-0.04, 0.04] |
| 6.4 21 G vs 25 G | 1 | 160 | Risk Difference (M-H, Random, 95% CI) | 0.0 [-0.02, 0.02] |
| 7 Any headache | 3 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |

Analysis 2.1. Comparison 2 Larger gauge traumatic needles versus smaller gauge traumatic needles, Outcome 1 PDPH larger gauge vs smaller gauge.

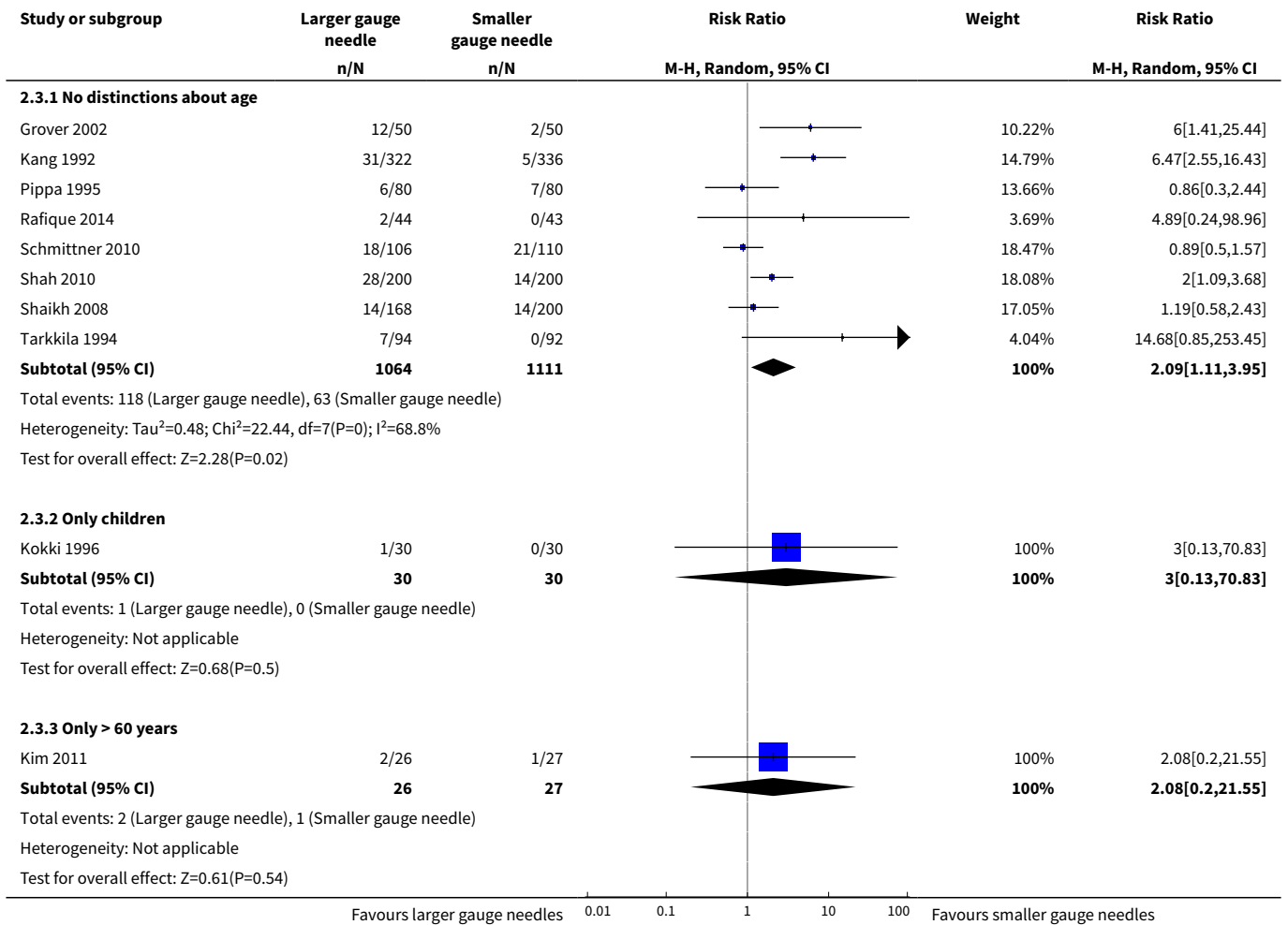




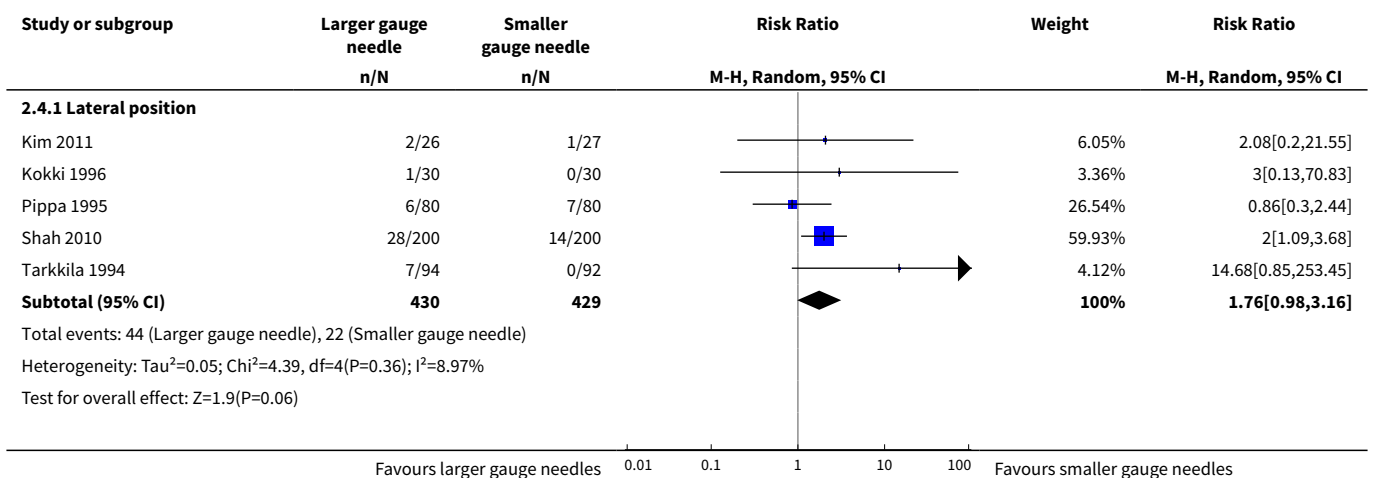
Analysis 2.2. Comparison 2 Larger gauge traumatic needles versus smaller gauge traumatic needles, Outcome 2 PDPH by type of surgery.

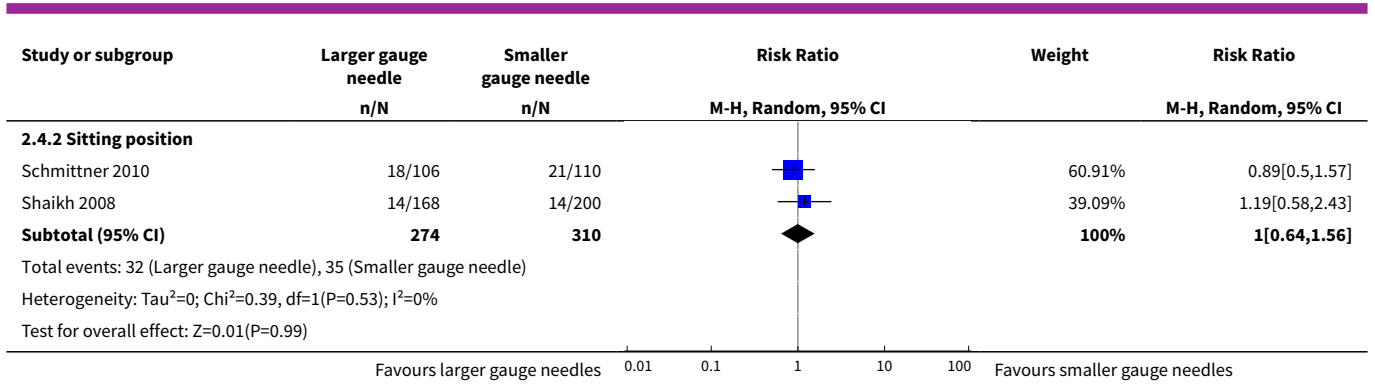


Analysis 2.3. Comparison 2 Larger gauge traumatic needles versus smaller gauge traumatic needles, Outcome 3 PDPH by age.

