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Percutaneous endoscopic gastrostomy versus nasogastric tube feeding for adults with swallowing disturbances (Review)

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TABLE OF CONTENTS

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[Intervention Review]

Percutaneous endoscopic gastrostomy versus nasogastric tube feeding for adults with swallowing disturbances

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ABSTRACT

Background

A number of conditions compromise the passage of food along the digestive tract. Nasogastric tube (NGT) feeding is a classic, time-proven technique, although its prolonged use can lead to complications such as lesions to the nasal wing, chronic sinusitis, gastro-oesophageal reflux, and aspiration pneumonia. Another method of infusion, percutaneous endoscopy gastrostomy (PEG), is generally used when there is a need for enteral nutrition for a longer time period. There is a high demand for PEG in patients with swallowing disorders, although there is no consistent evidence about its effectiveness and safety as compared to NGT.

Objectives

To evaluate the effectiveness and safety of PEG compared with NGT for adults with swallowing disturbances.

Search methods

We searched *The Cochrane Library*, MEDLINE, EMBASE, and LILACS from inception to January 2014, and contacted the main authors in the subject area. There was no language restriction in the search.

Selection criteria

We planned to include randomised controlled trials comparing PEG versus NGT for adults with swallowing disturbances or dysphagia and indications for nutritional support, with any underlying diseases. The primary outcome was intervention failure (e.g. feeding interruption, blocking or leakage of the tube, no adherence to treatment).

Data collection and analysis

We used standard methodological procedures expected by The Cochrane Collaboration. For dichotomous and continuous variables, we used risk ratio (RR) and mean difference (MD), respectively with the random-effects statistical model and 95% confidence interval (CI). We assumed statistical heterogeneity when $I^2 > 50\%$.

Main results

We included 11 randomised controlled studies with 735 participants which produced 16 meta-analyses of outcome data. Meta-analysis indicated that the primary outcome of intervention failure, occurred in lower proportion of participants with PEG compared to NGT (RR

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0.18, 95% CI 0.05 to 0.59, eight studies, 408 participants, *low quality evidence*) and this difference was statistically significant. For this outcome, we also subgrouped the studies by endoscopic gastrostomy technique into *pull,* and *push* and *not reported*. We observed a significant difference favouring PEG in the *pull* subgroup (RR 0.07, 95% CI 0.01 to 0.35, three studies, 90 participants). The*push* subgroup contained only one clinical trial and the result favoured PEG (RR 0.05, 95% CI 0.00 to 0.74, one study, 33 participants) techniques. We found no statistically significant difference in cases where the technique was not reported (RR 0.43, 95% CI 0.13 to 1.44, four studies, 285 participants).

There was no statistically significant difference between the groups for meta-analyses of the secondary outcomes of mortality (RR 0.86, 95% CI 0.58 to 1.28, 644 participants, nine studies, *very low quality evidence*), overall reports of any adverse event at any follow-up time point (ITT analysis, RR 0.83, 95% CI 0.51 to 1.34), 597 participants, 6 studies, *moderate quality evidence*), specific adverse events including pneumonia (aspiration) (RR 0.70, 95% CI 0.46 to 1.06, 645 participants, seven studies, *low quality evidence*), or for the meta- analyses of the secondary outcome of nutritional status including weight change from baseline, and mid-arm circumference at endpoint, although there was evidence in favour of PEG for meta-analyses of mid-arm circumference change from baseline (MD 1.16, 95% CI 1.01 to 1.31, 115 participants, two studies), and levels of serum albumin were higher in the PEG group (MD 6.03, 95% CI 2.31 to 9.74, 107 participants).

For meta-analyses of the secondary outcomes of time on enteral nutrition, there was no statistically significant difference (MD 14.48, 95% CI -2.74 to 31.71; 119 participants, two studies). For meta-analyses of quality of life measures (EuroQol) outcomes in two studies with 133 participants, for inconvenience (RR 0.03, 95% CI 0.00 to 0.29), discomfort (RR 0.03, 95% CI 0.00 to 0.29), altered body image (RR 0.01, 95% CI 0.00 to 0.18; P = 0.001) and social activities (RR 0.01, 95% CI 0.00 to 0.18) the intervention favoured PEG, that is, fewer participants found the intervention of PEG to be inconvenient, uncomfortable or interfered with social activities. However, there were no significant differences between the groups for pain, ease of learning to use, or the secondary outcome of length of hospital stay (two studies, 381 participants).

Authors' conclusions

PEG was associated with a lower probability of intervention failure, suggesting the endoscopic procedure may be more effective and safe compared with NGT. There is no significant difference in mortality rates between comparison groups, or in adverse events, including pneumonia related to aspiration. Future studies should include details of participant demographics including underlying disease, age and gender, and the gastrostomy technique.

PLAIN LANGUAGE SUMMARY

Nutritional support for adults with swallowing difficulties

Background

A number of conditions compromise the transport of food along the digestive tract. Patients with swallowing disturbances can develop low nutritional status, which affects their recovery from illness, surgery, and injury. Conditions associated with swallowing disorders include stroke, neurological diseases, dementia, cancers of the head and neck, amyotrophic lateral sclerosis, physical obstruction, and dysphagia from stroke. Nasogastric tube feeding is a time proven technique to provide nutritional support; the tube can be inserted by a nurse. Percutaneous endoscopy gastrostomy (PEG) involves a feeding tube inserted directly into the stomach through the abdomen and is particularly useful when enteral nutrition is needed for a length of time.

Review question

Prolonged use of a nasal tube can lead to adverse events such as damage to the nose and larynx, chronic sinusitis, gastro-oesophageal reflux, and aspiration pneumonia (which can result from inhalation of stomach contents leading to lower respiratory tract infection and pneumonia).

Study characteristics

We obtained updated evidence for this review from 11 randomised controlled studies comparing a nasogastric tube with PEG in a total of 735 patients. Seven studies measured treatment failure i.e. feeding interruption, blocking or leakage of the feeding tube in 408 patients randomised to either a nasal gastric tube or PEG.

Key results

The studies showed a higher probability of treatment failure with a nasal gastric tube. The number of deaths was no different with the two methods; nor was the overall occurrence of adverse events. Participants with PEGs may have a better quality of life.

Quality of the evidence

Possible limitations of this review include the small number of participants in the majority of studies, explained by the high cost of PEG and requirements for endoscopy in its use, the operational challenges to accomplish a clinical trial in this area and the different length of follow-up of the patients in the studies (from less than four weeks to six months). There were clinical differences between the trials, with the participants having different baseline diseases and different techniques used to insert the PEG. The findings of the present review of

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the literature should be interpreted with caution, given that there were methodological issues with most of the included studies which increase the risk of bias in the trial. This systematic review of the literature is valuable in analysing 11 studies, with a sample size of 735 patients. Nevertheless, further randomised clinical trials that adopt a rigorous method are warranted.

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Summary of findings for the main comparison. Percutaneous endoscopic gastrostomy compared with nasogastric tube feeding for adults with swallowing disturbances

Percutaneous endoscopic gastrostomy compared with nasogastric tube feeding for adults with swallowing disturbances

Patient or population: adult patients with swallowing disturbances
Settings: in-patient
Intervention: percutaneous endoscopic gastrostomy
Comparison: nasogastric tube feeding

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Nasogastric tube feeding	Percutaneous endoscopic gastrostomy				
Treatment failure Feeding interruption, blocking or leakage of the tube, non-adherence Follow-up: 0 to 6 months	**Study population**		**RR 0.18** (0.05 to 0.59)	408 (8 studies)	⊕⊕⊝⊝ **low** [1,3]	The subgroup of stroke/ neurological diseases was associated with a lower risk of intervention failure compared with the subgroup composed of mixed diseases. Favours PEG
	391 per 1000	**70 per 1000** (20 to 231)				
	Low					
	375 per 1000	**30 per 1000** (7 to 124)				
	High					
	319 per 1000	**102 per 1000** (26 to 421)				
Mortality irrespective of follow-up time Follow-up: 0 to 6 months	**366 per 1000**	**315 per 1000** (212 to 469)	**RR 0.86** (0.58 to 1.28)	644 (9 studies)	⊕⊝⊝⊝ **very low** [1,2,3]	Favours neither PEG nor NGT.
Pneumonia irrespective of follow-up time Follow-up: 0 to 6 months	**415 per 1000**	**291 per 1000** (24 to 45)	**RR 0.7** (0.46 to 1.06)	645 (7 studies)	⊕⊕⊝⊝ **low** [1,3]	Favours neither PEG nor NGT.
Adverse events irrespective of follow-up time	**458 per 1000**	**380 per 1000** (234 to 614)	**RR 0.83** (0.51 to 1.34)	597 (6 studies)	⊕⊕⊕⊝ **moderate** [1,3]	Favours neither PEG nor NGT.

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Follow-up: 0-17 months

*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; **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.

[1] Design limitation (risk of bias), unclear sequence generation, allocation concealment and loss to follow-up.
[2] Relatively few participants and few events and/or wide confidence intervals
[3] Widely differing estimates of the treatment effect (i.e. heterogeneity or variability in results) across studies

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BACKGROUND

A number of conditions compromise the passage of food along the digestive tract. Disturbances may be due to blockage, as seen in stenosis and cancer of the stomach or larynx, or due to swallowing difficulties such as in genetic diseases, stroke sequelae, cranial encephalic trauma, brain tumours, and amyotrophic lateral sclerosis (Heemskerk 2014; Löser 2005; Piecuch 2013; Schneider 2014). Several approaches are available to provide nutritional support (Nugent 2013). Nasogastric tube (NGT) feeding is a classic, time-proven technique, although its prolonged use can lead to adverse events such as lesions to the nasal wing, chronic sinusitis, gastro-oesophageal reflux, and aspiration pneumonia (Bastow 1986; Beavan 2010). Two meta-analyses comparing tube placement into the stomach or duodenum revealed no significant difference between the methods in terms of length of hospital stay, mortality, or adverse events (Ho 2006; Marik 2003). In addition to adverse events, the need to change the tube due to blockage inherent to its narrow gauge coupled with its disagreeable appearance in social settings have led to the election of alternative techniques whenever possible (Zaherah 2012).

Gastrostomy has been used to gain access to the stomach for long-term enteral feeding in patients with swallowing limitations who require nutritional support. The main criteria for indicating gastrostomy are (i) a reasonable prospect of patient survival and (ii) normal intestinal function (Friginal-Ruiz 2011). This surgical procedure was first carried out successfully in humans in 1876, by Verneuil in France. Following various modifications, Stamm devised the technique most frequently used to this day (Ljungdahl 2006). In 1980, Gauderer et al described a new technique of feeding tube placement in gastrostomy using endoscopy, called percutaneous endoscopic gastrostomy (PEG). This involves a local anaesthetic and does not require laparotomy (Gauderer 1980). Since the introduction of PEG, a number of studies comparing methods of gastrostomy have been conducted, such as operative, push and pull PEG techniques (Köhler 2014; Stiegmann 1990; Tucker 2003).

Previous systematic reviews and meta-analyses on enteral nutrition approaches have been performed, but not with the broad scope we propose. Langmore 2006 published a meta-analysis that investigated enteral nutrition, specifically in amyotrophic lateral sclerosis, comparing the use of several types of feeding tubes in patients being fed orally. However, they did not find any controlled or randomised studies. Another meta-analysis compared nutrition by endoscopic gastrostomy and NGT including only post-stroke patients (Bath 1999). Thereafter, a number of controlled and randomised studies were published that compared the two methods of nutritional support in stroke patients and those admitted to intensive care units with a range of different pathologies, as well as individuals on mechanical ventilation (Dennis 2005; Douzinas 2006; Hamidon 2006; McClave 2005).

Assessment of these latest studies in patients with a range of pathologies, together with analysis of the optimal moment to commence nutritional support, warrant mapping by means of a systematic review so as to offer the best evidence available on which to base decisions.

Description of the condition

Malnutrition encompasses overnutrition and undernutrition, but undernutrition is a prevalent, and undesired condition affecting up to 40% of hospitalised patients (Barker 2011). This condition has important causal associations with morbidity and mortality, by affecting, for example, length of stay in hospital; recovery from illness, surgery and injury; cardiac function, weak muscles (including respiratory muscles), with consequent higher risk of thromboembolism, chest infection, and pressure sores (Geeganage 2012; Iwamoto 2014; Löser 2010; Pearce 2002; Valente da Silva 2012). Mortality rates tend to be higher in elderly and undernourished patients in comparison to other subgroups of hospitalised patients (Ordoñez 2013; Valente da Silva 2012). In this sense, swallowing disturbances are of special interest, because of its direct relationship with undernutrition (Poisson 2014).

The clinical diagnosis of swallowing disturbances can be given based on clinical signals such as delay in swallowing, pharyngeal sensibility, abnormality or absence of tongue movements; loosening of water from lips, pocketing of food in the cheek, under the tongue or on the hard palate, coughing or choking while eating or signs of penetration or aspiration (Falsetti 2009; Simons 2014). Although not usually used in daily practice, radiological tests like videofluoroscopic modified barium swallow and videofluoroscopic swallowing study can be used for diagnosis of dysphagia (Finestone 2003; Scheeren 2014; Stec 2008).

Patients with indications for enteral nutrition (nutrients intake by means of feeding tubes) include those with conditions associated with swallowing disorders, such as motor neuron disease and multiple sclerosis; physical obstruction to swallowing, such as oesophageal tumours; an inability to ingest food due to head injury or stroke; and those with anorexia due to an underlying disease such as chronic lung disease, irritable bowel disease, or cancer (Botella Romero 2012; de Aguilar-Nascimento 2011; Fini 2014; Kolaček 2013; Manba 2014). Dysphagic patients and those with anorexia, malabsorption, or excessive catabolism also may need long-term enteral feeding (Le 2010; Gentile 2012; Pearce 2002). Aspiration risk often is an indication for nutritional support using tubes (Corry 2008; Metheny 2010). Enteral nutrition can be provided in the form of drink supplements or, if a patient is unable to take adequate nutritional supplements orally, fed via an enteral tube into the stomach or small bowel (Granell Vidal 2014; Löser 2005).

Description of the intervention

In general, tube systems for artificial enteral nutrition can be positioned by nasal insertion, guided percutaneous application, or surgical techniques (Abdel-Lah Mohamed 2006; Blumenstein 2014; Gopalan 2003; Schröder 2004). The superiority of percutaneously placed gastrostomies compared with the former surgical gastrostomy procedures (that is, Witzel, Stamm, Janeway techniques) has been clearly suggested (Löser 2005; Ljungdahl 2006). Lower complication rates, reduced hospital length of stay and costs have been reported (Grant 1988; Ljungdahl 2006). Most patients who require nutritional support need it for around one month or less, with the nasogastric sound probe being the main way of infusion (Blumenstein 2014; Pearce 2002). The probe used is made of thin polyurethane, size 14 with an internal diameter of 3.3 mm, and is inserted by a trained professional in order to prevent adverse events such as perforation and tracheobronchial location (Hamidon 2006; Löser 2005). Another method of infusion, percutaneous endoscopy gastrostomy (PEG), is generally used when there is a need for enteral nutrition for a longer time period (Löser 2005; Pearce 2002). This procedure can be done by either

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'pull' or 'push' techniques, the former being simpler and more frequently used. Both techniques use a silicon probe (for example 24 Fr, internal diameter 5.5 mm). The puncture site is marked with gastroscopic monitoring of the anterior gastric wall in the region of the distal corpus, after adequate local anaesthesia and intravenous sedation (Hamidon 2006; Löser 2005). Prospective studies have shown that the early insertion of the probe via PEG improves the patient's nutritional state (Hamidon 2006; Norton 1996). Patients treated for head and neck carcinoma have considered PEG to be more acceptable than a NGT, even though persistent dysphagia was associated with PEG (Mekhail 2001). A cohort study verified the acceptability of PEG, with significantly higher survival time and lower aspiration rates (Dwolatzky 2001) compared to NGT. On the other hand, a narrative review (Plonk 2005) reported increased risk of death in stroke patients with PEG compared with NGT and concluded that aspiration pneumonia rates were similar. Published guidelines on enteral nutrition recommend the performing of gastrostomy, preferably endoscopically (Löser 2005).

Radiologically placed gastrostomy (RIG) is another method of enteral nutrition, but operationally different from PEG. RIG is not an endoscopic procedure and utilises fluoroscopy, performed in an interventional radiologic suite (Barkmeier 1998; Chiò 2004).