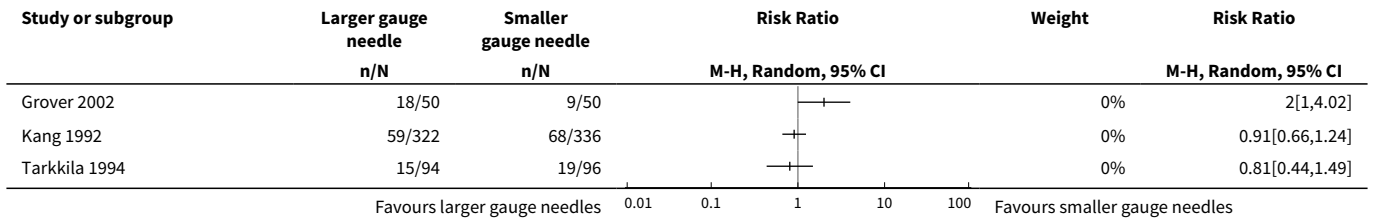


Analysis 2.4. Comparison 2 Larger gauge traumatic needles versus smaller gauge traumatic needles, Outcome 4 PDPH by position.

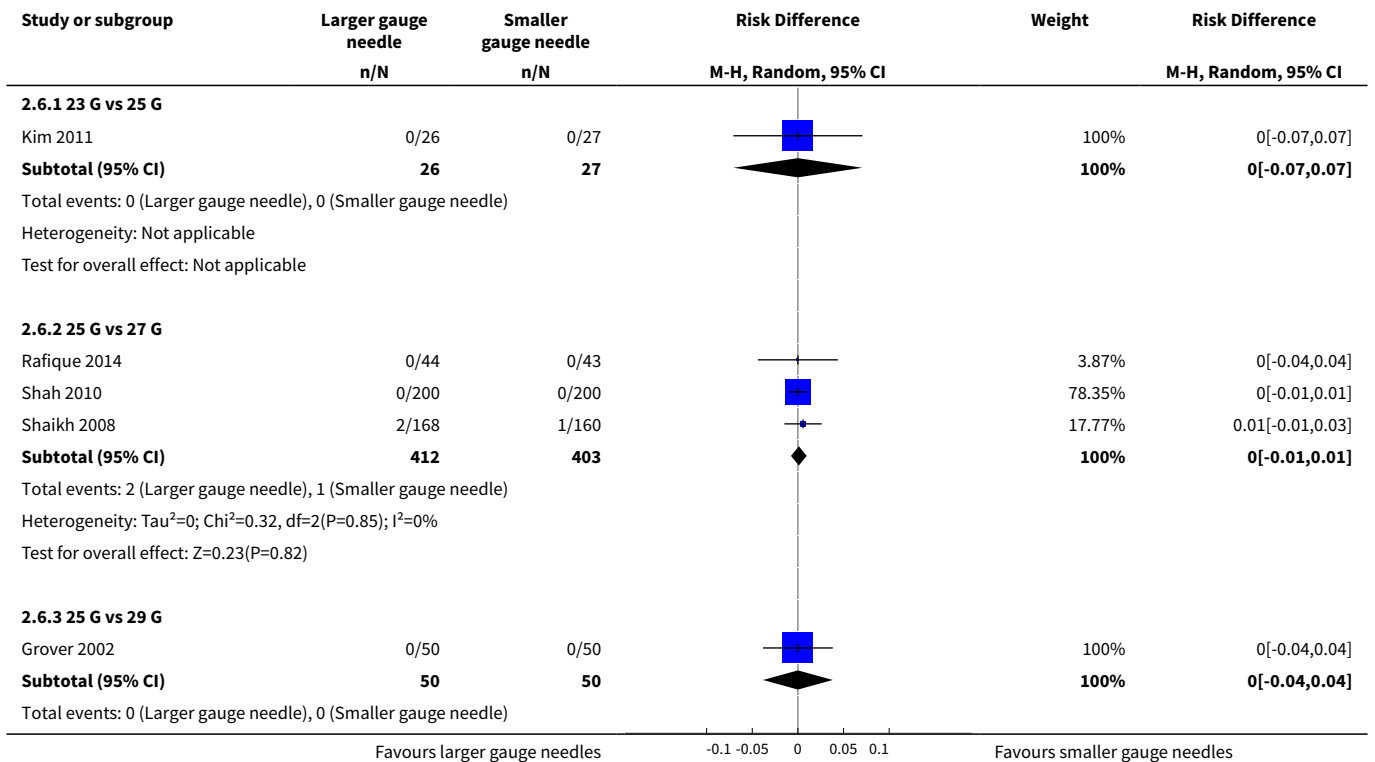


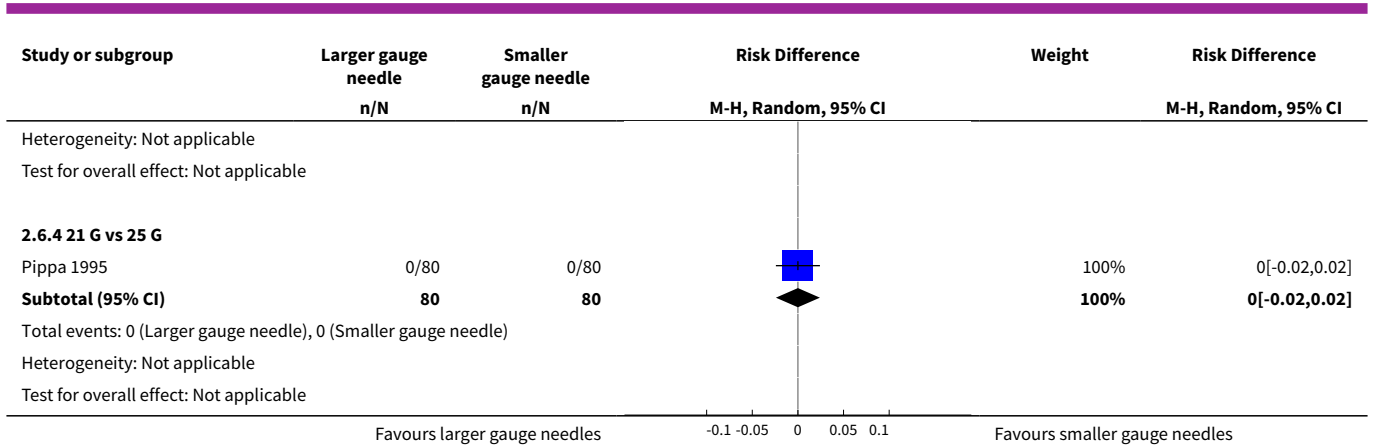


Analysis 2.5. Comparison 2 Larger gauge traumatic needles versus smaller gauge traumatic needles, Outcome 5 AE: backache.

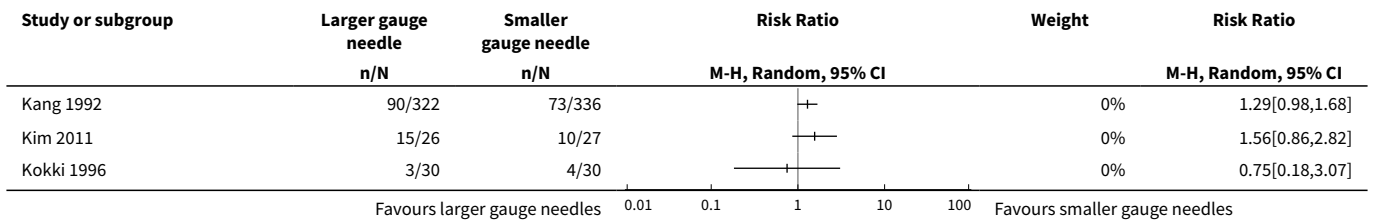


Analysis 2.6. Comparison 2 Larger gauge traumatic needles versus smaller gauge traumatic needles, Outcome 6 Severe PDPH by gauge.





Analysis 2.7. Comparison 2 Larger gauge traumatic needles versus smaller gauge traumatic needles, Outcome 7 Any headache.

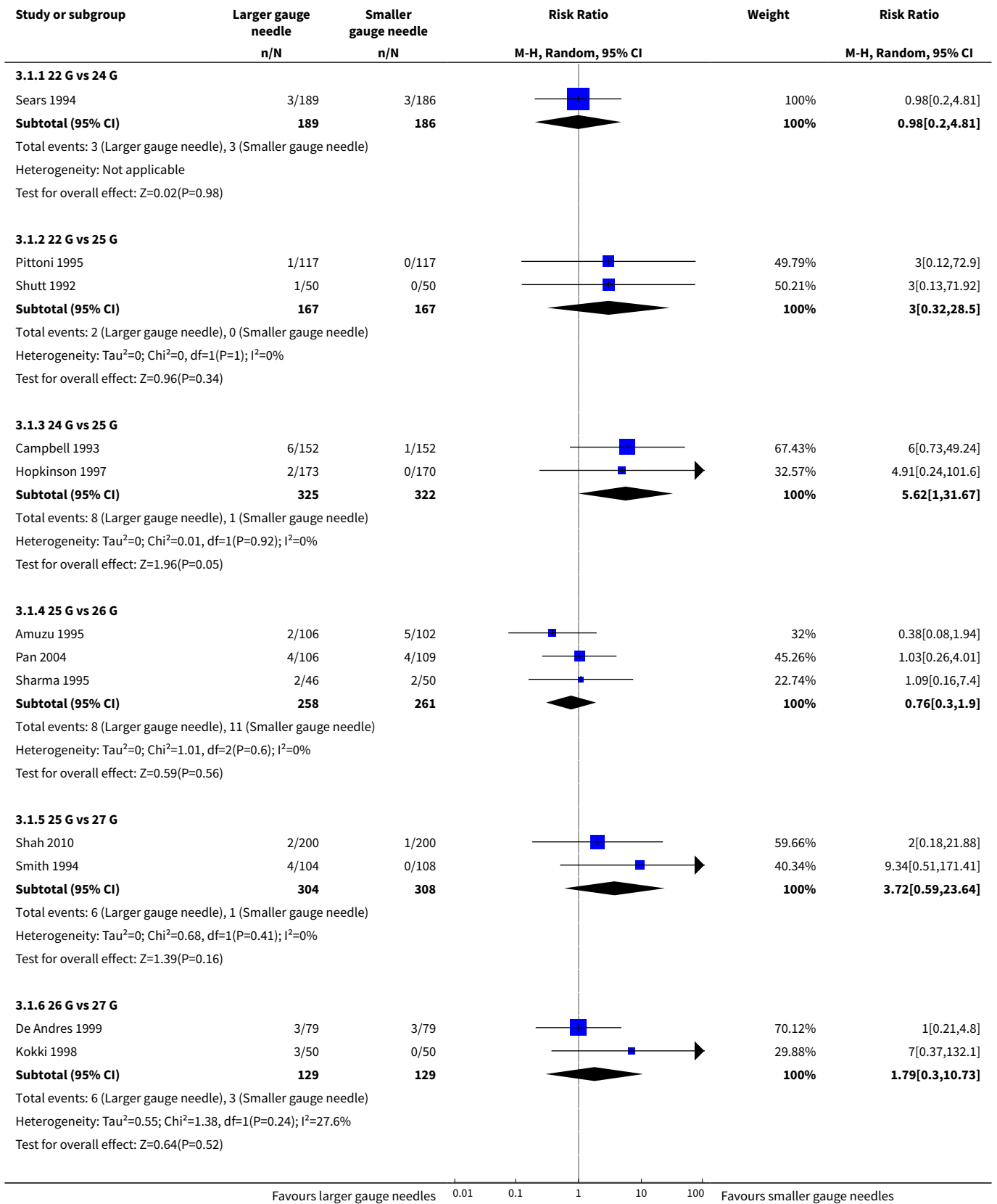


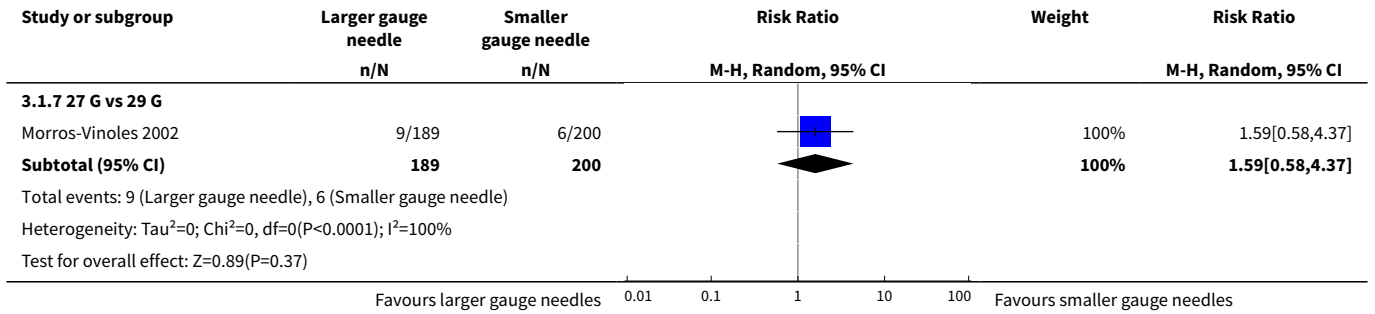
Comparison 3. Larger gauge atraumatic needles versus smaller gauge atraumatic needles

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|----------------------------------|--------------------|
| 1 PDPH larger gauge vs smaller gauge | 13 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 1.1 22 G vs 24 G | 1 | 375 | Risk Ratio (M-H, Random, 95% CI) | 0.98 [0.20, 4.81] |
| 1.2 22 G vs 25 G | 2 | 334 | Risk Ratio (M-H, Random, 95% CI) | 3.00 [0.32, 28.50] |
| 1.3 24 G vs 25 G | 2 | 647 | Risk Ratio (M-H, Random, 95% CI) | 5.62 [1.00, 31.67] |
| 1.4 25 G vs 26 G | 3 | 519 | Risk Ratio (M-H, Random, 95% CI) | 0.76 [0.30, 1.90] |
| 1.5 25 G vs 27 G | 2 | 612 | Risk Ratio (M-H, Random, 95% CI) | 3.72 [0.59, 23.64] |
| 1.6 26 G vs 27 G | 2 | 258 | Risk Ratio (M-H, Random, 95% CI) | 1.79 [0.30, 10.73] |
| 1.7 27 G vs 29 G | 1 | 389 | Risk Ratio (M-H, Random, 95% CI) | 1.59 [0.58, 4.37] |
| 2 PDPH by type of surgery | 13 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 2.1 Caesarean section | 6 | 1263 | Risk Ratio (M-H, Random, 95% CI) | 1.92 [0.64, 5.79] |