How the intervention might work

The percutaneous gastronomy probe is of a larger calibre compared with an NGT and is placed in the abdomen. This leads to less interruption of nutrition caused by the probe being withdrawn as well as reduced reflux with consequent aspiration, thus being less embarrassing for the patient (Dwolatzky 2001; Pearce 2002). Patients and carers believe that nutrition via PEG helps in feeding and the ability to cope, being more convenient than NGT (Anis 2006). PEG-related morbidity and mortality are 9.4% and 0.53%, respectively (Wollman 1995). There are, however, exclusive adverse events for endoscopy percutaneous gastrostomy, such as peritonitis, buried bumper syndrome, gastrocolocutaneous fistula, and wound infection (Potack 2008). Adverse events associated with NGT due to its nasogastric insertion and positioning are also cited, including sinusitis, laryngeal ulcerations, pneumothorax, and tracheoesophagic fistula; the latter due to incorrect positioning of the tube (Pearce 2002).

Why it is important to do this review

According to Potack 2008, there is a high demand for PEG in patients with swallowing disorders, with 160,000 to 200,000 PEG procedures performed per year in the USA. This makes PEG the procedure of choice for nutritional support in adults. The same author commented that many such procedures are performed, although there is no consistent evidence about what is the more effective and safe method. Because NGT and PEG are the most commonly used methods for feeding access (Pearce 2002), a systematic review is worth performing to resolve such questions.

OBJECTIVES

To evaluate the effectiveness and safety of percutaneous endoscopic gastrostomy (PEG) as compared to a nasogastric tube (NGT) for adults with swallowing disturbances, by updating our previous Cochrane review (Other published versions of this review), assessing the included studies with the revised 'Risk of bias' assessments, and to assess the overall level of evidence using the GRADE approach.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials comparing percutaneous endoscopic gastrostomy (PEG) versus nasogastric tube (NGT) for nutrition in adults with swallowing disturbances.

Types of participants

Adult patients presenting with swallowing disturbances or dysphagia and indications for nutritional support, as identified by the authors of primary studies. Patients with any underlying diseases were also acceptable.

Types of interventions

The comparison arms of interest are as follows.

- Intervention group: PEG performed by any method (e.g., pull and push methods, others).
- Control group: NGT irrespective of technique (e.g., conventional and looping).

We did not include studies with radiologically inserted gastrostomy (PRG), nasojejunal tubes, and jejunal tube percutaneous endoscopy gastrostomy (JET-PEG) in this review.

Types of outcome measures

Primary outcomes

- Intervention failures as defined by any event leading to failure to introduce the tube, recurrent displacement and treatment interruption (feeding interruption, blocking or leakage of the tube, no adherence to treatment) (based on Norton 1996).

Secondary outcomes

- Nutritional status, as measured by any validated instrument (such as upper-arm skin fold thickness, mid-arm circumference, body weight, serum albumin level, haemoglobin (Ramel 2008)).
- Mortality.
- Adverse events (e.g., aspiration, haemorrhage, pneumonia, wound infection, sinusitis, fistula).
- Time on enteral nutrition.
- Quality of life, as measured by any validated instrument (such as EUROQoL, SF-36 (Dorman 1997)).
- Length of hospital stay.
- Costs and economic issues.

Search methods for identification of studies

Electronic searches

We performed a computerised literature search in, re-running searches from the previous search date (August 2009). We carried out updated searches in September 2011 and in January 2014.

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- The Cochrane Central Register of Controlled Trials (CENTRAL, 2013, Issue 12) and other databases in *The Cochrane Library* (Appendix 1),
- Ovid MEDLINE(R) Daily Update January 31, 2014, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present Appendix 2.
- EMBASE via OVID (Embase 1980 to 2014 Week 05) Appendix 3.
- LILACS via BIREME (from inception to January 2014) Appendix 4.

Search terms and their synonyms for clinical conditions of interest to us (swallowing disturbance or dysphagia) and interventions of interest (percutaneous endoscopic gastrostomy and nasogastric tube feeding) are given in the appendices. They were adapted for each of the databases. There was no language restriction in the search. Search filters to identify randomised controlled trials involving humans were used when appropriate.

Searching other resources

We compiled a reference list of relevant studies (irrespective of study design) to identify trials with the potential for inclusion. We contacted authors via email requesting the data from unpublished trials. We also tried to identify ongoing trials on the Current Controlled Trials Web site (www.currentcontrolledtrials.gov).

Data collection and analysis

Selection of studies

Two review authors (CG, RA) checked the titles and abstracts found by the search strategy and other sources researched. Whenever titles or abstracts seemed relevant to the review, we analysed them by reading the full article. If they were truly randomised controlled trials that met the previously stated criteria, we included them in the review. If there remained any doubt or disagreement, all of the authors assessed the study in question.

Data extraction and management

Two review authors (CG, DRW) extracted data based on CONSORT (Moher 2001). For the update in 2014, CB with CG and DRW extracted data from new included studies. We settled doubts by consensus of the authors.

Assessment of risk of bias in included studies

Two review authors (CG, RBA, with CB) independently assessed the methodological quality of included studies using the following items (Higgins 2011).

- Random sequence generation (selection bias) . Biased allocation to interventions due to inadequate generation of a randomised sequence.
- Allocation concealment (selection bias). Biased allocation to interventions due to inadequate concealment of allocations prior to assignment.
- Blinding (performance bias and detection bias). Performance bias or detection bias due to knowledge of the allocated interventions after assignment.
- Blinding of participants and personnel (performance bias). Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.
- Blinding of outcome assessment (detection bias). Detection bias due to knowledge of the allocated interventions by outcome assessors.
- Incomplete outcome data (attrition bias). Attrition bias due to amount, nature or handling of incomplete outcome data.
- Selective reporting (reporting bias). Reporting bias due to selective outcome reporting.
- Other bias that is bias due to problems not covered elsewhere in the table.

For the above biases, we classified studies according to their risk of systematic error.

- High risk: when the appropriate method to avoid systematic error was not met.
- Unclear risk: when the appropriate method to avoid systematic error was not described or the information was not acquired by contacting the authors of primary studies.
- Low risk: when the appropriate method to avoid systematic error was met.

We did not use performance bias as a criterion to analyse the risk of systematic error since this was not compatible with the characteristics of the intervention.

Measures of treatment effect

For dichotomous and continuous variables, we calculated risk ratio (RR), mean difference (MD), and 95% confidence intervals (CIs). When data from primary studies were not parametric (for example, effects were reported as medians, quartiles) or without sufficient statistical information (such as standard deviations, number of patients), we inserted them into Table 1 if authors did not provide the necessary information.

Unit of analysis issues

The unit of analysis was based on the individual patient (unit to be randomised for interventions to be compared). We planned to analyse events happening to a person more than once (for example pneumonia, bronchoaspiration) by using risk ratio, which compares the rate of events in the two groups (PEG and NGT) by dividing one by the other. We planned to analyse cross-over study designs separately from the parallel-group randomised controlled trials.

Dealing with missing data

For continuous and dichotomous data, we carried out available case analysis. In this update, for mean values of outcome data with missing standard deviations, we calculated this from the difference between means (*Cochrane Handbook for Systematic Reviews of Interventions* 7.7.3.3. Higgins 2011). We investigated the effects of making these assumptions by performing sensitivity analyses where appropriate.

Assessment of heterogeneity

We assessed statistical heterogeneity using the I^2 statistic. We assumed a statistically significant heterogeneity between the estimated effects of included studies with an $I^2 > 50\%$.

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Assessment of reporting biases

We had planned to assess publication bias by preparing a funnel plot, and will do so in future versions of this review if a sufficient number of studies is available. However, we are aware that asymmetry in the funnel plot can be associated with reasons other than that of publication bias (for example, by chance, real heterogeneity, or clinical particulars inherent to each one of the included studies such as patients at high risk for the outcome).

Data synthesis

Qualitative information

We synthesised qualitative information relative to methods, risk of bias, description of participants, and outcomes measures in the Characteristics of included studies table.

Quantitative information

For dichotomous variables, we calculated the risk ratio (RR). For continuous variables, we calculated the mean difference (MD) when studies reported their results through the same variables measured with the same instruments (same units of measure). When continuous data were measured with different instruments (different and non-interchangeable units of measure), we planned to pool them using the standardised mean difference (SMD). We used 95% CIs for all statistical methods to pool data.

Irrespective of the nature of the data, we used a random-effects statistical model as we were expecting substantial clinical and methodological heterogeneity, which could generate substantial statistical heterogeneity.

Subgroup analysis and investigation of heterogeneity

We planned to carry out subgroup analyses using different NGT and PEG methods (for example pull, push, nasal loop, conventional). We assumed that heterogeneity between studies in both the direction and magnitude of estimate effect had a suspected causal relationship (the subgroup characteristic and the estimate of effect), and we have considered these in the Discussion section.

Sensitivity analysis

We planned sensitivity analysis to examine the effects of intention-to-treat (ITT) analysis and available data analysis for dichotomous data. We planned to carry out ITT analysis by using imputation based on the analysis of the total number of randomised participants, irrespective of how the original study authors analysed the data. We assumed that all missing participants experienced the event. The other factors were study quality, trials reported only in abstracts, and testing for fixed-effect and random-effects statistical models.

RESULTS

Description of studies

See Characteristics of included studies and Characteristics of excluded studies for more information.

Results of the search

For details of the process of studies selection, see Figure 1.

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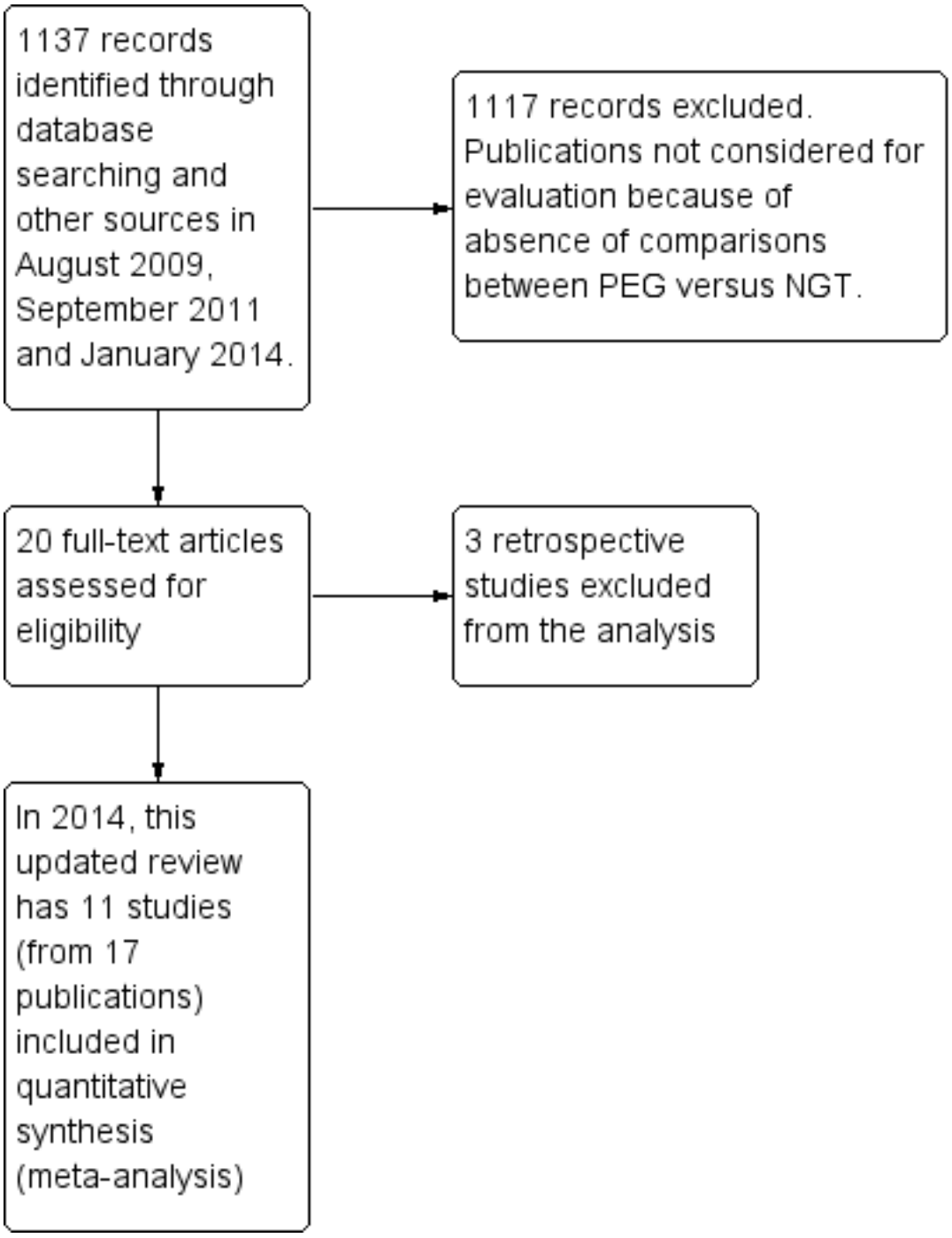
Figure 1. Study flow diagram.



The first literature search (August 2009 to September 2011) yielded 474 hits. From this, 18 papers were retrieved for full text review. Three papers were excluded due to inappropriate study design and intervention. In January 2014, an update search yielded 663 additional records and two additional studies were identified for inclusion in the review.

Included studies

The 11 randomised controlled studies selected were published in English. In many cases the data we required were not available in the published report of the study and we obtained further information from the study investigators (e.g. Bath 2009; Corry 2008b), which were used to estimate the effects of the interventions for clinically relevant outcomes (i.e., treatment failure, mortality, pneumonia, adverse events, and length of hospital stay). Yata 2001 was only available in abstract form, which hampered the gleaning of all the relevant data, and the corresponding author could not be contacted. Data from another study (Bath 1997) came from a systematic review by the same author, and doubts were resolved via email with the corresponding author. Elbadawy 2014

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was an unpublished study and we obtained further information by correspondence with the study investigator.

Participants and study design

We sought to compare percutaneous endoscopic gastrostomy (PEG) (n = 373 participants) with nasogastric tube (NGT) (n = 362 participants) placement for enteral feeding in adults (n = 735 total randomised participants).

The sample in Baeten 1992 included patients with different diseases, including neoplasia of the ear, nose, and throat and neurologic and post-operative diseases. The mean age of these patients was 72 years (range: 62 to 82 years). Park 1992 included only patients with dysphagia secondary to neurologic diseases in their sample. The mean age of these patients in the NGT group was 65 years, whereas the mean age of those in the PEG group was 56 years. Norton 1996 and Bath 1997 included in their sample patients with dysphagia after acute stroke with a mean age of 77 years. Yata 2001 studied patients with dysphagia in several diseases, such as dementia, Parkinson's disease, and cerebrovascular disease. These patients had a mean age of 75.1 years (range: 50 to 96 years) in the PEG group and 76.5 years (range: 38 to 93 years) in the NGT group. Dennis 2005 included in their sample patients who presented with dysphagia after acute stroke. Their mean age was 76 years (SD = 10 years). Douzinas 2006 assessed patients with different diseases, some of whom presented with recurrent or persistent ventilator-associated pneumonia. These patients had a median age of 53 years (range: 20 to 82 years) in the PEG group and 58 years (range: 25 to 85 years) in the NGT group. Hamidon 2006 investigated patients with dysphagia after acute stroke with a median age of 65 years (range: 48 to 79 years) in the PEG group and 72 years (range: 54 to 77 years) in the NGT group. Finally, Corry 2008 included in their sample patients with cancer of the head and neck with a median age of 60 years (range: 46 to 80 years). In Sadasivan 2012, participants had advanced stage two or three squamous cell carcinoma of the head and neck and were scheduled either for radical surgery with adjuvant radiotherapy (RT), chemo-RT, or for concurrent chemo and radiation therapy were included in the study. The age of participants in the study was not reported and we were unable to obtain further data. Elbadawy 2014, included participants with close traumatic severe brain injury in a study to determine whether PEG or NGT resulted in lower rates of ventilator-assisted pneumonia. The mean age of participants in the study was not reported and we were unable to obtain further data.

Interventions and comparisons

The interventions were PEG, inserted by any method, versus NGT. Further details can be found in the Characteristics of included studies tables.

In Elbadawy 2014, a three-arm study, NGT plus intubation was compared with PEG plus intubation and PEG plus tracheostomy. For the purposes of this review, we combined the two PEG groups and compared these results with the NGT group.

Outcomes

Follow-up times varied across the 11 studies analysed. Baeten 1992, Douzinas 2006, Park 1992, and Hamidon 2006 studied patients for no more than four weeks. On the contrary, the follow-up times of Bath 1997, Dennis 2005, Norton 1996, Yata 2001, and Corry 2008 ranged from three to six months. Elbadawy 2014 and Sadasivan 2012 followed up participants at one week, six weeks and six months.

The included studies reported our review outcomes as follows:

Our primary outcome, intervention failure, was reported in eight studies (Baeten 1992; Bath 1997; Corry 2008; Hamidon 2006; Norton 1996; Park 1992; Sadasivan 2012; Yata 2001). Elbadawy 2014 reported the number of adverse events in each group; we requested further information, but the study investigators were not able to provide the number of patients with the primary review outcome of intervention failures (e.g., feeding interruption, blocking or leakage of the tube, no adherence to treatment). Participant non-adherence to treatment was reported in Sadasivan 2012,

Mortality was reported in nine studies (Baeten 1992; Bath 1997; Corry 2008; Dennis 2005; Douzinas 2006; Elbadawy 2014; Hamidon 2006; Norton 1996; Park 1992).

Adverse effects were reported in seven studies (Baeten 1992; Corry 2008; Dennis 2005; Douzinas 2006; Elbadawy 2014; Norton 1996; Sadasivan 2012). Pneumonia, the result of aspirating food into the airway, was reported in seven studies (Baeten 1992; Corry 2008; Dennis 2005; Douzinas 2006; Elbadawy 2014; Norton 1996; Yata 2001). Reflux oesophagitis was reported in Yata 2001.

Two studies additionally reported measures related to the nutritional status of the participants: weight gain (Norton 1996; Sadasivan 2012), mid-arm circumference (Norton 1996; Sadasivan 2012), serum albumin levels (Norton 1996), and haemoglobin levels (Sadasivan 2012).

The length of hospital stay was reported in two studies (Dennis 2005; Elbadawy 2014); and the time of entry nutrition in days was reported in Baeten 1992 and Park 1992.

Other outcome measures included quality-of-life measures using the EORTC QLQ-H&N35 scale in Corry 2008 and Sadasivan 2012. Scores of patient satisfaction and inconvenience of maintaining PEG or NGT by nursing staff were reported in Baeten 1992; it is unclear if these were validated scales. Participant functional ability (modified Rankin scale (MRS)), an indicator of quality of life, was reported in Dennis 2005.

The mean survival time in months was reported in Yata 2001.

Excluded studies

The three excluded studies did not meet the aforementioned inclusion criteria. McClave 2005 conducted a randomised controlled trial without interventions of interest for this review; Mekhail 2001 and Schulz 2009 performed retrospective studies. McClave 2008 was excluded following contact with the corresponding author to clarify the randomisation process employed.

Risk of bias in included studies

See Figure 2 and Figure 3.

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

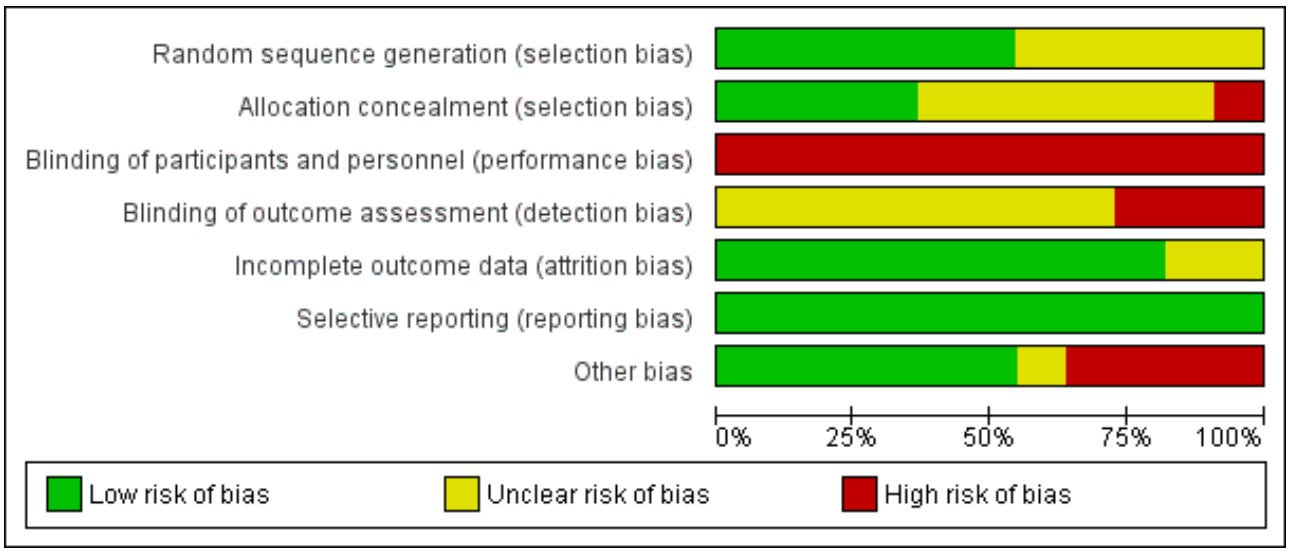

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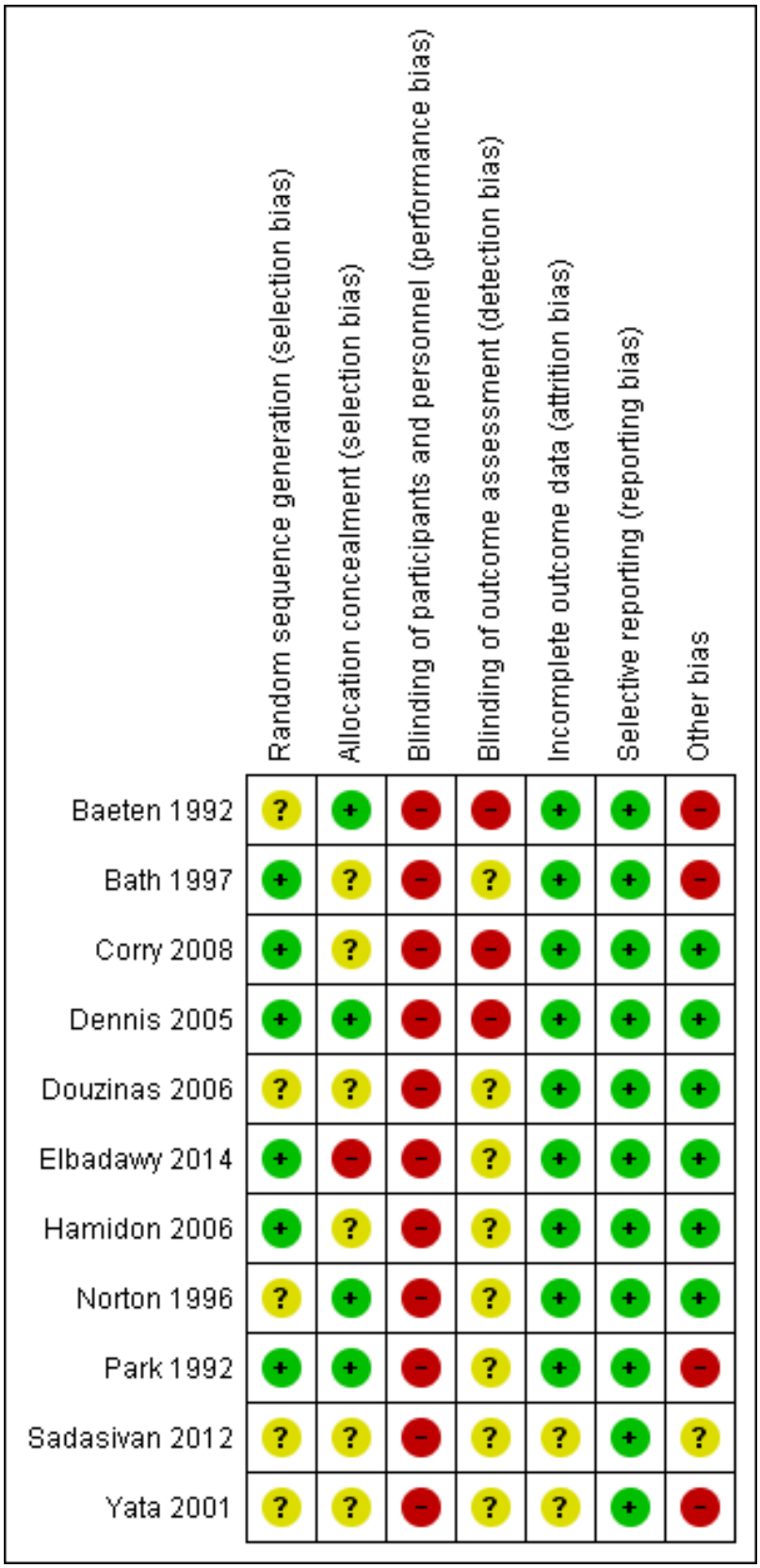
Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



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Allocation

The methods employed for allocation by Bath 1997; Corry 2008; Dennis 2005; Elbadawy 2014; Hamidon 2006; Park 1992 were suitable for this procedure; therefore, they were deemed low risk for systemic errors of a methodological nature. The remaining studies in this review (i.e., Baeten 1992; Douzinas 2006; Norton 1996; Sadasivan 2012; Yata 2001) were considered to be unclear for risk of bias because the methods used for allocation were not reported.

The methods used for allocation by Dennis 2005; Baeten 1992; Park 1992; and Norton 1996 were sufficiently sound to ensure concealment of the allocation process. Consequently, they were deemed low risk for systematic errors of a methodological nature. On the contrary, the studies by Bath 1997; Corry 2008; Douzinas 2006; Hamidon 2006; Sadasivan 2012; Yata 2001 were considered to be unclear for risk of bias. Although the authors described random allocation, they did not report the methods used for allocation concealment. No attempt was made to conceal allocation in Elbadawy 2014.

Overall, no unusually large differences were noted in the demographic characteristics of patients from each group on study entry, except in Sadasivan 2012, where there were more participants in the PEG group who had radical surgery and adjuvant radio or chemotherapy, and more participants in the NGT group had concurrent chemo or radio therapy. Participants in the NGT group weighed more at the start of the trial.

Blinding

The characteristics of the interventions compared in this systematic review prevented the patients and physicians from being blinded to the interventions. Eight studies made no mention of blinding data assessors (Bath 1997; Douzinas 2006; Elbadawy 2014; Hamidon 2006; Norton 1996; Park 1992; Sadasivan 2012; Yata 2001). Three studies were considered as of high risk of detection bias, because their authors explicitly described either the absence of (Baeten 1992; Corry 2008), or flawed method of blinding data assessors (Dennis 2005).

Incomplete outcome data

Nine studies clearly reported both missing data and the flow of the patients during the study. As a result, they were considered low risk for systematic errors in follow-up losses. However, Yata 2001 and Sadasivan 2012 did not report losses or patient flow in their work; therefore, the study was considered to be unclear for risk of bias for this domain.

In Park 1992, 18 of the 19 patients in the NGT group presented intervention failure. The researchers did not follow these patients for the full 28 days. In contrast, all 19 patients from the PEG group completed the recommended follow-up period. Despite the significant number of failures in the NGT group, this clinical trial was considered low risk for systematic error for dichotomous variables because the authors clearly described the flow of patients from randomisation through to the study endpoint.

Selective reporting

All of the studies were associated with a low risk of bias, given that relevant outcomes were reported in all cases.

Other potential sources of bias

The following studies were rated as having a high risk of bias: Baeten 1992 (follow-up not previously established), Bath 1997 and Yata 2001 (unpublished studies), Park 1992 (dropout rate of 95% (19/20) in the NGT group due to treatment failure and death).

Effects of interventions

See: **Summary of findings for the main comparison** Percutaneous endoscopic gastrostomy compared with nasogastric tube feeding for adults with swallowing disturbances

Comparison 1: percutaneous endoscopic gastrostomy versus nasogastric tube

Primary outcomes

Intervention failure

The outcome of intervention failure (e.g., feeding interruption, blocking or leakage of the tube, no adherence to treatment) was reported in eight studies comprising 408 participants (Baeten 1992; Bath 1997; Corry 2008; Hamidon 2006; Norton 1996; Park 1992; Sadasivan 2012; Yata 2001). We were unable to obtain data on overall intervention failure rates in each group from Elbadawy 2014.

Failure occurred in 9.22% (19 out of 206 participants) in the PEG group and 39.11% (79 out of 202 participants) in the NGT group. A meta-analysis of these eight studies using the random-effects model favoured the PEG group, that is, fewer participants in the PEG group experienced an intervention failure (risk ratio (RR) 0.18, 95% confidence interval (CI) 0.05 to 0.59, P = 0.005; Analysis 1.1) (Mantel-Haenszel's statistical method). We found significant statistical heterogeneity in this analysis; I^2 = 73%.

Non-adherence to treatment

Non-adherence to treatment at six weeks was reported in only one study, Sadasivan 2012 and was not statistically significantly different in an analysis of 94 participants (RR 0.07, 95% CI 0.00 to 1.17). Intention-to-treat (ITT) analyses of non-adherence at six weeks (RR 0.02, 95% CI 0.00 to 0.36) and at six months (RR 0.01, 95% CI 0.00 to 0.16) however, were statistically significantly different and favoured the PEG group Analysis 1.2.

Subgroup analyses

We further subgrouped the studies by endoscopic gastrostomy technique into *pull* (n = 90), *push* (n = 33), and not reported (n = 285) in Analysis 1.3. We observed a significant difference favouring PEG in the *pull* subgroup (RR 0.07, 95% CI 0.01 to 0.35, three studies, P = 0.001). The*push* subgroup contained only one clinical trial and the result favoured PEG (RR 0.05, 95% CI 0.00 to 0.74, P = 0.03) techniques. We found no statistically significant difference in cases where technique was not reported (RR 0.43, 95% CI 0.13 to 1.44). Statistically significant heterogeneity was found in the unreported technique subgroup (I^2 statistic = 73%), and the statistical significance of this result was unchanged in ITT analyses (RR 0.37, 95% CI 0.09 to 1.45) Analysis 1.5.1.

We made a post-hoc decision to investigate the possible reasons for this heterogeneity in Analysis 1.4 using subgroup analysis. Therefore we subgrouped the studies by participant condition (Analysis 1.4). For participants with cerebrovascular events or neurological baseline diseases (n = 109), the result favoured the

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PEG group (RR 0.08, 95% CI 0.02 to 0.33, P = 0.0005). There was no statistical heterogeneity in this analysis. For participants with mixed baseline diseases (n = 299), the intervention favoured neither PEG nor NGT(RR 0.32, 95% CI 0.08 to 1.32), and statistical heterogeneity was high (I^2 = 79%), The statistical non-significance of this result, was unchanged in ITT analyses (RR 0.29, 95% CI 0.06 to 1.33; Analysis 1.5.2).

Secondary outcomes

Mortality

The outcome of mortality was examined in nine studies (Baeten 1992; Bath 1997; Corry 2008; Dennis 2005; Douzinas 2006; Elbadawy 2014; Hamidon 2006; Norton 1996; Park 1992) (644 participants) and was assessed independently of study follow-up time. The results showed 35.76% (118 out of 330 participants) in the PEG group and 36.62% (115 out of 314 participants) in the NGT group (RR 0.86, 95% CI 0.58 to 1.28) (Mantel-Haenszels statistical method). The result of the meta-analysis for mortality revealed no statistically significant difference between comparison groups. Finally, we observed statistical heterogeneity between included studies: I^2 statistic = 47%. Because of the radiologically placed gastrostomy technique used in a small number of participants in Dennis 2005, we carried out a sensitivity analysis to test the differences in the estimate effects by including and excluding this study. The sensitivity analysis shows that the inclusion of the FOOD study (Dennis 2005) did not change the statistical significance of the result for mortality (RR 0.81 (95% CI 0.47 to 1.41, P = 0.84; Analysis 1.6) without Dennis 2005 (analysis not shown).

One study (n = 82) reported the mean survival time in months (Yata 2001) (MD 4.3, 95% CI 3.28 to 5.32; Analysis 1.7). The result favoured the PEG group, that is participants in the PEG group survived longer, for a mean of 11.4 months compared with 7.1 months in the NGT group.