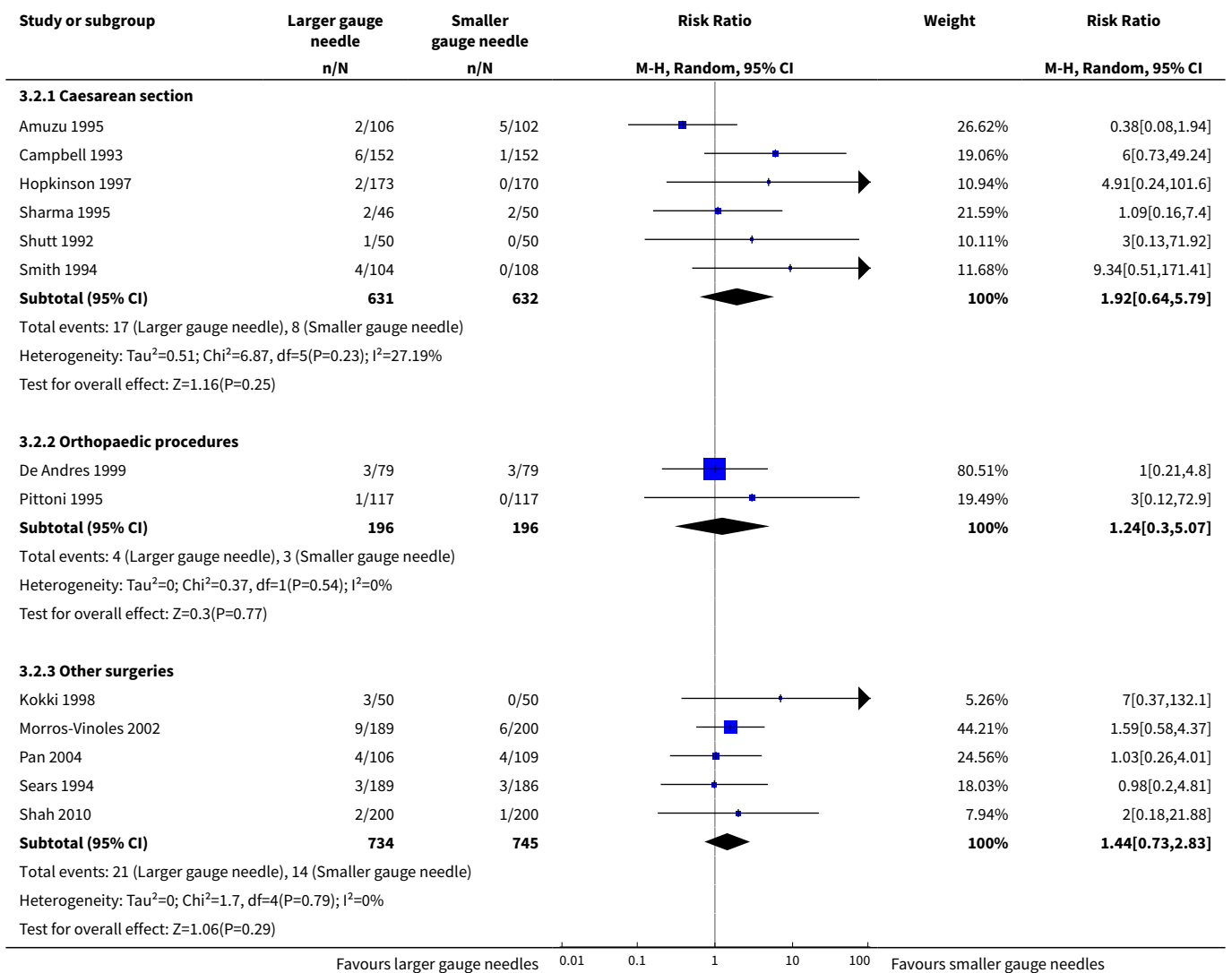
| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--------------------------------|----------------|---------------------|---------------------------------------|--------------------|
| 2.2 Orthopaedic procedures | 2 | 392 | Risk Ratio (M-H, Random, 95% CI) | 1.24 [0.30, 5.07] |
| 2.3 Other surgeries | 5 | 1479 | Risk Ratio (M-H, Random, 95% CI) | 1.44 [0.73, 2.83] |
| 3 PDPH by gender | 8 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 3.1 Only women | 8 | 1853 | Risk Ratio (M-H, Random, 95% CI) | 1.06 [0.51, 2.20] |
| 4 PDPH by position | 10 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 4.1 Sitting position | 5 | 1106 | Risk Ratio (M-H, Random, 95% CI) | 0.96 [0.45, 2.06] |
| 4.2 Lateral position | 5 | 992 | Risk Ratio (M-H, Random, 95% CI) | 1.88 [0.65, 5.41] |
| 5 AE: paraesthesia | 2 | 439 | Risk Ratio (M-H, Random, 95% CI) | 2.19 [0.31, 15.30] |
| 6 AE: backache | 4 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 7 Severe PDPH by gauge | 8 | | Risk Difference (M-H, Random, 95% CI) | Subtotals only |
| 7.1 22 G vs 24 G | 1 | 375 | Risk Difference (M-H, Random, 95% CI) | 0.0 [-0.01, 0.01] |
| 7.2 22 G vs 25 G | 1 | 234 | Risk Difference (M-H, Random, 95% CI) | 0.0 [-0.02, 0.02] |
| 7.3 24 G vs 25 G | 1 | 304 | Risk Difference (M-H, Random, 95% CI) | 0.01 [-0.02, 0.03] |
| 7.4 25 G vs 26 G | 2 | 311 | Risk Difference (M-H, Random, 95% CI) | 0.01 [-0.01, 0.03] |
| 7.5 25 G vs 27 G | 1 | 212 | Risk Difference (M-H, Random, 95% CI) | 0.01 [-0.02, 0.04] |
| 7.6 26 G vs 27 G | 1 | 158 | Risk Difference (M-H, Random, 95% CI) | 0.0 [-0.02, 0.02] |
| 7.7 27 G vs 29 G | 1 | 389 | Risk Difference (M-H, Random, 95% CI) | 0.0 [-0.01, 0.01] |
| 8 Any headache by gauge | 7 | | Risk Ratio (M-H, Random, 95% CI) | Subtotals only |
| 8.1 22 G vs 25 G | 1 | 234 | Risk Ratio (M-H, Random, 95% CI) | 2.17 [0.85, 5.51] |
| 8.2 24 G vs 25 G | 2 | 645 | Risk Ratio (M-H, Random, 95% CI) | 1.17 [0.49, 2.77] |
| 8.3 25 G vs 26 G | 2 | 311 | Risk Ratio (M-H, Random, 95% CI) | 1.13 [0.65, 1.99] |
| 8.4 25 G vs 27 G | 1 | 212 | Risk Ratio (M-H, Random, 95% CI) | 1.87 [0.65, 5.39] |
| 8.5 27 G vs 29 G | 1 | 389 | Risk Ratio (M-H, Random, 95% CI) | 1.80 [0.85, 3.83] |

Analysis 3.1. Comparison 3 Larger gauge atraumatic needles versus smaller gauge atraumatic needles, Outcome 1 PDPH larger gauge vs smaller gauge.

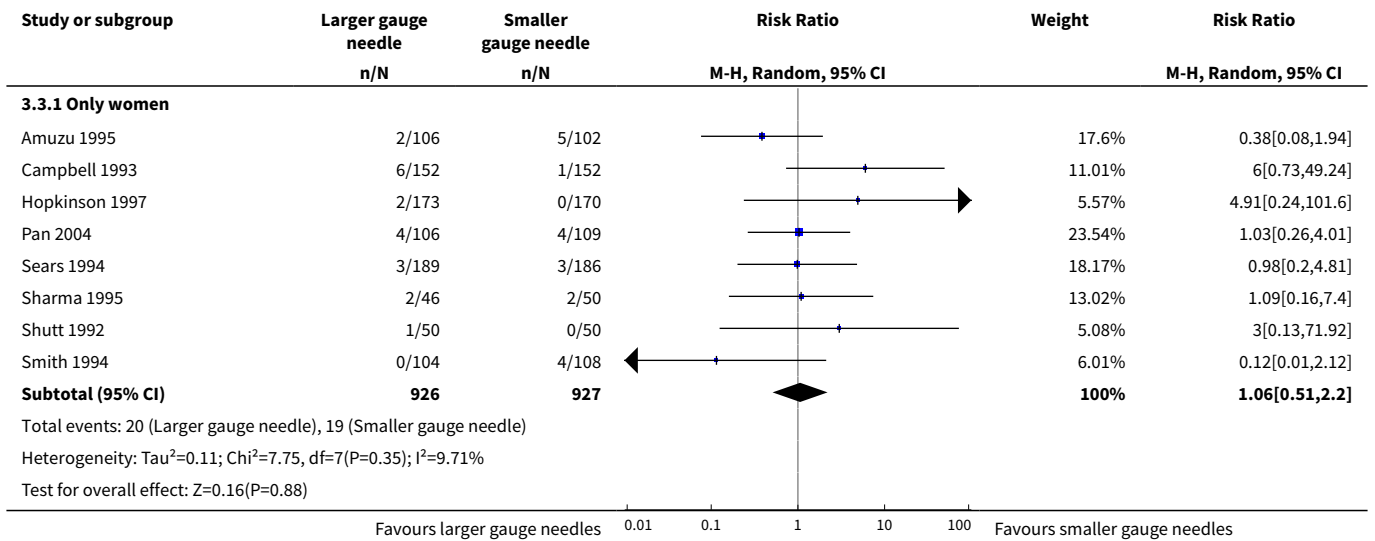




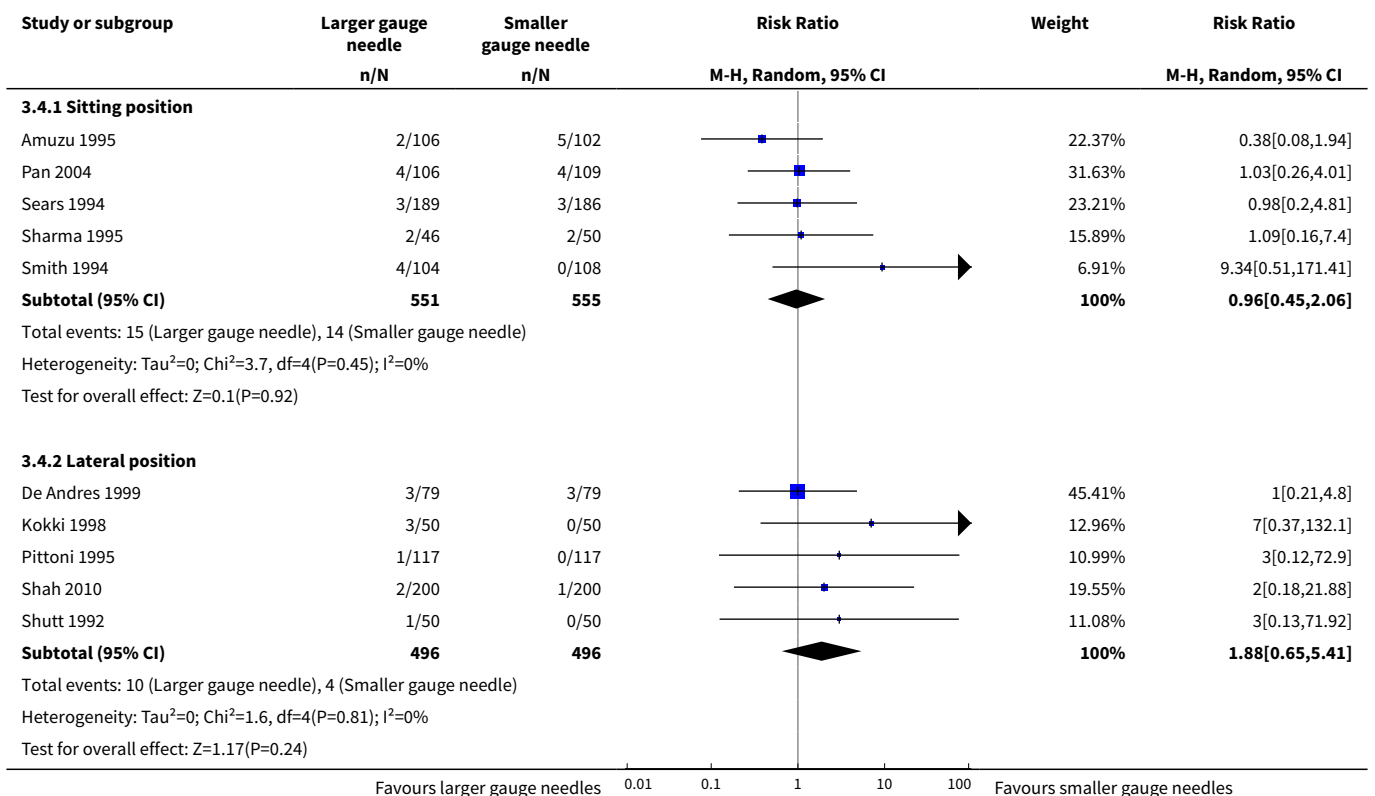
Analysis 3.2. Comparison 3 Larger gauge atraumatic needles versus smaller gauge atraumatic needles, Outcome 2 PDPH by type of surgery.