Complications and adverse effects

Complications and adverse effects (e.g., aspiration, haemorrhage, wound infection, sinusitis, fistula) were examined in six studies (Baeten 1992; Corry 2008; Dennis 2005; Douzinas 2006; Norton 1996; Sadasivan 2012) (597 participants) and was assessed independently of study follow-up time or severity of adverse effect. Although some of adverse events were characteristic of only one intervention, we analysed them together for the purposes of this review. The results showed 35.67% (107 out of 300 participants) in the PEG group and 45.79% (136 out of 297 participants) in the NGT group had adverse effects (RR 0.83, 95% CI 0.51 to 1.34; Analysis 1.8) (Mantel-Haenszel's statistical method). The result of the meta-analysis for adverse effects revealed no statistically significant difference between the groups. We observed high statistical heterogeneity in the comparison: I^2 statistic = 87%. An ITT analysis of these data did not change the statistical significance of the result (RR 0.81, 95% CI 0.48 to 1.35; Analysis 1.9)

In Elbadawy 2014, which was a study of critically ill participants who had experienced head injury, adverse events associated with PEG tracheostomy and nasogastric tube were reported. Adverse events were reported as number of events, rather than number of participants experiencing adverse events (that is, participants may have experienced more than one type of adverse event). In this study, the adverse events in the PEG group were infection in the gastrostomy tube in 19 participants, leakage around the gastrostomy tube in 21 participants, dislodgement of the gastrostomy tube in 19 and obstruction of the PEG tube in two participants. Fistulas, perforations and 'buried pumper' syndrome (where the PEG tube migrates) were not seen. In the NGT group, paranasal sinusitis from the nasogastric tube was found in 12 participants (60%) (Table 2).

Aspiration (pneumonia)

The outcome of pneumonia (as a result of aspiration) was examined in seven studies (Baeten 1992; Corry 2008; Dennis 2005; Douzinas 2006; Elbadawy 2014; Norton 1996; Yata 2001) (645 participants) and was assessed independently of study follow-up time. The results showed 31.93% (106 out of 332 participants) pneumonia in the PEG group and 41.54% (130 out of 313 participants) in the NGT group (RR 0.70, 95% CI 0.46 to 1.06; Analysis 1.10). However, the result of the meta-analysis for the pneumonia outcome did not favour PEG. We observed high levels of statistical heterogeneity between studies: I^2 statistic = 81%.

Reflux oesophagitis

Douzinas 2006 reported median change in gastro-oesophageal reflux at endpoint (day seven) as percentage of the time when the oesophageal pH was less than 4 in a given 24-hour period of time. The percentage was statistically significant, that is, less severe reflux was seen in the PEG group.

Yata 2001 reported reflux oesophagitis. In this single study analysis of 82 patients in total, there was a statistically significant result that favoured the PEG group (RR 0.45, 95% CI 0.22 to 0.92; Analysis 1.11).

Nutritional status

We analysed data for nutritional status, as measured by any validated instrument (e.g. as upper-arm skin fold thickness, mid-arm circumference, body weight, serum albumin level, haemoglobin)

Weight

In a single study analysis of weight (kg) at the study endpoint (Norton 1996) (mean difference (MD) 3.20, 95% CI -5.95 to 12.35; Analysis 1.12) The outcome favoured neither NGT or PEG. Three studies contributed to an analysis of weight change from baseline (n = 148, Corry 2008; Norton 1996; Sadasivan 2012) (MD 3.11, 95% CI -0.52 to 6.75; Analysis 1.13), that is, the outcome favoured neither NGT or PEG. In this analysis statistical heterogeneity was high I^2 = 93%.

Mid-arm circumference

Norton 1996 reported mid-arm circumference in centimetres at the end point of the study and the change from baseline. The published report of Corry 2008 provided upper-arm circumference data for the NGT and PEG group as the median 300 mm (range 240 to 352) verus PEG 302.5, P= 0.69 (range 270 to 370) (mean 283 mm versus 295 mm respectively, P=0.25, not statistically significant, no standard deviations (SDs) reported Table 1). We calculated the missing SD values for the data from Corry 2008 and the result for a meta-analysis of both studies (n = 54) for arm circumference favoured neither intervention or control (MD 1.58, 95% CI -0.11 to 3.27; Analysis 1.14). No statistical heterogeneity was observed in this analysis I^2 = 0%. This overall result was unchanged in a sensitivity analysis (MD 2.50, 95% CI -0.64 to 5.64; Analysis 1.14.2)

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The change in mid-arm circumference from baseline was measured in Norton 1996 and Sadasivan 2012. In this analysis of 115 participants, the results were statistically significant in favour of PEG (MD 1.16, 95% CI 1.01 to 1.31; Analysis 1.15).

The included studies also reported anthropometric outcome data as median values which we could not include in our meta-analyses (Table 1). Median triceps skin fold thickness was reported in Corry 2008 and Hamidon 2006 and these were not significantly different in either study, however in Corry 2008, the study reports states that the NGT patients had significantly lower triceps skin fold thickness (mean 9.5 versus 13.5 mm; P = 0.03 than the PEG patients at six weeks post-treatment). Median biceps skin fold (mm) and median arm circumference was reported in Hamidon 2006 (Table 1) and the differences between groups were not statistically significantly different in either case.

Serum albumin

Mean serum albumin levels (g/dL) were reported in Yata 2001 and Norton 1996.

Yata 2001 was a short conference report and did not include SD values but reported that the serum albumin levels at three and six months were significantly different in the study report of Yata 2001 favouring PEG (P = <0.01) (Table 1). We calculated SD for this study using the difference between means and in an analysis of albumin levels of two studies of 107 participants, the result was statistically significant favouring the PEG group (MD 6.03, 95% CI 2.31 to 9.74; P = 0.001). Statistical heterogeneity was high I^2 = 75%. In a sensitivity analysis excluding Yata 2001, the result remained statistically significant, that is, using data only from Norton 1996, an analysis of albumin levels at endpoint in 25 participants indicated a statistically significant result in favour of PEG (MD 7.80, 95% CI 5.52 to 10.08; Analysis 1.16).

Sadasivan 2012 reported change in albumin levels from baseline and again this result was statistically significant in an analysis of 94 participants favouring PEG (MD 0.12, 95% CI 0.11 to 0.14; Analysis 1.17).

The median serum albumin endpoint values were lower in the NGT group in Hamidon 2006 (P = 0.054) (Table 1).

Hamidon 2006 also reported nutritional status outcome data as median values which we could not include in our meta-analyses (Table 1). Median serum albumin (g/L) was 39.5 (R 36 to 44) in the PEG groups versus 36.0 (R 31 to 45) in the NGT group. The P value was 0.045, which was statistically significantly different .

Haemoglobin

Haemoglobin levels were reported as a change from baseline in Sadasivan 2012, In this single study analysis of 94 participants, the results favoured PEG and was statistically significant (MD 0.59, 95% CI 0.49 to 0.69; Analysis 1.18).

Yata 2001 reported that mean haemoglobin levels (g/L) were 11.7 in the NG group and in the PEG group were 11.9 at three months, and 11.1 versus 12.4 at six months (Table 1).

Time of enteral nutrition

Two studies (n = 119) reported the duration of enteral feeding in days (Baeten 1992; Park 1992) (MD 14.48, 95% CI -2.74 to 31.71; Analysis 1.21), this favoured neither NGT nor PGT and there were high levels of statistical heterogeneity present in this analysis (I^2 = 94%). These results should be interpreted cautiously as the assumption of normality for these outcomes may not be met.

Length of hospital stay

Two studies (n= 381) reported the length of hospital stay in days (Dennis 2005; Elbadawy 2014) (MD -12.67, 95% CI -40.18 to 14.84; Analysis 1.24), this favoured neither NGT nor PGT. There were high levels of statistical heterogeneity present in this analysis (I^2 = 93%). These results should be interpreted cautiously as the assumption of normality for these outcomes may not be met.

Quality of life

Patient satisfaction

Patient satisfaction was reported in Baeten 1992 (a five-point graded scale graded from 1 = very satisfied to 5 = very dissatisfied). In an analysis of 43 participants, the result favoured neither PEG nor NGT (MD -0.56, 95% CI -1.32 to 0.20) (Analysis 1.19). The inconvenience score (that is, inconvenience of maintaining the intervention to nursing staff in a scale with five categories) was also a statistically non-significantly different in an analysis of 68 patients in Baeten 1992 (MD -0.58, 95% CI -1.18 to 0.02; Analysis 1.20).

Quality-of-life was measured in two studies (Corry 2008; Sadasivan 2012) and included in a meta-analysis (Analysis 1.22), Using the EORTC QLQ-H & N 35 Scale, and the number of participants who scored three or four (in this scale a high score is a worse outcome), the outcomes of pain, in an analysis of 133 participants, (RR 0.33, 95% CI 0.00 to 471.74) and ease of learning to use (RR 0.18, 95% CI 0.00 to 149.53), there was no statistically significant difference between the PEG and the NGT group. In analyses of 133 participants each for the outcomes of inconvenience (RR 0.03, 95% CI 0.00 to 0.29; P=0.002) and discomfort (RR 0.03, 95% CI 0.00 to 0.29; P = 0.002), altered body image (RR 0.01, 95% CI 0.00 to 0.18; P = 0.001), and social activities (RR 0.01, 95% CI 0.00 to 0.18; n= 100, P = 0.001), the intervention favoured PEG, that is, fewer participants found the intervention of PEG to be inconvenient, uncomfortable or interfered with family life or social activities, and this was a statistically significantly different between the groups. There was statistical heterogeneity present in the analysis of pain (I^2 = 95%) and ease of learning to use (I^2 = 94%), and low levels of statistical heterogeneity in the analyses of inconvenience and discomfort (I^2 = 21%).

The outcome of family life could not be entered into a meta-analysis as Corry 2008 did not report this subscale. Using data from Sadasivan 2012 only, this outcome favoured the PEG group and this was a statistically significantly different (RR 0.01, 95% CI 0.00 to 0.18; n=100, P = 0.001).

Dennis 2005 reported the mean difference between comparison groups at endpoint derived from the EuroQol (reported as 0.035 95% CI -0.024 to 0.093). We could not include these data in our meta-analyses, but the report of the study states that the results were not statistically significantly different.

Functional ability

A decline in functional ability while under treatment may be related to overall quality of life. Functional ability is the ability to perform basic activities of daily life without support, an important aspect of

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overall independence and quality of life. Just one study reported functional ability by using a modified Rankin Scale (MRS) (Dennis 2005). There was no statistically significant difference between comparison groups (Analysis 1.23) for the following ranges of Modified Rankin Scales (MRS): MRS 0 to 3 (RR 0.59, 95% CI 0.34 to 1.01, P = 0.06) and MRS 4 to 5 (RR 1.20, 95% CI 0.90 to 1.61, P = 0.21) and for the outcome composed by MRS scales from 4 to 5 or death as showed by the RR of 1.10, 95% CI 1.00 to 1.20, P = 0.05).

Costs and economic issues

Only one study provided information about costs and we did not include these data in any analyses. Corry 2008 stated that the "cost of each feeding tube is $26 for a NGT and $110 for a PEG tube" and "The insertion costs are significantly different as the NGT are inserted by nursing staff in outpatients and the PEG tubes are inserted by surgeons in theatre. The cost for insertion of a NGT is $50 (includes nursing time and cost of chest X-ray), whereas the cost of insertion of a PEG tube is $626".

DISCUSSION

Summary of main results

This systematic review of 11 included studies comprising 735 randomised participants in total (373 receiving percutaneous endoscopic gastrostomy (PEG) and 362 nasogastric tube (NGT)), produced 16 meta-analyses in total, for the primary outcome of intervention failure (subgrouped by gastrostomy technique and by baseline disease) and for the secondary outcomes of mortality, adverse effects in total and also pneumonia as a result of aspiration, nutritional status including weight change from baseline, mid-arm circumference at endpoint and change from baseline, time of enteral nutrition in days, length of stay in days, and quality of life measured by the EuroQol scale.

In our meta-analyses, overall, the estimated effects for the primary outcome of intervention failure showed a statistically significant lower risk in the PEG group compared with the NGT group, and this was confirmed in subgroup analyses of intervention failure for both the 'push' and 'pull' gastrostomy techniques (subgroup analysis of those studies which did not report the gastrostomy technique showed no statistically significant difference between PEG or NGT). However, we cannot infer from the effect sizes that one technique (push or pull) is superior to the other as we did not carry out comparisons (indirect analysis) of the different techniques using data from separate studies.

We carried out additional intention-to-treat (ITT) analyses for the outcome of intervention failure specifically for the four studies with participants with mixed baseline diseases, and for intervention failure in the four studies where the gastrostomy technique was not reported, and we found no statistically significant differences between the PEG and NGT groups.

No direct causal relationship with the procedures was established for the secondary outcome of mortality i.e. there was no statistically significant difference between PEG or NGT for this outcomes. Only Dennis 2005 and Baeten 1992 reported a relationship between procedure-related mortality and global mortality, ranging from 0% to 10%. These low rates support the notion that the use of these methods may have no significant influence on risk of death.

Meta-anaysis of adverse effects irrespective of follow-up time showed no statistically significant differences between the groups, and an ITT analysis of five studies for this outcome showed no statistically significant differences between the PEG and NGT groups. Fewer participants in the PEG group experienced pneumonia, an adverse event precipitated by aspiration of stomach contents or oro-pharyngeal secretions into the airway, but this difference was not statistically significant.

The meta-analyses of the secondary outcome of nutritional status i.e. weight change from baseline showed no statistically significant difference between the groups; endpoint mid-arm circumference was not statistically significantly different between the groups, although the outcome of mid-arm circumference in centimetres (change from baseline) was statistically significant in favour of PEG.

The meta-analysis of quality-of-life measures (a secondary outcome) was statistically significant favouring PEG (that is, more patients in the NGT group reported worse outcomes) for the outcomes of inconvenience, discomfort, altered or bad body image, social activities and in a single study analysis, interference with family life.

We also present analyses of data from single studies for the primary outcome of intervention failure that is non-adherence to treatment, and the secondary outcomes of adverse effects (specifically reflux oesophagitis), nutritional status including weight at endpoint, serum albumin levels and change from baseline, changes in haemoglobin levels g/dL from baseline, and measures of quality of life including scores of patient satisfaction and of inconvenience in maintaining the PEG or NGT by nurses, participant functional ability, and impact on family life measured by the EORTCQLQ-H&N35 (in one study).The single study analyses of the primary outcome non-adherence to treatment was statistically significant in favour of the PEG group at the six-week and six-month follow-up point in Sadasivan 2012 and notably all the dropouts from treatment were from the NGT group in that study (at six months there were no patients in the NGT group due to resumption of oral feeds (n = 10) or conversion to a PEG tube (n = 34).

For the secondary outcome of adverse effects, fewer patients in the Yata 2001 study reported reflux oesophagitis in the PEG group and this was statistically significant favouring PEG. For the secondary outcome of nutritional status, the mean participant body weight in kilograms at the endpoint, showed no statistically significant difference favouring PEG or NGT. Serum albumin levels at endpoint were statistically significant in Norton 1996, favouring the PEG group and also the serum albumin change from baseline were statistically significant favouring PEG in Sadasivan 2012. Haemoglobin levels expressed as a change from baseline also were higher in the PEG group and this was a statistically significant in the only study that reported this outcome (Sadasivan 2012).

Outcomes relating to quality of life, including the scores of patient satisfaction and inconvenience in maintaining the intervention by nurses as reported in Baeten 1992, were not statistically significant in favour of either PEG or NGT. Functional ability reported in Dennis 2005 favoured neither PEG nor NGT.

Analyses of time on enteral nutrition and length of hospital stay favoured neither PEG nor NGT. However, these analyses of time are very unlikely to follow a normal distribution, so the analyses of mean differences are not necessarily accurate.These results should

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be interpreted cautiously as the assumption of normality for these outcomes may not be met.

These conclusions were not changed by the 2014 update of the review.

Overall completeness and applicability of evidence

Based on the findings of this review, outcomes in participants who received nutritional support via a PEG may be more favourable that in those who have a NGT, especially for the outcome of intervention failure, based on an examination of 408 participants who had heterogeneous clinical and demographic characteristics.

Participants receiving PEG may be more likely to adhere to treatment at six weeks and six months. However, we found no evidence of a difference in mortality or adverse events (aspiration pneumonia) between the comparison groups. This non significant result does not imply no difference and we suggest that the review may not have had sufficient power to look at these less common events. Participants receiving PEG may experience less reflux oesophagitis (an adverse event). There is limited evidence, derived from single study results and small meta-analyses that PEG results in better outcomes in terms participants' nutritional status (mid-arm circumference, haemoglobin levels and serum albumin), and report better quality of life.

We found clinical heterogeneity between the studies and noted statistical heterogeneity in some of our analyses. For example, for our analyses of intervention failure, our primary outcome, we observed high levels of statistical heterogeneity resulting from the inclusion of the Baeten 1992 and Yata 2001 trials. One explanation for this may be the clinical heterogeneity between the trials, with the participants having different baseline diseases. We made a post-hoc decision to investigate the possible reasons for heterogeneity in the intervention failure meta-analysis as we assumed that the source of this statistical heterogeneity would be related to clinical heterogeneity. We hypothesised that baseline disease may have contributed to clinical heterogeneity and we categorised the studies by baseline disease, i.e. cerebrovascular event or neurological disorder versus mixed baseline disease (i.e. participants who may have had severe co-morbidities including cancer) and found that for the outcome of intervention failures in participants with cerebrovascular or neurological disease only, the results favoured PEG (i.e. fewer participants in the PEG group experienced any of the adverse events evaluated in the studies), but there was no difference between the groups for the mixed baseline disease subgroups and these studies included Baeten 1992 and Yata 2001. However, our hypothesis and the results of this analysis only point to one possible cause of heterogeneity, and this should be adequately tested in future studies. One further source of clinical heterogeneity in the remaining analyses could be because of the different techniques used to insert the PEG.

Many of the studies reported continuous outcome data in a format that could not be incorporated in to our meta-analyses for example, median values. This limited the number of analyses that we could perform and we reported these data narratively in the review. Information reported in this way should be regarded as providing additional information only and the analyses we performed including meta-analysis, forest plots, tests for statistical heterogeneity provide more precise estimates of effects.

Quality of the evidence

The findings of the present review of the literature should be interpreted with caution, given that almost half of the authors failed to report the method used to sequence and conceal the allocation (Figure 2; Figure 3). This is one of the main causes of error in randomised systematic studies. In addition, other potential risks of bias stemmed from the absence of prior planning of follow-up time, as well as the unpublished or high rates of losses during follow-up. However, almost all of the authors attempted to prevent attrition by making the flow of patients clear and through selective reporting bias by selecting clinically relevant outcomes. There are also challenges relating to the study design in terms of the numbers available for randomisation, following up such seriously ill patients and the high cost of the procedures in question. These factors may explain why the majority of studies involve small samples. It should be noted that all of the studies were judged at high risk of performance bias because it is not possible to blind participants and personnel in studies of this nature. In all cases of uncertainly we attempted to obtain further information or disaggregated data from the trial investigator, but where this was not available it was because the investigator no longer had access to historical trial data, or was unable to provide additional information. This systematic review of the literature is valuable in analysing 11 studies, thereby increasing the sample size to 735 participants. Nevertheless, further randomised clinical trials that adopt a rigorous method are warranted.

We rated the overall quality of the evidence as moderate or low for the key outcomes of treatment failure, mortality, pneumonia and adverse events (Summary of findings for the main comparison), resulting in lower confidence in the estimate of effect for those outcomes and further research is likely to have an important impact in our confidence in the estimate of effect and may even change the estimate. Where we downgraded the evidence, it was because there was risk of bias in the trial, out of eight estimates of potential bias (random sequence generation; allocation concealment; incomplete outcome data; selective reporting; blinding of participants and personnel; blinding of outcome assessment, and other bias) only six studies obtained scores of four or more. The included studies involved relatively few participants and wide confidence intervals (imprecision), although it is accepted that large scale studies of this type would be very difficult to perform. The results of many meta-analyses had high levels of statistical heterogeneity (inconsistency).

Potential biases in the review process

In view of the sensitive search strategy involving electronic correspondence with the eminent authors in this area of research, we believe that it is highly unlikely that other studies meeting the inclusion criteria of this systematic review were overlooked, however this remains a possibility and could be regarded as a limitation of this review.

While we included adverse effects reported in the studies included in this the review, we may not have detected reports of all of serious and/or rare adverse events associated with PEG or NGT, and in common with many systematic review and meta-analyses, this is a could be limitation of this review.

As outlined, all efforts were made to ensure that relevant qualitative or quantitative data were included in this review.

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Agreements and disagreements with other studies or reviews

In one of the major controlled randomised trials performed to date (Dennis 2005), the authors suggested that NGT should be the method of choice in the first two to three weeks of enteral feeding, probably in light of the increased absolute risk of death associated with the use of PEG (RR 1.02, P = 0.86) and the absolute risk of the outcome composed by MRS scale (modified Rankin scale) from four to five or death (RR 1.10, P = 0.05). However, combining the results of 11 different studies with ≅ 400 patients, it seems that the PEG option is associated with a lower risk of intervention failure. Given the importance of this finding, selecting PEG might reduce the difference in cost between the two procedures. The findings of all of the other studies included in this analysis seem to support the use of PEG. Guidelines suggest that PEG is a highly effective and safe procedure when modern equipment is used, established standards are followed (Löser 2005). However, a careful patient selection and professional proficiency are fundamental for better outcomes (Blumenstein 2014; Skitt 2011). In a narrative review, Plonk 2005 suggested that the use of PEG should only be considered in amyotrophic lateral sclerosis, intestinal blockage by malignant tumour with incoercible vomiting, persistent dysphagia after acute stroke, and early head and neck cancer. However, the results of a systematic review that included studies with different designs suggests that PEG and NGT have the same effectiveness and safety for patients with head and neck cancer, even considering relevant outcomes, such as mortality and nutritional status (Wang 2014). Although no study included in our systematic review made available information about the use of nasal looping technique, there is some evidence that such NGT technique has potential to be preferable over PEG (Anderson 2004).

AUTHORS' CONCLUSIONS

Implications for practice

Based on the findings of this meta-analysis, the results favoured PEG rather than NGT for intervention failure, but not for mortality and pneumonia rates, and other adverse events. There may be some advantage in terms of nutritional status in using PEG over NGT, and patients may report better quality of life when using a PEG tube.

In routine practice, however, the costs and benefits of both procedures should be taken into account. Some health service providers, particularly under the public health system, face difficulties acquiring endoscopic gastrostomy apparatus due to their high cost. Possible reasons for the current state of the research in this area include the high cost of the procedures in question. Corry 2008 provided an example of this stating that the "cost of each feeding tube is $26 for a NGT and $110 for a PEG tube" However, it is noteworthy that because nasogastric tubes are easier to introduce (more often by the nursing team) and less weight is placed on the cost of constantly changing them as stated in Corry 2008 "The insertion costs are significantly different as the NGT are inserted by nursing staff in outpatients and the PEG tubes are inserted by surgeons in theatre. The cost for insertion of a NGT is $50 (includes nursing time and cost of chest X-ray), whereas the cost of insertion of a PEG tube is $626". Therefore endoscopic gastrostomies may be less frequently indicated (Corry 2008).

It is important to note that in clinical practice, an endoscopic examination performed prior to PEG insertion is indicated in all cases, as the patient might present with lesions of the gastrointestinal tract, which prevents the passage of the endoscopy device and even tubes. In such patients, gastric tumours might also be present, which precludes gastrostomy. Partial gastric resections can also influence patients to elect to use alternative methods of enteral feeding.

Implications for research

Our systematic review of the current evidence, carried out in 2014, indicated that information is available on important outcomes such as intervention failure, mortality, pneumonia and adverse events. The included studies were carried out with participants with varying baseline diseases including neurological baseline diseases and those with malignancies. Future studies should provide adequate baseline information such as baseline disease, gender and age of the participants. The gastrostomy technique was described only in some of the included studies, and future researchers should ideally specify the technique used and the experience of the professionals involved to allow for the analysis of more specific subgroups. Data on the nutritional status of the patients would prove valuable, as would a cost/benefit analysis of the number of feeding tubes used. Quality-of-life measures provide useful information about patient important outcomes and may help explain differences in adherence to treatment.

The high cost of the procedures in question combined with the difficulties associated with the randomisation and long-term follow-up of patients and explain why the majority of studies examine a small number of participants. Nevertheless, we believe that further randomised clinical trials should be conducted with rigorous observation of internal validity. They should also include previously planned and executed follow-up periods.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Baeten 1992

Methods	Single-centre parallel randomised controlled trial Setting: 1 hospital in the Netherlands Sample size: not reported
Participants	Ninety patients with neurologic problems, ear, nose and throat tumours and surgical problems. 56 male, 34 female; mean age 72 (62 to 82) Inclusion criteria: indication for enteral nutrition Exclusion criteria: contra-indication for either method
Interventions	PEG (n = 44) - Freka set (Fresenius) NGT (n = 46) -silicone tube 14 inch inserted by nurse
Outcomes	1. Mortality 2. Treatment failures 3. Adverse events 4. Pneumonia 5. Patient convenience (5-point graded scale from 1 = very convenient to 5 = very inconvenient) 6. Nurse convenience (5-point graded scale from 1 = very convenient to 5 = very inconvenient) 7. Time for enteral nutrition (days) 8. Time for insertion (minutes)
Notes	Follow-up: mean nutrition time 17.9 ± 19.9 days

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported

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Baeten 1992 *(Continued)*

Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors not blinded as explicitly referred by the authors
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no withdrawals reported by the study investigators
Selective reporting (reporting bias)	Low risk	Relevant outcomes analysed
Other bias	High risk	Follow-up was not previously established

Bath 1997

Methods	Single-centre parallel randomised controlled trial Setting: 1 hospital in UK Sample size: not reported
Participants	Nineteen patients (8 male, 11 female); mean age: 77 years (11) Baseline disease: 13 Ischaemic stroke, six haemorrhagic stroke Inclusion criteria: stroke within two weeks of stroke onset Exclusion criteria: oro-gastrointestinal disease concurrent severe illness, coagulopathy, pre-morbid dependency, severe dementia, psychiatric illness
Interventions	PEG: details not available NGT: details not available
Outcomes	Primary outcomes 1. Resumption of safe feeding at 12 weeks 2. Weight loss < 5% at 6 weeks 3. Discharge by 6 weeks Secondary outcomes 1. Impairment 2. Disability 3. Handicap 4. Quality of life 5. Tube failures 6. Chest infection

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Bath 1997 *(Continued)*

	7. Oropharyngeal delay time at 4 weeks
Notes	Follow-up: three months Risks of bias was judged from a systematic review previously published by the author (Bath 2009) and by email contact with the author

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated by minimisation
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not explicitly stated to be blinded by the study investigators
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis
Selective reporting (reporting bias)	Low risk	Relevant outcomes were analysed
Other bias	High risk	Unpublished study

Corry 2008

Methods	Parallel randomised controlled trial Setting: hospitals in Australia; enteral feeding on an outpatient basis Sample size: the study planned to recruit 150 patients over two years, allowing a difference of at least 1.4 kg in mean weight loss to be detected between the two feeding tubes with 80% power using a two-sided test with significance level of 5%
Participants	42 patients; 24 male, 9 female; median age 60 (46 to 80) Inclusion criteria: patients with squamous cell carcinoma of the head and neck planned for curative radiotherapy or chemoradiation who were anticipated to require enteral feeding Exclusion criteria: refusal to be randomised and refusal to receive any tube for nutrition
Interventions	PEG (n = 22); push technique by Tucker (Kimberley-Clark MIC e Wilson-Cook) NGT (n = 20); fine bore tube inserted by nurse and confirmed the correct placement by a chest X-ray and aspiration of stomach contents All patients received enteral feeding at home

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Corry 2008 *(Continued)*

Outcomes	1. Nutritional status (weight, upper-arm circumference, triceps skin fold thickness) 2. Duration of enteral feeding 3. Complication 4. Patient satisfaction (modified QoL questionnaire) 5. Costs All patients were assessed 6 months post-treatment
Notes	Nine patients did not receive the intervention to which they were allocated Outcome four was not considered for analysis because the instrument of evaluation is not formally validated Outcome one was not suitable for analysis because it was not explicitly informed if they were reported as means or medians

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Adaptive biased coin technique
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors not blinded as explicitly referred by the authors
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow of patients was clearly reported
Selective reporting (reporting bias)	Low risk	Relevant outcomes were analysed
Other bias	Low risk	None suspected

Dennis 2005

Methods	Multicentric parallel randomised controlled trial Setting: multicentric study involving many countries, mainly UK Sample size: 1000 patients based on 85% power to detected and absolute risk difference for death or poor outcome of 9%. Type one error: 0.05
Participants	321 patients: 144 male, 177 female; mean age 76 (10); dysphagic stroke patients Inclusion criteria: recent stroke (within 7 days before admission), first-ever or recurrent, if the responsible clinician was uncertain of the best feeding (PEG or NGT)

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Dennis 2005 *(Continued)*

	Exclusion criteria: patients with subarachnoid haemorrhage
Interventions	PEG (n = 162) NGT (n = 159)
Outcomes	1. Mortality or poor outcome 2. Overall survival 3. Utility score (EUROQoL) 4. Quality of life (EUROQoL) 5. Length of hospital stay 6. Adverse events in hospital stay 7. Pneumonia 8. Causes of death 9. Treatment effect 10.Number of tubes inserted 11.Reasons for stopping feeding 12.Vital status 13.Functional ability (Modified Rankin scale) 14.Clinicians' satisfaction about enteral feeding 15.Time in enteral nutrition
Notes	Follow-up: six months Outcomes 3, 10 and 13 were not suitable for analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated, stratified by country, age, gender, and predicted probability of poor outcome (by minimisation)
Allocation concealment (selection bias)	Low risk	The randomisation systems were housed on a secure server with access permitted, via a password. Participating centres were issued with codes in order for them to access the randomisation services (three separate numerical codes).
Blinding of participants and personnel (performance bias) All outcomes	High risk	According to the authors, "the randomising clinician, the clinical team, and the patients were not unaware to treatment allocation— doing so would have been impossible".
Blinding of outcome assessment (detection bias) All outcomes	High risk	According to the authors, "the randomising clinician, the clinical team, and the patients were not unaware to treatment allocation— doing so would have been impossible". However, 6 month of follow-up was carried out for the following variables: patients' vital status, functionalability with themodified Rankin score (MRS), 19 place of residence, method of feeding, and quality of life with the EUROQoL. For these variables, the authors referred that "follow-up was masked to treatment allocation (except where patients or carers inadvertently unmasked an interviewer at follow-up; such occurrences were unusual but their frequency was not systematically recorded)". Because of these divergences the study was considered as of high risk of bias.
Incomplete outcome data (attrition bias)	Low risk	Flow of patients was clearly reported

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Dennis 2005 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Low risk	Relevant outcomes were analysed
Other bias	Low risk	None suspected

Douzinas 2006

Methods	Single-centre parallel randomised controlled trial Setting: 1 hospital (intensive care unit) in Greece Sample size: not reported; pilot study was made
Participants	39 patients; 22 male, 14 female; median age: PEG 53 (20 to 82), NGT 58 (25 to 85). Inclusion criteria: 1. patients on mechanical ventilation with NGT in place for more than 10 days, suffering from persistent or recurrent ventilator-associated pneumonia and reflux rate above 6%. Exclusion criteria: unstable haemodynamic state, administration of morphine, atropine, theophylline, barbiturates, and cisapride, and a past history of GER or hiatal hernia.
Interventions	PEG (n = 19): pull technique NGT (n = 20): fine bore 14
Outcomes	1. Investigate if long-standing presence of NGT for feeding is associated with increased incidence of gastro-oesophageal reflux (GER) 2. Investigate if PEG combined with semi-recumbent position and avoidance of gastric nutrient retention lead to decreased incidence of GER in mechanically-ventilated patients 3. Mortality 4. Pneumonia 5. Adverse events
Notes	Follow-up: 20 days Three patients randomly allocated to receive PEG were excluded because of hiatal hernia (2) and intestinal bloating

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention
Blinding of outcome assessment (detection bias)	Unclear risk	Not explicitly stated by the study investigators

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Douzinas 2006 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow of patients was clearly reported
Selective reporting (reporting bias)	Low risk	Relevant outcomes were analysed
Other bias	Low risk	None suspected

Elbadawy 2014

Methods	Single-centre parallel randomised controlled 3-arm trial Setting: Department of Critical Care Medicine, Egypt Sample size; minimum sample size required was 20 patients for each group to achieve a power of 80 % and alpha of 0.05.
Participants	60 participants, with closed traumatic severe brain injury in need for prolonged MV who continued to have a Glasgow coma score (GCS) of less than 8 after initial stabiliSation of their haemodynamic and oxygenation. Mean age not available. Gender (male/female ratio): NGT + intubation: 8/12 PEG + intubation: 9/11 PEG + tracheostomy: 11/9 Exclusion criteria: History of known respiratory disease, thoracic trauma, multiple traumatic injuries including abdominal or spinal trauma, massive or untreatable loculated ascites, previous abdominal surgery, uncorrected coagulopathy.
Interventions	NGT + intubation (n = 20): nasogastric tube and endotracheal tube was inserted through which MV was applied. PEG + intubation (n = 20): PEG was done within 24 hours of endotracheal intubation using percutaneous pull gastrostomy kit using Bard Ponsky pull through technique PEG + tracheostomy (n = 20): percutaneous dilatational tracheostomy (PDT) and PEG were done within 24 hours of endotracheal intubation. In all study groups, bolus enteral nutrition was given which was initiated within 24 hours after intubation for patients in group (A) and 24 hours after performance of gastrostomy for group (B and C). All the patients were nursed in a semi recumbent position (30-45º). Proton pump inhibitor was given intravenously for stress ulcer prophylaxis (pantoprazole 40mg once daily) for each patient in all the study groups
Outcomes	Primary 1. Intervention failures as defined by any event leading to failure to introduce the tube, recurrent displacement and treatment interruption (feeding interruption, blocking or leakage of the tube, no adherence to treatment).