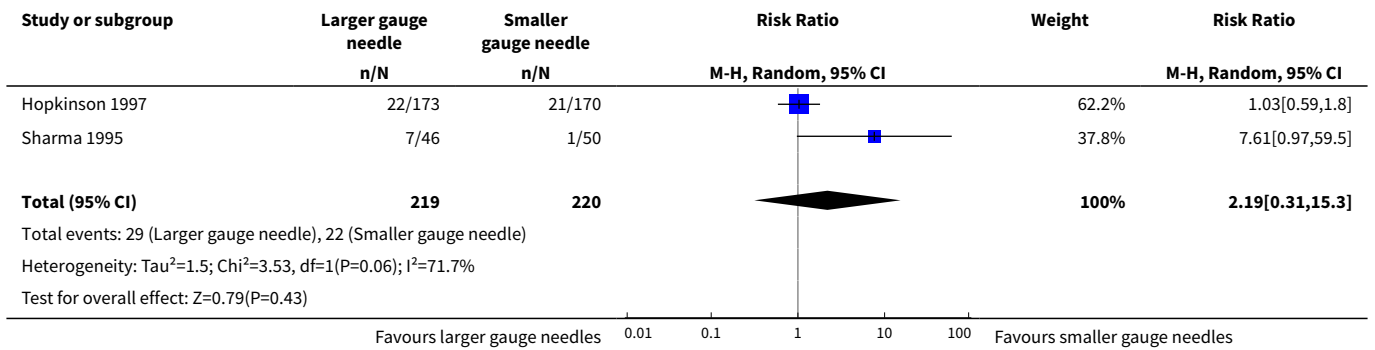
Analysis 3.3. Comparison 3 Larger gauge atraumatic needles versus smaller gauge atraumatic needles, Outcome 3 PDPH by gender.



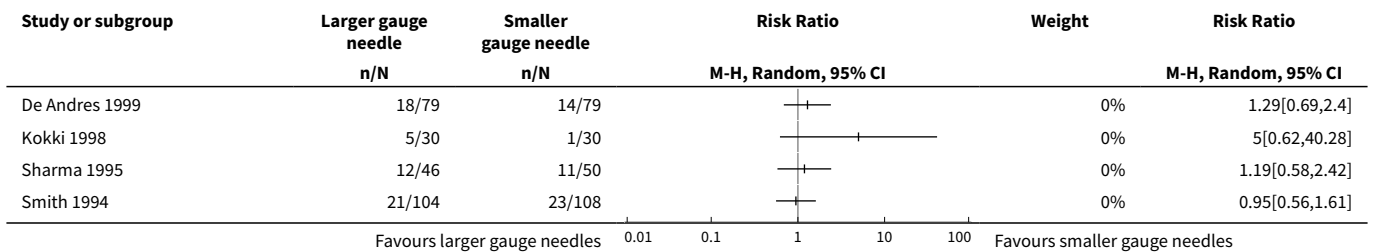
Analysis 3.4. Comparison 3 Larger gauge atraumatic needles versus smaller gauge atraumatic needles, Outcome 4 PDPH by position.



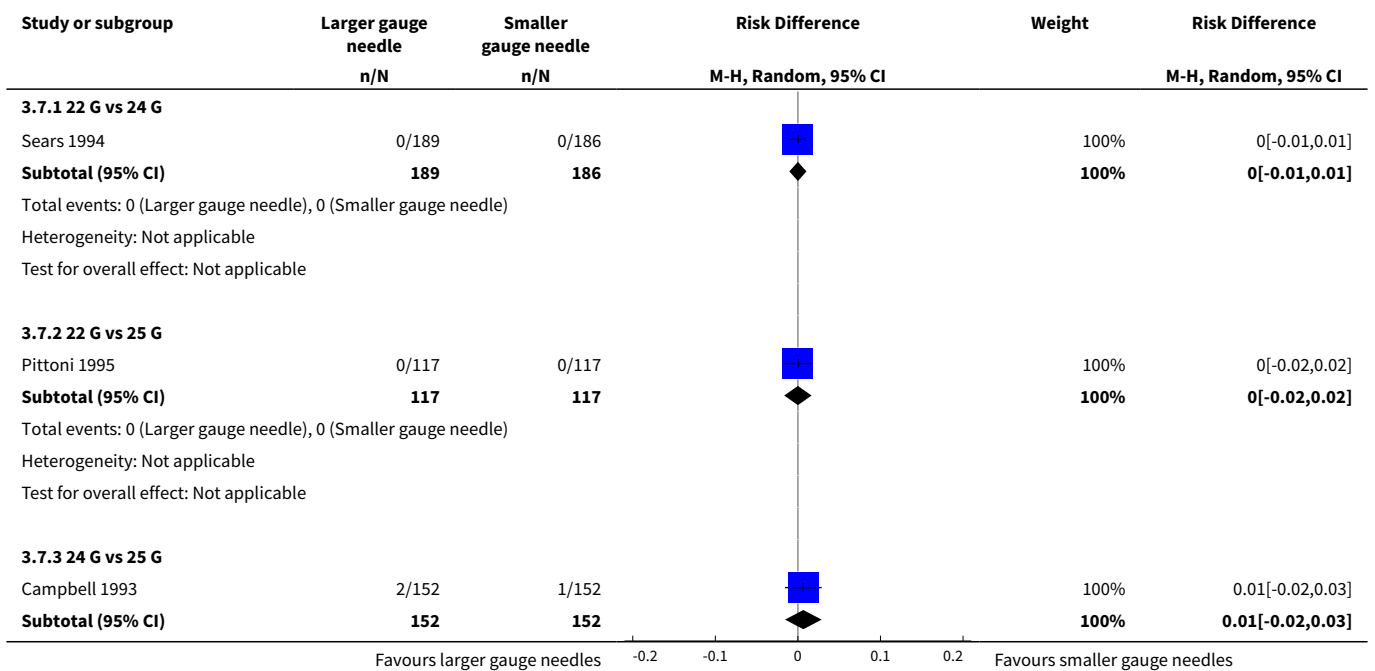
Analysis 3.5. Comparison 3 Larger gauge atraumatic needles versus smaller gauge atraumatic needles, Outcome 5 AE: paraesthesia.