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Elbadawy 2014 *(Continued)*

	Secondary 1. Adverse events including ventilation assisted pneumonia 2. Duration of ICU stay. 3. Duration of mechanical ventilation 4. Duration of hospital stay. 5. Mortality rate of the patients 6. Vital signs Adverse events including: infection of tracheostomy wound, bleeding from tracheostomy, pneumothorax, tracheo-oesophageal fistula, infection of gastrostomy wound, GIT Fistula, GIT Perforation, buried pumper syndrome (PEG tube erodes and migrates through the gastric wall), paranasal sinusitis.
Notes	No statistically or clinically significant differences between comparison groups at baseline for gender, mechanism of injury, characteristics based on computer tomography, APACHE II score, Glasgow coma score, or other vital sign sand biochemical parameters. We combined data for the PEG + intubation and PEG + tracheostomy groups into a single PEG group for comparison with NGT.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Described as randomised, consecutive computer randomisation (further information from study investigator)
Allocation concealment (selection bias)	High risk	Not concealed (further information from study investigator)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not explicitly stated by the study investigators
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition reported
Selective reporting (reporting bias)	Low risk	Relevant outcomes were analysed, protocol not available for assessment
Other bias	Low risk	None

Hamidon 2006

Methods	Single-centre parallel randomised controlled trial Setting: 1 hospital in Malaysia; patients were discharged in one or two days after the intervention Sample size: not reported
Participants	23 patients; 11 male, 11 female; median age: PEG 65 (48 to 79), NGT 72 (54 to 77)

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Hamidon 2006 *(Continued)*

	Inclusion criteria: patients with acute Ischaemic stroke and persistent dysphagia for seven or more days Exclusion criteria: not related
Interventions	PEG (n = 10): pull technique, Wilson CooK silicone tube 24 FR, inserted by a doctor NGT (n = 12): Steril Cathline polyurethane tube, size 14 inserted by a nurse and checked by aspirating asteric contents
Outcomes	1. Nutritional status assessed by recording anthropometric parameters and nutritional markers 2. Treatment failure
Notes	There was one dropout because it was impossible to contact the patient after four weeks

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random table
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention; although only surgeons were responsible for the PEG and nurses by the NGT
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Information given by the patients by telephone, but blinding of outcome assessment was not explicitly stated by the study investigators
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow of patients was clearly reported (1 dropout due to failure to turn-up)
Selective reporting (reporting bias)	Low risk	Relevant outcomes were analysed
Other bias	Low risk	None suspected

Norton 1996

Methods	Parallel randomised controlled trial Setting: 1 university hospital and one district general hospital in UK Sample size: not reported
Participants	30 patients: 11 male, 19 female; mean age 77 Inclusion criteria: acute cerebrovascular accident with persisting dysphagia for eight or more days, in need for sedation and prolonged mechanical ventilation.

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Norton 1996 *(Continued)*

	Exclusion criteria: patients with a previous history of gastrointestinal disease which would preclude siting a gastrostomy tube or who were unfit for upper gastrointestinal endoscopy and IV sedation
Interventions	PEG (n = 16): pull technique, Wilson Cook tube 24 FR or 12 FR Fresenius NGT (n = 14): fine bore tube Flocare 500, inserted by a senior nurse
Outcomes	1. Mortality 2. Treatment failure 3. Adverse events 4. Pneumonia 5. Amount of feed administered 6. Change in nutritional status 7. Length of hospital stay
Notes	Follow-up: six weeks for main outcomes For continuous data, results were not available for all patients

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not explicitly stated by the study investigators
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow of patients was clearly reported
Selective reporting (reporting bias)	Low risk	Relevant outcomes were analysed
Other bias	Low risk	None suspected

Park 1992

Methods	Parallel randomised controlled trial Setting: three teaching hospitals in Glasgow Sample size: 40 patients was selected to detect a two-sided difference between the success of gastrostomy feeding at 90% and NGT feeding at 40% with a power of 0.9 and significance of 0.05

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Park 1992 *(Continued)*

Participants	40 patients with neurological dysphagia, 22 male, 18 female; mean age: PEG 56, NGT 65 Inclusion criteria: longstanding (4 weeks or more) dysphagia due to neurological disease; stable medical condition with likely survival of at least one month; ability to communicate verbally or in writing; and presence of a normal gastrointestinal tract Exclusion criteria: dementia; mechanical lesions causing obstruction of the oesophagus or stomach; active intra-abdominal inflammation including inflammatory bowel disease or pancreatitis; history of partial gastrectomy, reflux oesophagitis, or intestinal obstruction; and presence of ascites, notable hepatomegaly, severe obesity, coagulopathy, untreated aspiration pneumonia, and major systemic disease including malignancy and respiratory, liver, or renal failure
Interventions	PEG (n = 20) Bard 20Fr silicone tube, technique by Ponsky - Gauderer NGT (n = 20) fine bore Abbott Flexitube, polyurethane, 850 mm length,1.5 mm internal diameter
Outcomes	1. Mortality 2. Duration of feeding (days) 3. Treatment failure 4. Adverse events 5. Pneumonia 6. Nutritional status (weight, albumin, mean difference weight, mid-arm muscle circumference, triceps skin fold thickness) 7. Received/prescribed feed
Notes	Outcome six was not considered for analysis because only one patient completed the follow-up Outcome seven was not considered clinically relevant by itself, unless it causes failure or affects nutritional status (anthropometric parameters) Follow-up: 28 days

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers (Epistat Statistical Package)
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not explicitly stated by the study investigators
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow of patients was clearly reported
Selective reporting (reporting bias)	Low risk	Relevant outcomes were analysed

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Park 1992 *(Continued)*

Other bias	High risk	There was 95% (19/20) of dropouts in the NGT group due to failures in the treatment and death

Sadasivan 2012

Methods	Single-centre parallel randomised controlled trial. Sample size: a minimum of 40 cases in each group, with 80%- to –90% power and 95% confidence (80% on tube dislodgement and 90% on infection). So, 50 cases were included in each group. Setting: India, Department of ENT (Ear, Nose, Throat; Otorhinolaryngology).
Participants	100 participants Gender: PEG: 34/16 (male/female ratio); NGT: 33/17 (male/female ratio) Age (mean): not reported Inclusion criteria: patients with advanced stage 2 or 3 squamous cell carcinoma of the head and neck and who were scheduled either for radical surgery with adjuvant radiotherapy (RT), chemo-RT, or for concurrent chemo and radiation therapy were included in the study. Exclusion criteria: patients with early stage 1 or 2 head and neck cancer were excluded from the study
Interventions	PEG n = 50; NGT n = 50 The majority of NG tubes were inserted by nurses, all PEG tubes were inserted by gastroenterologists.
Outcomes	Follow-up: 1 week; 6 weeks and 6 month Primary outcomes 1. Intervention failures as defined by any event leading to failure to introduce the tube, recurrent displacement and treatment interruption (feeding interruption, blocking or leakage of the tube, no adherence to treatment) (based on Norton 1996). Secondary outcomes 1. Nutritional status, as measured by any validated instrument (such as upper-arm skin fold thickness, mid-arm circumference, body weight, serum albumin level, haemoglobin (Ramel 2008)). 2. Quality of life, EORTC QLQH& N35 at 6 weeks (Dorman 1997)): pain, learning to use, inconvenience, uncomfortable feeds, altered body image, family life, social activities.
Notes	Statistical differences at baseline: radical surgery and adjuvant radiotherapy or chemo and radiation therapy (PEG: 92%; NGT: 72%; P = 0.01); concurrent chemo- and radiation therapy (PEG: 8%; NGT: 28% P = 0.01); baseline weight: PEG: 56.5 *versus* NGT: 61 (P < 0.01)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported by the study investigators
Allocation concealment (selection bias)	Unclear risk	Not reported by the study investigators

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Sadasivan 2012 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported by the study investigators
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study investigators did not perform ITT analysis
Selective reporting (reporting bias)	Low risk	None suspected: relevant variables were analysed. The protocol was not assessed.
Other bias	Unclear risk	None suspected

Yata 2001

Methods	Single-centre parallel randomised controlled trial. Sample size: not reported Setting: 1 hospital in Inagawa Town (Japan)
Participants	82 patients: 22 male, 60 female; mean age: PEG 75.1 (50 to 96), NGT 76.5 (38 to 93) Inclusion criteria: dysphagic patients Exclusion criteria: not reported
Interventions	PEG n = 42 NGT n = 40
Outcomes	1. Nutrition status (albumin, haemoglobin and cholesterol) 2. Adverse events 3. Mean survival time 4. Pneumonia 5. Reflux oesophagitis 6. Anaemia 7. Peristomal leakage 8. Gastric ulcer 9. Treatment failure
Notes	Study available only as a meeting abstract

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported

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Yata 2001 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible for this type of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not explicitly described by the study investigators
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow of patients was not clearly reported
Selective reporting (reporting bias)	Low risk	Relevant outcomes were analysed, Outcome 7. was reported only for NGT group Outcomes 8 and 9 were reported only for the PEG group
Other bias	High risk	Unpublished study

GER: gastroesophogeal reflux
ITT: intention-to-treat
IV: intravenous
NGT: nasogastric tube
PEG: percutaneous endoscopic gastrostomy
QoL: quality of life

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
McClave 2005	Retrospective study
Mekhail 2001	Randomised controlled trial with intervention out of interest for this review (patients randomised to stop the enteral nutrition according to different residual gastric volume)
Schulz 2009	Retrospective study

DATA AND ANALYSES

Comparison 1. PEG versus NGT

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intervention failure	8	408	Risk Ratio (M-H, Random, 95% CI)	0.18 [0.05, 0.59]
1.1 All baseline diseases	8	408	Risk Ratio (M-H, Random, 95% CI)	0.18 [0.05, 0.59]

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Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Non adherence to treatment	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Non adherence at 6 weeks	1	94	Risk Ratio (M-H, Random, 95% CI)	0.07 [0.00, 1.17]
2.2 ITT non adherence at 6 weeks	1	100	Risk Ratio (M-H, Random, 95% CI)	0.02 [0.00, 0.36]
2.3 ITT non adherence at 6 months	1	100	Risk Ratio (M-H, Random, 95% CI)	0.01 [0.00, 0.16]
3 Intervention failure (sub-grouped by gastrostomy technique)	8	408	Risk Ratio (M-H, Random, 95% CI)	0.18 [0.05, 0.59]
3.1 Pull technique	3	90	Risk Ratio (M-H, Random, 95% CI)	0.07 [0.01, 0.35]
3.2 Push technique	1	33	Risk Ratio (M-H, Random, 95% CI)	0.05 [0.00, 0.74]
3.3 Non-reported technique	4	285	Risk Ratio (M-H, Random, 95% CI)	0.43 [0.13, 1.44]
4 Intervention failure (sub-grouped by baseline disease)	8	408	Risk Ratio (M-H, Random, 95% CI)	0.18 [0.05, 0.59]
4.1 Cerebrovascular event or neurological baseline diseases	4	109	Risk Ratio (M-H, Random, 95% CI)	0.08 [0.02, 0.33]
4.2 Mixed baseline diseases	4	299	Risk Ratio (M-H, Random, 95% CI)	0.32 [0.08, 1.32]
5 ITT analyses	5		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.1 ITT intervention failure non-reported gastrostomy technique	4	285	Risk Ratio (M-H, Random, 95% CI)	0.37 [0.09, 1.45]
5.2 ITT intervention failure mixed baseline diseases	4	305	Risk Ratio (M-H, Random, 95% CI)	0.29 [0.06, 1.33]
6 Mortality irrespective of follow-up time	9	644	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.58, 1.28]
7 Mean survival (months)	1	82	Mean Difference (IV, Random, 95% CI)	4.30 [3.28, 5.32]
8 Adverse effects irrespective of follow-up time	6	597	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.51, 1.34]
8.1 Adverse effects	6	597	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.51, 1.34]
9 Adverse effects irrespective of follow-up time	6	603	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.48, 1.35]
9.1 ITT adverse effects irrespective of follow-up time	6	603	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.48, 1.35]

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Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10 Pneumonia irrespective of follow-up time	7	645	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.46, 1.06]
11 Reflux oesophagitis	1	82	Risk Ratio (M-H, Random, 95% CI)	0.45 [0.22, 0.92]
12 Weight kg (endpoint)	1	21	Mean Difference (IV, Random, 95% CI)	3.20 [-5.95, 12.35]
13 Weight (change from baseline)	3	148	Mean Difference (IV, Random, 95% CI)	3.11 [-0.52, 6.75]
14 Mid-arm circumference in cm (endpoint)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
14.1 Mid-arm circumference	2	54	Mean Difference (IV, Random, 95% CI)	1.58 [-0.11, 3.27]
14.2 Sensitivity analysis	1	21	Mean Difference (IV, Random, 95% CI)	2.5 [-0.64, 5.64]
15 Mid-arm circumference in cm (change from baseline)	2	115	Mean Difference (IV, Random, 95% CI)	1.16 [1.01, 1.31]
16 Albumin	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
16.1 Mean serum albumin levels	2	107	Mean Difference (IV, Random, 95% CI)	6.03 [2.31, 9.74]
16.2 Sensitivity analysis	1	25	Mean Difference (IV, Random, 95% CI)	7.80 [5.52, 10.08]
17 Albumin (change from baseline)	1	94	Mean Difference (IV, Random, 95% CI)	0.12 [0.11, 0.14]
18 Haemoglobin g/dL (change from baseline)	1	94	Mean Difference (IV, Random, 95% CI)	0.59 [0.49, 0.69]
19 Score of patients satisfaction	1	43	Mean Difference (IV, Random, 95% CI)	-0.56 [-1.32, 0.20]
20 Score of inconvenience by nurses	1	68	Mean Difference (IV, Random, 95% CI)	-0.58 [-1.18, 0.02]
21 Time on enteral nutrition (days)	2	119	Mean Difference (IV, Random, 95% CI)	14.48 [-2.74, 31.71]
22 Quality of life measures EORTC QLQ-H&N35 number scoring 3 or 4 (worst)	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
22.1 Pain	2	133	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.00, 471.74]
22.2 Learning to use	2	133	Risk Ratio (M-H, Random, 95% CI)	0.18 [0.00, 149.53]

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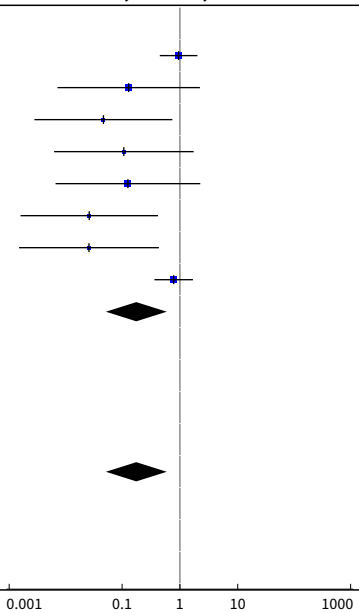
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
22.3 Inconvenient	2	133	Risk Ratio (M-H, Random, 95% CI)	0.03 [0.00, 0.29]
22.4 Uncomfortable	2	133	Risk Ratio (M-H, Random, 95% CI)	0.03 [0.00, 0.29]
22.5 Altered/bad body image	2	133	Risk Ratio (M-H, Random, 95% CI)	0.01 [0.00, 0.18]
22.6 Family life	1	100	Risk Ratio (M-H, Random, 95% CI)	0.01 [0.00, 0.18]
22.7 Social activities	2	133	Risk Ratio (M-H, Random, 95% CI)	0.01 [0.00, 0.18]
23 Functional ability (MRS)	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
23.1 MRS scale from 0-3	1	321	Risk Ratio (M-H, Random, 95% CI)	0.59 [0.34, 1.01]
23.2 MRS scale from 4-5	1	321	Risk Ratio (M-H, Random, 95% CI)	1.20 [0.90, 1.61]
23.3 MRS scale from 4-5 or death	1	321	Risk Ratio (M-H, Random, 95% CI)	1.10 [1.00, 1.20]
24 Length of hospital stay (days)	2	381	Mean Difference (IV, Random, 95% CI)	-12.67 [-40.18, 14.84]

Analysis 1.1. Comparison 1 PEG versus NGT, Outcome 1 Intervention failure.

Study or subgroup	PEG n/N	NGT n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
1.1.1 All baseline diseases					
Baeten 1992	10/44	11/46		19.9%	0.95[0.45,2.01]
Bath 1997	0/10	3/9		9.89%	0.13[0.01,2.22]
Corry 2008	0/15	12/18		10.23%	0.05[0,0.74]
Hamidon 2006	0/10	5/12		10.1%	0.11[0.01,1.73]
Norton 1996	0/16	3/14		9.72%	0.13[0.01,2.25]
Park 1992	0/19	18/19		10.26%	0.03[0,0.42]
Sadasivan 2012	0/50	16/44		10.08%	0.03[0,0.43]
Yata 2001	9/42	11/40		19.83%	0.78[0.36,1.68]
Subtotal (95% CI)	**206**	**202**		**100%**	**0.18[0.05,0.59]**
Total events: 19 (PEG), 79 (NGT)					
Heterogeneity: Tau^2=1.78; Chi^2=26.11, df=7(P=0); I^2=73.19%					
Test for overall effect: Z=2.8(P=0.01)					
Total (95% CI)	**206**	**202**		**100%**	**0.18[0.05,0.59]**
Total events: 19 (PEG), 79 (NGT)					
Heterogeneity: Tau^2=1.78; Chi^2=26.11, df=7(P=0); I^2=73.19%					
Test for overall effect: Z=2.8(P=0.01)					



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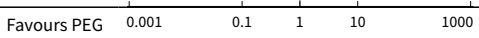
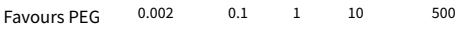
Analysis 1.2. Comparison 1 PEG versus NGT, Outcome 2 Non adherence to treatment.

Study or subgroup	Favours PEG n/N	NGT n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
1.2.1 Non adherence at 6 weeks					
Sadasivan 2012	0/50	6/44		100%	0.07[0,1.17]
Subtotal (95% CI)	**50**	**44**		**100%**	**0.07[0,1.17]**
Total events: 0 (Favours PEG), 6 (NGT)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.85(P=0.06)					
1.2.2 ITT non adherence at 6 weeks					
Sadasivan 2012	0/50	22/50		100%	0.02[0,0.36]
Subtotal (95% CI)	**50**	**50**		**100%**	**0.02[0,0.36]**
Total events: 0 (Favours PEG), 22 (NGT)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.69(P=0.01)					
1.2.3 ITT non adherence at 6 months					
Sadasivan 2012	0/50	50/50		100%	0.01[0,0.16]
Subtotal (95% CI)	**50**	**50**		**100%**	**0.01[0,0.16]**
Total events: 0 (Favours PEG), 50 (NGT)					
Heterogeneity: Not applicable					
Test for overall effect: Z=3.28(P=0)					
Test for subgroup differences: Chi^2=0.91, df=1 (P=0.63), I^2=0%					



Analysis 1.3. Comparison 1 PEG versus NGT, Outcome 3 Intervention failure (subgrouped by gastrostomy technique).

Study or subgroup	Favours PEG n/N	NGT n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
1.3.1 Pull technique					
Hamidon 2006	0/10	5/12		10.1%	0.11[0.01,1.73]
Norton 1996	0/16	3/14		9.72%	0.13[0.01,2.25]
Park 1992	0/19	18/19		10.26%	0.03[0,0.42]
Subtotal (95% CI)	**45**	**45**		**30.08%**	**0.07[0.01,0.35]**
Total events: 0 (Favours PEG), 26 (NGT)					
Heterogeneity: Tau^2=0; Chi^2=0.79, df=2(P=0.67); I^2=0%					
Test for overall effect: Z=3.23(P=0)					
1.3.2 Push technique					
Corry 2008	0/15	12/18		10.23%	0.05[0,0.74]
Subtotal (95% CI)	**15**	**18**		**10.23%**	**0.05[0,0.74]**
Total events: 0 (Favours PEG), 12 (NGT)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.17(P=0.03)					
1.3.3 Non-reported technique					
Baeten 1992	10/44	11/46		19.9%	0.95[0.45,2.01]
Bath 1997	0/10	3/9		9.89%	0.13[0.01,2.22]
Sadasivan 2012	0/50	16/44		10.08%	0.03[0,0.43]



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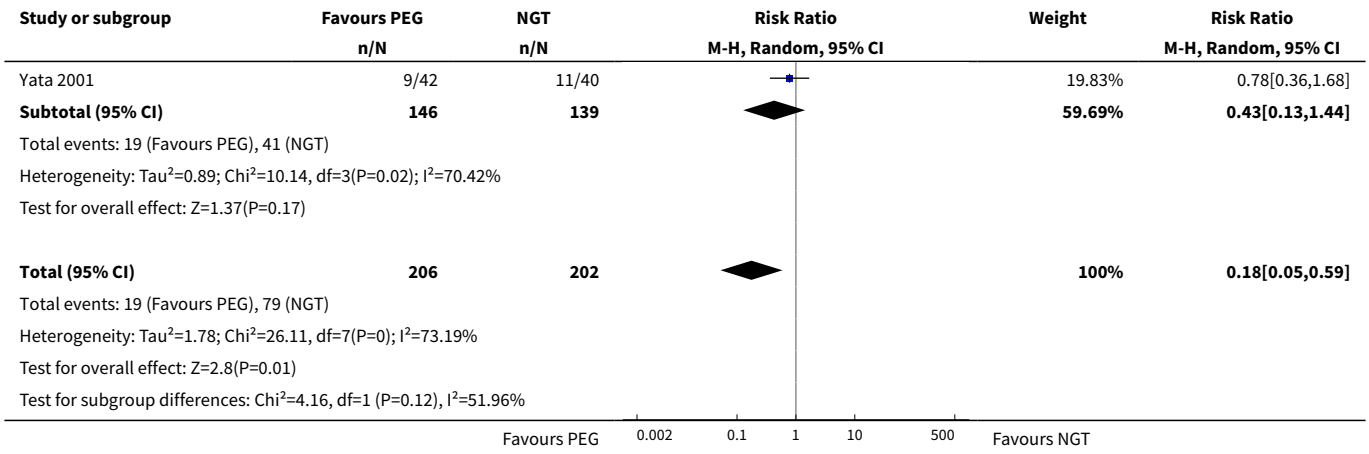
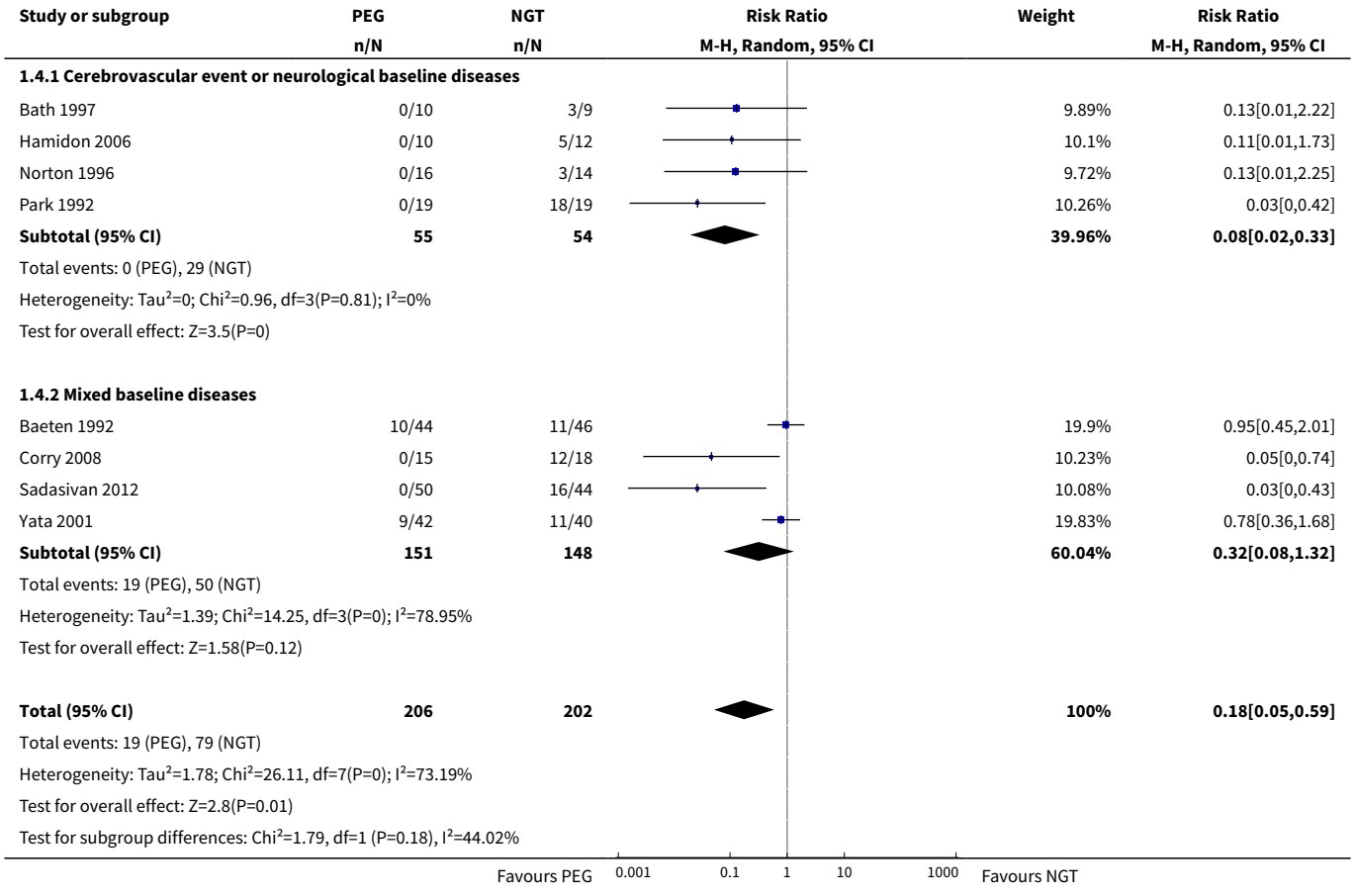


Analysis 1.4. Comparison 1 PEG versus NGT, Outcome 4 Intervention failure (subgrouped by baseline disease).



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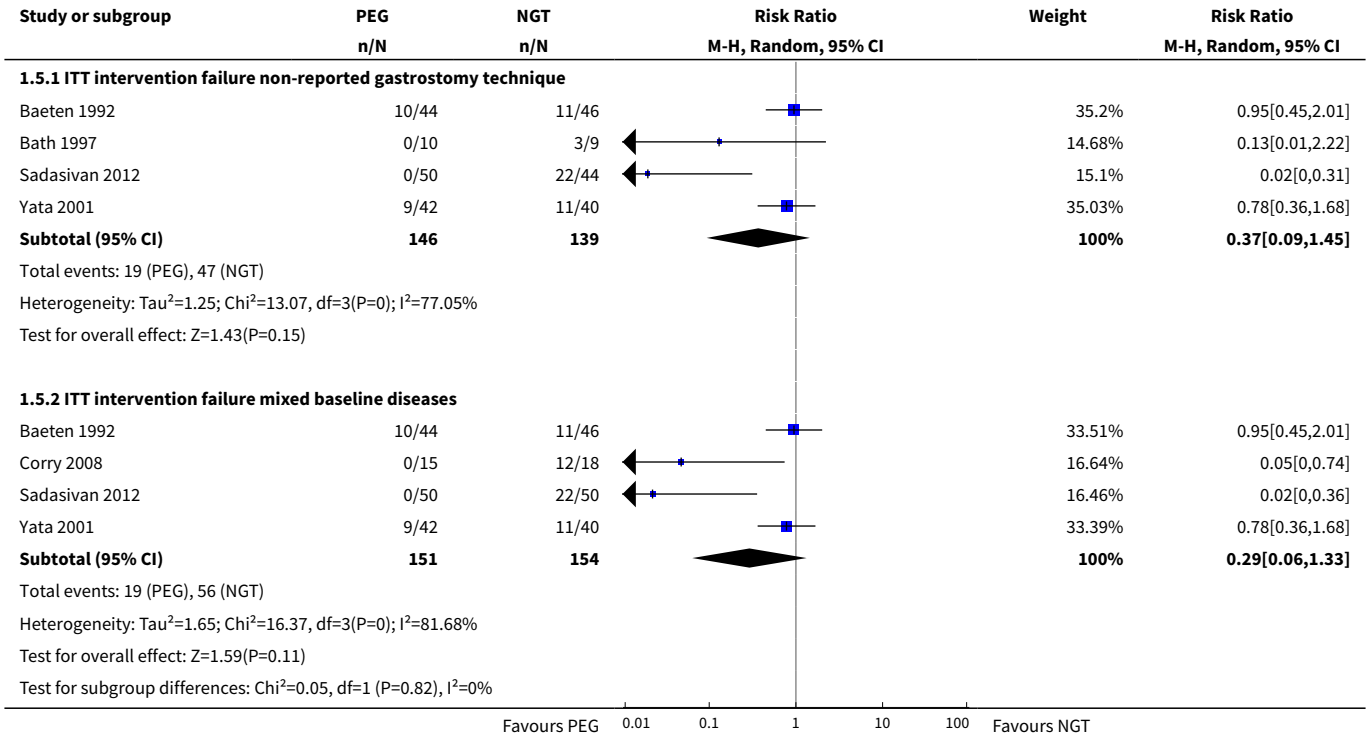
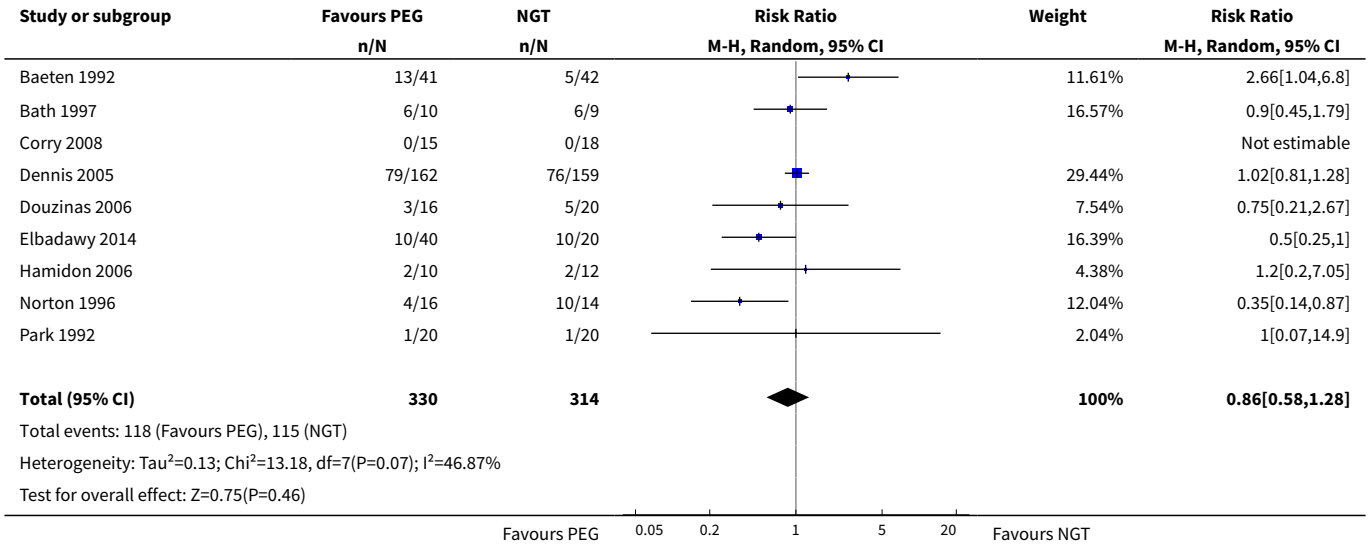
Analysis 1.5. Comparison 1 PEG versus NGT, Outcome 5 ITT analyses.