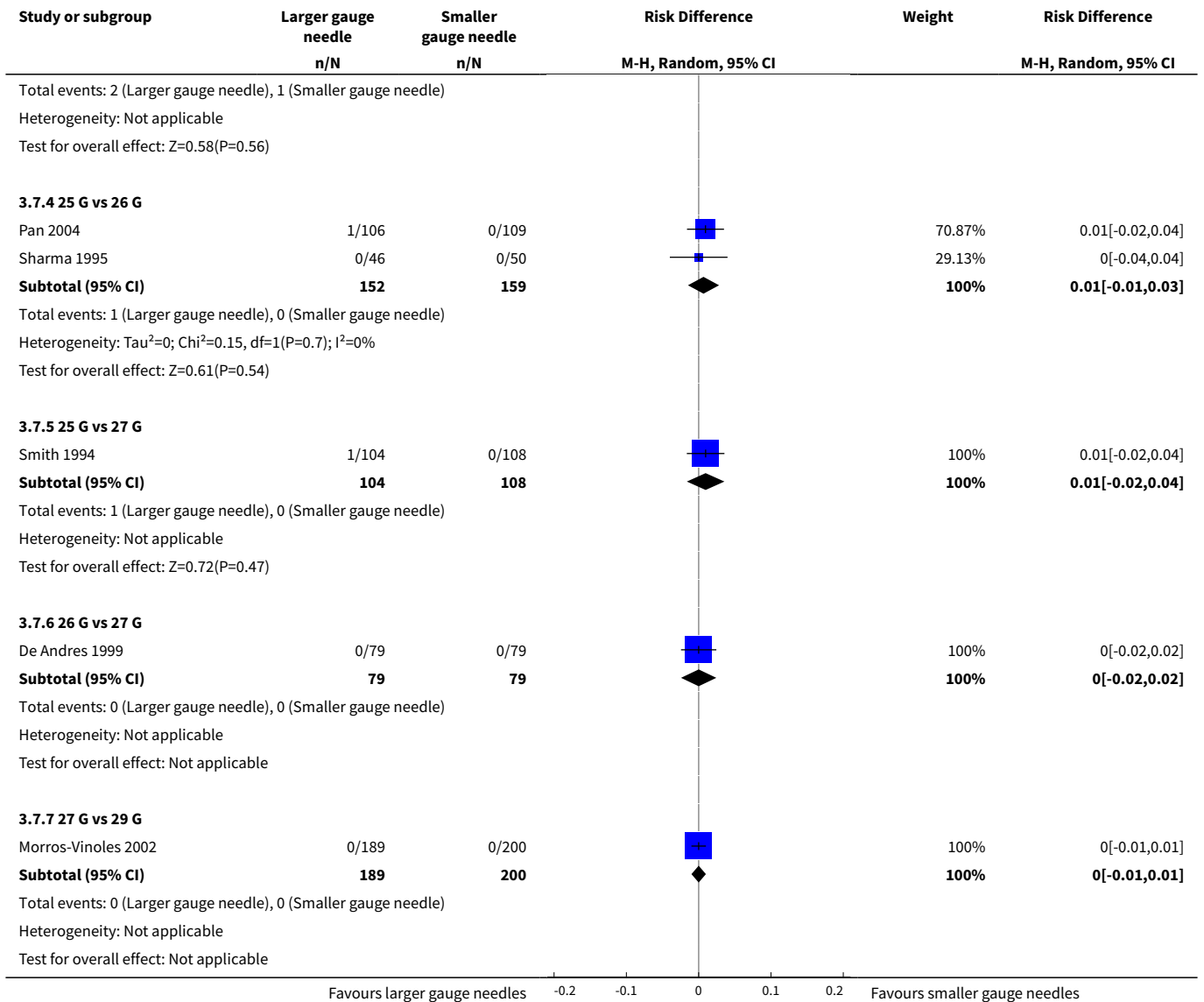


Analysis 3.6. Comparison 3 Larger gauge atraumatic needles versus smaller gauge atraumatic needles, Outcome 6 AE: backache.

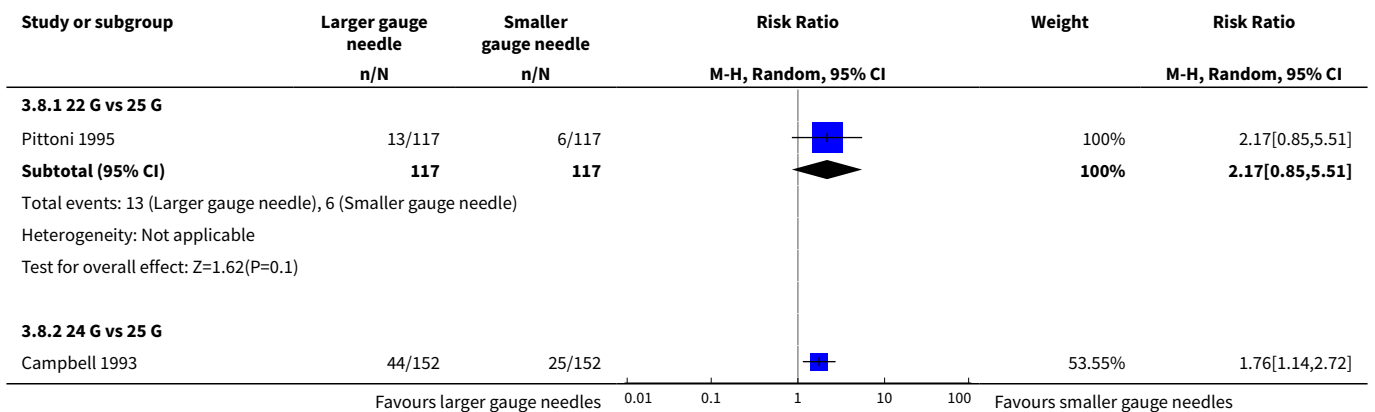


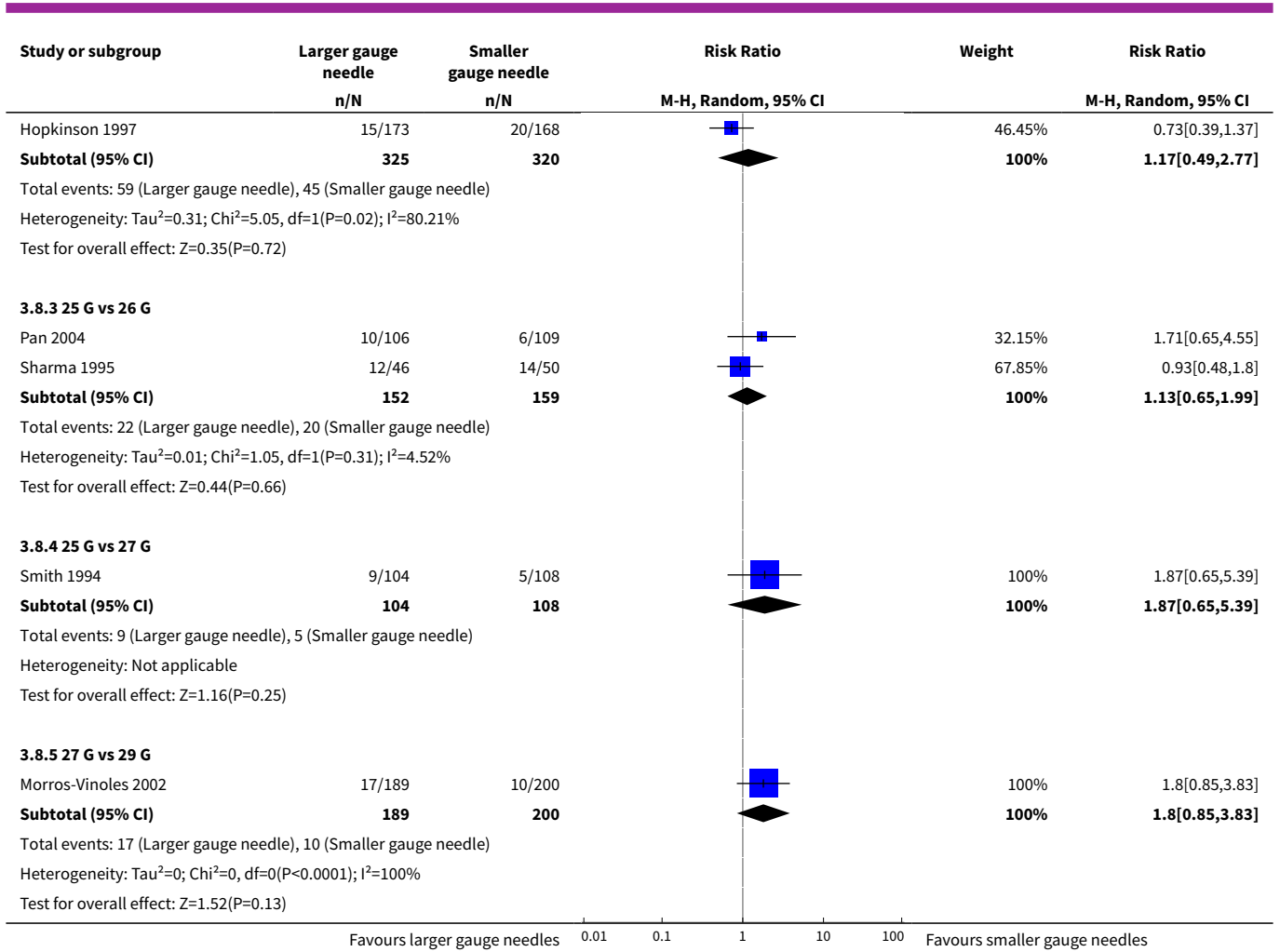
Analysis 3.7. Comparison 3 Larger gauge atraumatic needles versus smaller gauge atraumatic needles, Outcome 7 Severe PDPH by gauge.





Analysis 3.8. Comparison 3 Larger gauge atraumatic needles versus smaller gauge atraumatic needles, Outcome 8 Any headache by gauge.





APPENDICES

Appendix 1. Glossary of terms

| Term | Definition | Source |
|-----------------------|---|---|
| Analgesia, epidural | Relief of pain without loss of consciousness through the introduction of an analgesic agent into the epidural space of the vertebral canal. | http://www.ncbi.nlm.nih.gov/mesh |
| Analgesia, obstetric | Elimination of pain, without loss of consciousness, during obstetrical labour; obstetrical delivery; or the postpartum period, usually through the administration of analgesics. | http://www.ncbi.nlm.nih.gov/mesh |
| Blood patch, epidural | Injection of autologous blood into the epidural space either as a prophylactic treatment immediately after an epidural puncture or for treatment of headache resulting from an epidural puncture. | http://www.ncbi.nlm.nih.gov/mesh |

(Continued)

| | | |
|------------------------------|--|---|
| Cerebrospinal fluid-pressure | Manometric pressure of the cerebrospinal fluid as measured by lumbar, cerebroventricular or cisternal puncture. Within the cranial cavity, it is called <i>intracranial pressure</i> . | http://www.ncbi.nlm.nih.gov/mesh |
| Dura mater | The outermost of the three meninges, a fibrous membrane of connective tissue that covers the brain and the spinal cord. | http://www.ncbi.nlm.nih.gov/mesh |
| Myelography | X-ray visualization of the spinal cord after injection of contrast medium into the spinal arachnoid space. | http://www.ncbi.nlm.nih.gov/mesh |
| Needle | Sharp instruments used for puncturing or suturing. | http://www.ncbi.nlm.nih.gov/mesh |
| Primary prevention | Specific practices for the prevention of disease or mental disorders in susceptible individuals or populations. These include health promotion, including mental health; protective procedures, such as communicable disease control; and monitoring and regulation of environmental pollutants. | http://www.ncbi.nlm.nih.gov/mesh |
| Post-dural puncture headache | A secondary headache disorder attributed to low cerebrospinal fluid pressure caused by spinal puncture, usually after dural or lumbar puncture. | http://www.ncbi.nlm.nih.gov/mesh |
| Spinal puncture | Tapping fluid from the subarachnoid space in the lumbar region, usually between the third and fourth lumbar vertebrae. | http://www.ncbi.nlm.nih.gov/mesh |

Appendix 2. CENTRAL, the Cochrane Library search strategy

#1 MeSH descriptor: [Post-Dural Puncture Headache] explode all trees
 #2 (pdp or plph or pph or post dural or postdural or headach* or cephalea* or cephalalgi*):ti,ab
 #3 MeSH descriptor: [Anesthesia, Epidural] explode all trees
 #4 MeSH descriptor: [Anesthesia, Spinal] explode all trees
 #5 MeSH descriptor: [Injections, Spinal] explode all trees
 #6 MeSH descriptor: [Myelography] explode all trees
 #7 MeSH descriptor: [Spinal Puncture] explode all trees
 #8 (#1 or #2) and (#3 or #4 or #5 or #6 or #7)
 #9 ((spinal or intraspinal or dural or intradural or epidural or lumbar* or thecal* or intrathecal or sub?arachnoid*) near (puncture* or inject* or anesth* or anaesth* or needle* or tap)):ti,ab
 #10 #8 or #9
 #11 (caliber or needle gauge* or needle tip* or needle size* or traumatic tap* or traumatic needle* or atraumatic needle* or pencil point* or diamond tip* or spinal needle* or ((quincke or greene or hingson or lutz or brace or rovenstine or lemmon or whitacre or atraucan or sprotte or cappe or gertie marx or deutsch) and (needle*)):ti,ab
 #12 #10 and #11

Appendix 3. MEDLINE (PubMed) search strategy

(Post-Dural Puncture Headache[Mesh] OR PDPH[tiab] OR PLPH[tiab] OR PPH[tiab] OR Post dural[tiab] OR Postdural[tiab] OR Headache[Mesh] OR Headach*[tiab] OR cephalea*[tiab] OR cephalalgi*[tiab]) AND (Anesthesia, Epidural[Mesh] OR Anesthesia, Spinal[Mesh] OR Injections, Spinal[Mesh] OR Myelography[Mesh] OR Spinal Puncture[Mesh] OR ((spinal[tiab] OR intraspinal[tiab] OR dural[tiab] OR intradural[tiab] OR epidural[tiab] OR lumbar*[tiab] OR thecal*[tiab] OR intrathecal[tiab] OR subarachnoid*[tiab] OR subarachnoid*[tiab]) AND (Spinal Puncture[Mesh] OR puncture*[tiab] OR inject*[tiab] OR anesth*[tiab] OR anaesth*[tiab] OR needle*[tiab] OR Tap[tiab]))) AND (caliber[tiab] OR Needle Gauge*[tiab] OR Needle Tip*[tiab] OR Needle size*[tiab] OR Traumatic Tap*[tiab] OR Traumatic Needle*[tiab] OR Atraumatic Needle*[tiab] OR Pencil Point*[tiab] OR Diamond Tip*[tiab] OR Spinal Needle*[tiab] OR ((Quincke[tiab] OR Greene[tiab] OR Hingson[tiab] OR Lutz[tiab] OR Brace[tiab] OR Rovenstine[tiab] OR Lemmon[tiab] OR Whitacre[tiab] OR Atraucan[tiab] OR Sprotte[tiab] OR Cappe[tiab] OR Gertie Marx[tiab] OR Deutsch[tiab]) AND (Needle*[tiab])))

Appendix 4. EMBASE (Ovid SP) search strategy

1. (postdural puncture headache/ or pdph.ti,ab. or plph.ti,ab. or pph.ti,ab. or post dural.ti,ab. or postdural.ti,ab. or headache/ or headach*.ti,ab. or cephalaea*.ti,ab. or cephalalgi*.ti,ab.) and (epidural anesthesia/ or spinal anesthesia/ or intraspinal drug administration/ or myelography/ or puncture/ or ((spinal or intraspinal or dural or intradural or epidural or lumbar* or thecal* or intrathecal or sub? arachnoid*) and (puncture* or inject* or anesth* or anaesth* or needle* or tap)).ti,ab.) and (caliber or needle gauge* or needle tip* or needle size* or traumatic tap* or traumatic needle* or atraumatic needle* or pencil point* or diamond tip* or spinal needle* or ((quincke or greene or hingson or lutz or brace or rovenstine or lemmon or whitacre or atraucan or sprotte or cappe or gertie marx or deutsch) and needle*)).ti,ab.

Appendix 5. CINAHL (EBSCOhost) search strategy

S1. ((MM "Anesthesia, Epidural") OR (MM "Analgesia, Epidural") OR (MM "Anesthesia, Spinal") OR (MM "Injections, Intraspinal+") OR (MM "Myelography") OR (MH "Spinal Puncture")) AND ((MH "Headache") OR TI (pdph or plph or pph or post dural or postdural or headach* or cephalaea* or cephalalgi*) OR AB (pdph or plph or pph or post dural or postdural or headach* or cephalaea* or cephalalgi*))

S2. TI ((spinal or intraspinal or dural or intradural or epidural or lumbar* or thecal* or intrathecal or subarachnoid* or sub arachnoid*) and (puncture* or inject* or anesth* or anaesth* or needle* or tap)) OR AB ((spinal or intraspinal or dural or intradural or epidural or lumbar* or thecal* or intrathecal or subarachnoid* or sub arachnoid*) and (puncture* or inject* or anesth* or anaesth* or needle* or tap))

S3. S1 OR S2

S4. TI ((caliber or needle gauge* or needle tip* or needle size* or traumatic tap* or traumatic needle* or atraumatic needle* or pencil point* or diamond tip* or spinal needle* or ((quincke or greene or hingson or lutz or brace or rovenstine or lemmon or whitacre or atraucan or sprotte or cappe or gertie marx or deutsch) and (needle*)))) OR AB ((caliber or needle gauge* or needle tip* or needle size* or traumatic tap* or traumatic needle* or atraumatic needle* or pencil point* or diamond tip* or spinal needle* or ((quincke or greene or hingson or lutz or brace or rovenstine or lemmon or whitacre or atraucan or sprotte or cappe or gertie marx or deutsch) and (needle*))))

S5. S3 AND S4

Appendix 6. LILACS (BIREME) search strategy

((pdph or plph or pph or post dural or postdural or headach\$ or cephalaea\$ or cephalalgi\$) and (epidural or spinal anesthesia or spinal injections or myelography or spinal puncture)) or ((spinal or intraspinal or dural or intradural or epidural or lumbar\$ or thecal\$ or intrathecal or subarachnoid\$ or sub arachnoid\$) and (puncture\$ or inject\$ or anesth\$ or anaesth\$ or needle\$ or tap)) [Words] and (caliber or needle gauge\$ or needle tip\$ or needle size\$ or traumatic tap\$ or traumatic needle\$ or atraumatic needle\$ or pencil point\$ or diamond tip\$ or spinal needle\$ or ((quincke or greene or hingson or lutz or brace or rovenstine or lemmon or whitacre or atraucan or sprotte or cappe or gertie marx or deutsch) and (needle\$)))

Appendix 7. Study eligibility screening and data extraction form

Needle Gauge and Tip designs for Preventing PDPH – Intervention Cochrane Review

Study Selection, Quality Assessment & Data Extraction Form

| First Author | Journal/Conference proceedings, etc | Year |
|--------------|-------------------------------------|------|
|--------------|-------------------------------------|------|

1. Study Eligibility

| RCT/CCT | Relevant participants | Relevant interventions | Relevant outcomes* |
|---------|-----------------------|------------------------|--------------------|
| Yes | | | |
| No | | | |
| Unclear | | | |

^aIssues related to selective reporting when authors may have taken measurements for particular outcomes but did not report these within the paper(s). Review authors should contact trialists for information on possible non-reported outcomes and reasons for exclusion from publication. Study should be listed in 'Studies awaiting assessment' until clarified. If no clarification is received after three attempts, study should then be excluded.

Do not proceed if any of the above answers is "No".

2. References to Trial

Check other references identified in searches. If further references to this trial are identified, link the papers and list below. All references to a trial should be linked under one Study ID in RevMan.

| Author | Journal/Conference proceedings, etc | Year |
|--------|-------------------------------------|------|
| | | |

3. Participant and Trial Characteristics

| | Further details |
|---|-----------------|
| Age, years (mean, median, range, etc.) | |
| Gender of participants | |
| Country | |
| Reason for puncture (dx, anaesthesia, radiology) | |
| Surgical procedure (obstetrical, orthopaedic, etc.) | |
| Type of anaesthesia used | |
| Trial design (parallel, etc.) | |
| Single centre/multi-centre | |
| Eligibility criteria | |
| Exclusion criteria | |
| Follow-up, years (mean, median, range, etc.) | |
| Time points reported in the study | |
| Other | |

4. Intervention Characteristics

Further details

Needle tip

Needle gauge

Number of attempts

5. Number of Participants

| | Enrolled participants | Randomly assigned participants | Participants included in analysis | Lost to follow-up | Reasons |
|--------------|-----------------------|--------------------------------|-----------------------------------|-------------------|---------|
| At beginning | | | | | |
| A Group | | | | | |
| B Group | | | | | |
| C Group | | | | | |
| D Group | | | | | |

6. Methodological Quality

| | Low risk of bias | Unclear risk of bias | High risk of bias | Details |
|--|------------------|----------------------|-------------------|---------|
| Random sequence generation | | | | |
| Allocation concealment | | | | |
| Blinding of participants and personnel | | | | |
| Blinding of outcome assessment | | | | |
| Selective reporting bias | | | | |
| Incomplete outcome data | | | | |
| Other bias | | | | |
| Withdrawals | | | | |
| Other (describe) | | | | |

7. Results

| | A Group (define) | | B Group (define) | |
|---------------------------------------|-----------------------------|-------------------------|-----------------------------|-------------------------|
| | # Participants with outcome | # Participants analysed | # Participants with outcome | # Participants analysed |
| PDPH | | | | |
| Severe PDPH (define) | | | | |
| Any headache after spinal anaesthesia | | | | |
| Other (define) | | | | |

WHAT'S NEW

| Date | Event | Description |
|------------------|---------|--|
| 21 December 2017 | Amended | We have corrected an error in the data from Smith 1994 regarding the incidence of PDPH. The RR point estimates, confidence intervals and I-square values were modified for the following comparisons Analysis 3.1. 5 ; 5 , Analysis 3.2.1 ; and Analysis 3.4.1 . However, these changes did not change the interpretations and conclusions of the published version. |

CONTRIBUTIONS OF AUTHORS

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Conceiving the review: IA-R, LM

Designing the review: IA-R, LM, JJA, AC, MRF

Co-ordinating the review: IA-R

Undertaking manual searches: IA-R, NG-C

Screening search results: IA-R, LM, JJA, NG-C

Organizing retrieval of papers: LM, NG-C

Screening retrieved papers against inclusion criteria: IA-R, LM, JJA, AC, MRF, NG-C, SB

Appraising quality of papers: IA-R, LM, SB, AC, MRF, NG-C

Abstracting data from papers: LM, JJA, NG-C, IAR

Writing to authors of papers for additional information: IAR

Providing additional data about papers: IA-R, AC

Obtaining and screening data on unpublished studies: IA-R, LM

Needle gauge and tip designs for preventing post-dural puncture headache (PDPH) (Review)

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Providing data management for the review: RM, IAR

Entering data into Review Manager ([RevMan 5.3](#)): IA-R, LM, NG-C

Managing RevMan statistical data: MRF, IAR

Performing other statistical analyses not using RevMan: MR

Ensuring double entry of data (data entered by person one: MRF; data entered by person two: IA-R)

Interpreting data: IA-R, LM, AC, MRF, NG-C

Making statistical inferences: IA-R, LM, AC, MRF

Writing the review: IA-R, LM, JJA, AC, MRF, NG-C, SB

Providing guidance on the review: AC, MRF

Securing funding for the review: IA-R

Performing previous work that served as the foundation of the present study: IA-R, LM, AC, MRF

Serving as guarantor for the review (one author): IA-R

Taking responsibility for reading and checking the review before submission: IA-R, LM, JJA, AC, MRF, NG-C, SB

DECLARATIONS OF INTEREST

Ingrid Arevalo-Rodriguez: none known.

Luis Muñoz: none known.

Natalia Godoy-Casasbuenas: none known.

Jimmy J Arevalo: none known.

Sabine Boogaard: none known

Agustín Ciapponi: none known.

Marta Roqué i Figuls: none known.

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Internal sources

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- Iberoamerican Cochrane Centre, Barcelona, Spain.
- Universidad El Bosque, Bogotá, Colombia.

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External sources

- Agencia de Calidad del Sistema Nacional de Salud, Ministry of Health, Spain.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We made the following changes to the published protocol ([Arevalo-Rodriguez 2013a](#)).

- Due to heterogeneity in the reporting of adverse events, we chose paraesthesia and backache as the most important adverse events (additional to PDPH) related to needle gauge and tip designs. We extracted all numerical information related to these two events and we reported the results in the corresponding sections.
- In order to make a comprehensive 'Risk of bias' assessment, we considered seven domains (random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias)

instead of the six domains planned in our protocol (Arevalo-Rodriguez 2013a). However, we did not consider blinding of personnel because of the nature of the intervention (lumbar puncture).

- We did not expect to encounter any unit of analysis issues, as we do not expect to find cross-over studies or cluster-randomized trials. However, we did identify four such studies (one cross-over trial and three parallel-group studies with punctures instead of patients as the unit of analysis) with our search strategies. We included these trials in our review in the qualitative report, but we did not include their results in our main analyses.
- Subgroup analysis for age (younger than 18 years of age, older than 65 years of age and 18 to 65 years of age). Due to heterogeneity in the reporting of age, we classified studies into three groups: a) only children; b) no distinctions about age; c) 60 years or more. We analysed the numerical information into these three categories.
- Subgroup analysis by type of surgery: in participants receiving anaesthesia, we analysed the primary outcome by type of surgical procedure in order to explain all sources of heterogeneity. We identified at least three groups: caesarean section, orthopaedic surgeries and other surgeries. It has been reported that some subgroups of patients, such as obstetric women, have an increased risk of PDPH.
- We did not use number needed to treat to harm (NNTH) figures to illustrate the harms or benefits of interventions, taking into account the quality of evidence and its limitations.
- In order to consider all possible studies, we performed a sensitivity analysis to measure the risk difference (RD) in those analyses that presented zero events in both treatment arms; they were then not included in the risk ratio analysis.

INDEX TERMS

Medical Subject Headings (MeSH)

*Needles; Back Pain [epidemiology] [etiology]; Equipment Design; Headache [epidemiology] [etiology]; Paresthesia [epidemiology] [etiology]; Post-Dural Puncture Headache [epidemiology] [*prevention & control]; Randomized Controlled Trials as Topic; Sensitivity and Specificity; Spinal Puncture [*adverse effects] [instrumentation]

MeSH check words

Humans