Analysis 1.6. Comparison 1 PEG versus NGT, Outcome 6 Mortality irrespective of follow-up time.



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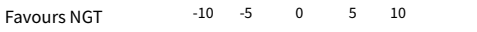
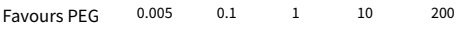
Analysis 1.7. Comparison 1 PEG versus NGT, Outcome 7 Mean survival (months).

Study or subgroup	PEG N	PEG Mean(SD)	NGT N	NGT Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Yata 2001	42	11.4 (1.6)	40	7.1 (2.9)		100%	4.3[3.28,5.32]
Total ***	**42**		**40**			**100%**	**4.3[3.28,5.32]**
Heterogeneity: Not applicable							
Test for overall effect: Z=8.26(P<0.0001)							



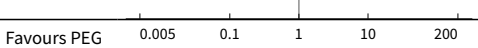
Analysis 1.8. Comparison 1 PEG versus NGT, Outcome 8 Adverse effects irrespective of follow-up time.

Study or subgroup	PEG n/N	NGT n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
1.8.1 Adverse effects					
Baeten 1992	21/41	17/42		19.68%	1.27[0.79,2.03]
Corry 2008	8/15	6/18		14.49%	1.6[0.71,3.59]
Dennis 2005	56/162	59/159		22.25%	0.93[0.69,1.25]
Douzinas 2006	16/16	20/20		23.94%	1[0.9,1.11]
Norton 1996	4/16	6/14		11.43%	0.58[0.21,1.65]
Sadasivan 2012	2/50	28/44		8.2%	0.06[0.02,0.25]
Subtotal (95% CI)	**300**	**297**		**100%**	**0.83[0.51,1.34]**
Total events: 107 (PEG), 136 (NGT)					
Heterogeneity: Tau^2=0.25; Chi^2=37.33, df=5(P<0.0001); I^2=86.61%					
Test for overall effect: Z=0.77(P=0.44)					
Total (95% CI)	**300**	**297**		**100%**	**0.83[0.51,1.34]**
Total events: 107 (PEG), 136 (NGT)					
Heterogeneity: Tau^2=0.25; Chi^2=37.33, df=5(P<0.0001); I^2=86.61%					
Test for overall effect: Z=0.77(P=0.44)					



Analysis 1.9. Comparison 1 PEG versus NGT, Outcome 9 Adverse effects irrespective of follow-up time.

Study or subgroup	PEG n/N	NGT n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
1.9.1 ITT adverse effects irrespective of follow-up time					
Baeten 1992	21/41	17/42		19.51%	1.27[0.79,2.03]
Corry 2008	8/15	6/18		14.9%	1.6[0.71,3.59]
Dennis 2005	56/162	59/159		21.67%	0.93[0.69,1.25]
Douzinas 2006	16/16	20/20		23.05%	1[0.9,1.11]
Norton 1996	4/16	6/14		12.01%	0.58[0.21,1.65]
Sadasivan 2012	2/50	34/50		8.87%	0.06[0.01,0.23]
Subtotal (95% CI)	**300**	**303**		**100%**	**0.81[0.48,1.35]**
Total events: 107 (PEG), 142 (NGT)					
Heterogeneity: Tau^2=0.3; Chi^2=43.56, df=5(P<0.0001); I^2=88.52%					
Test for overall effect: Z=0.81(P=0.42)					



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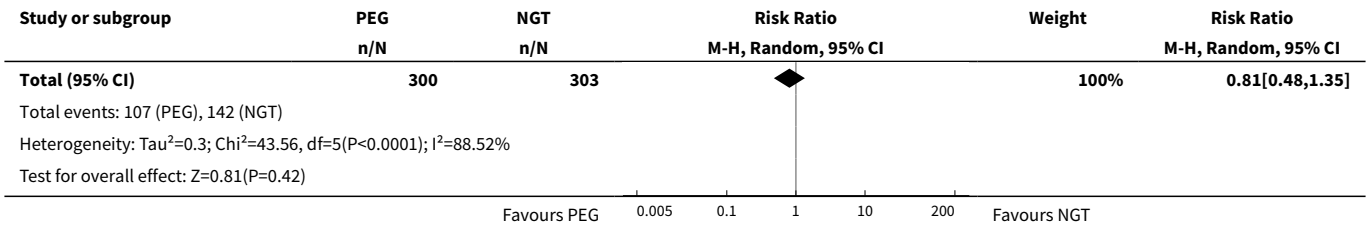
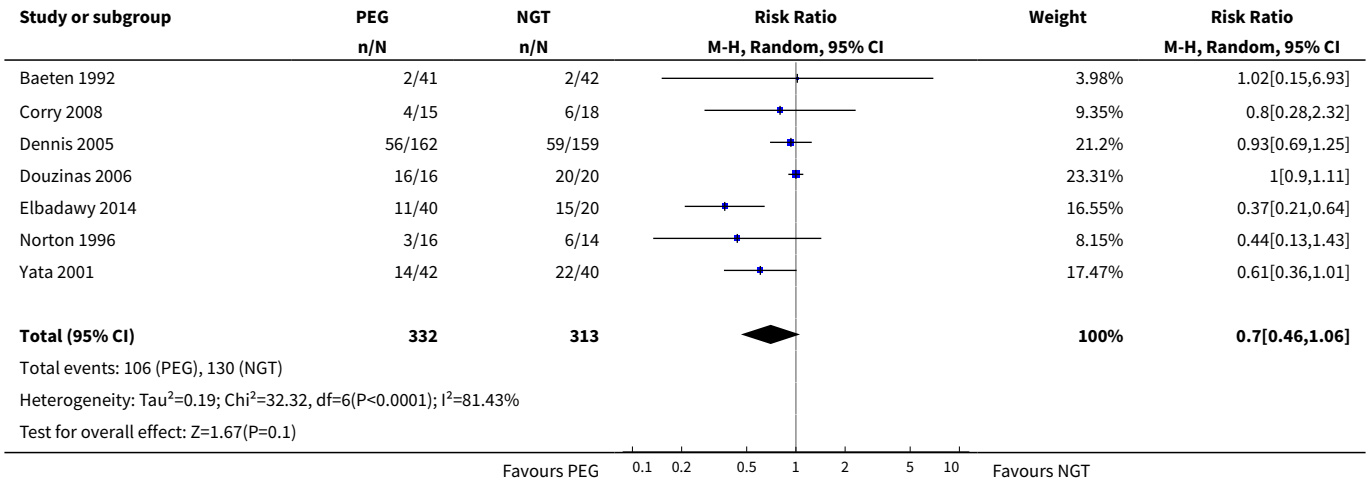
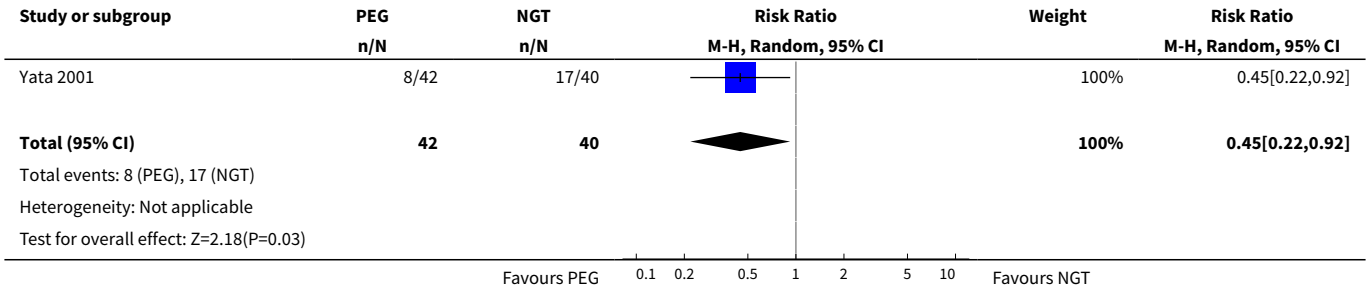


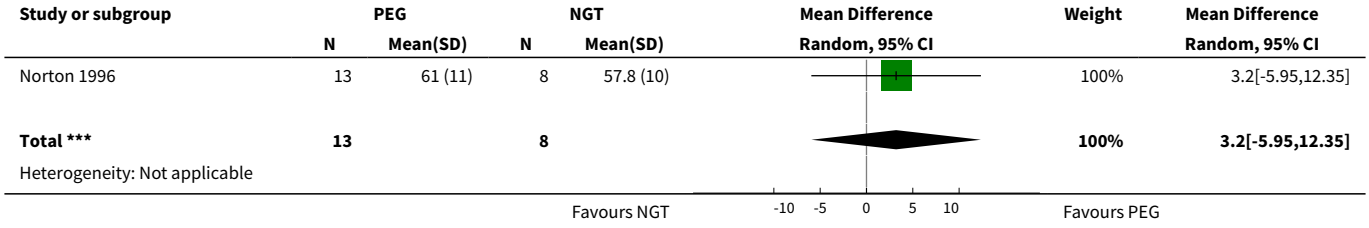
Analysis 1.10. Comparison 1 PEG versus NGT, Outcome 10 Pneumonia irrespective of follow-up time.



Analysis 1.11. Comparison 1 PEG versus NGT, Outcome 11 Reflux oesophagitis.



Analysis 1.12. Comparison 1 PEG versus NGT, Outcome 12 Weight kg (endpoint).



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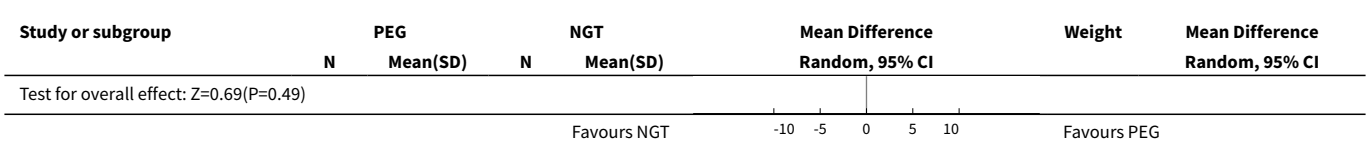
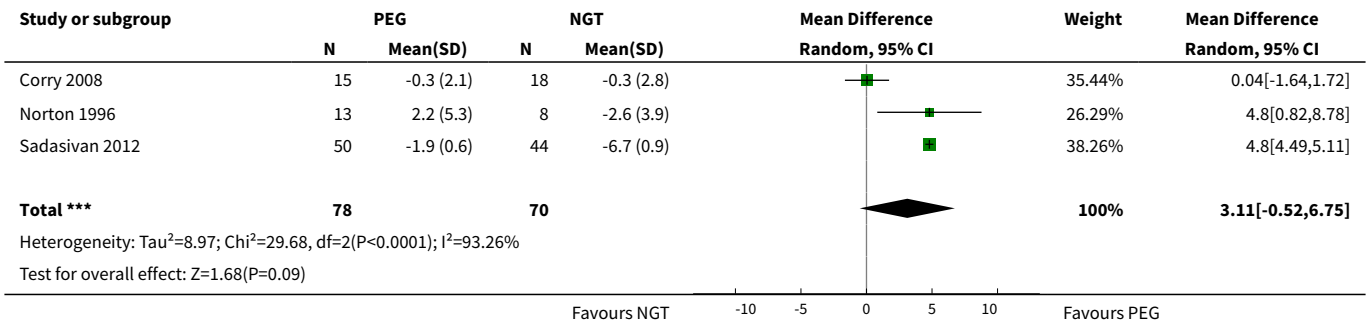
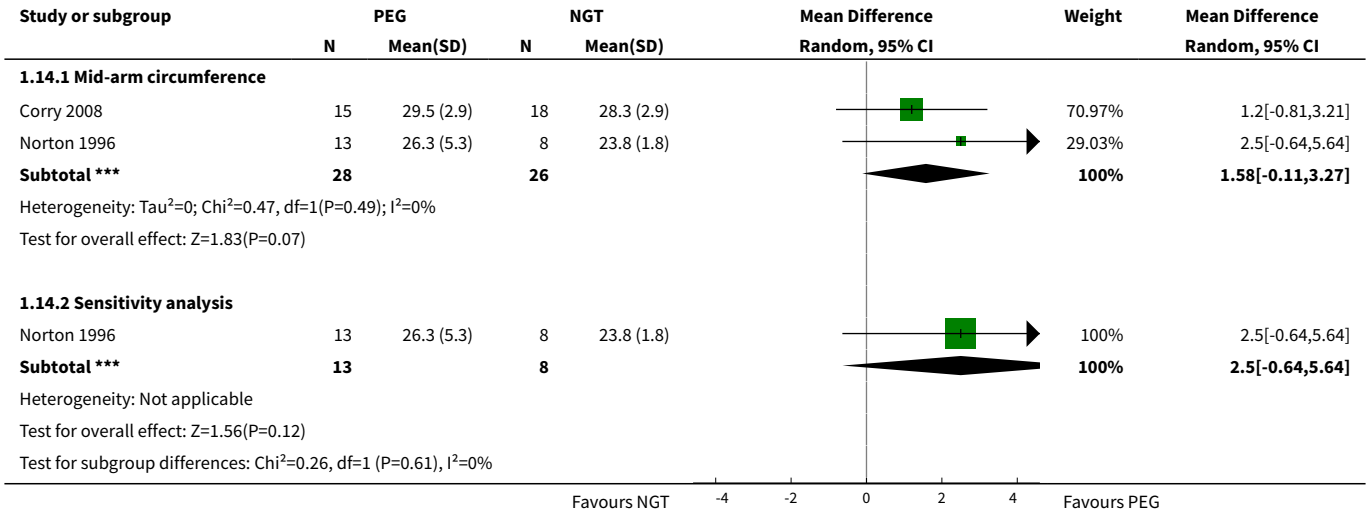


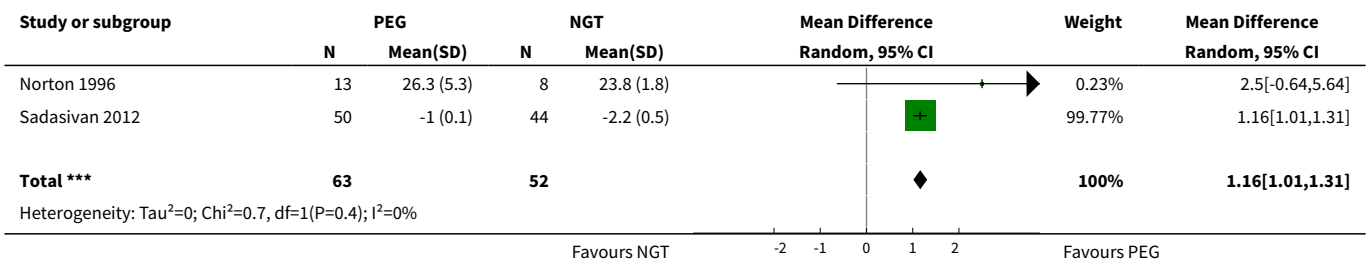
Analysis 1.13. Comparison 1 PEG versus NGT, Outcome 13 Weight (change from baseline).



Analysis 1.14. Comparison 1 PEG versus NGT, Outcome 14 Mid-arm circumference in cm (endpoint).



Analysis 1.15. Comparison 1 PEG versus NGT, Outcome 15 Mid-arm circumference in cm (change from baseline).



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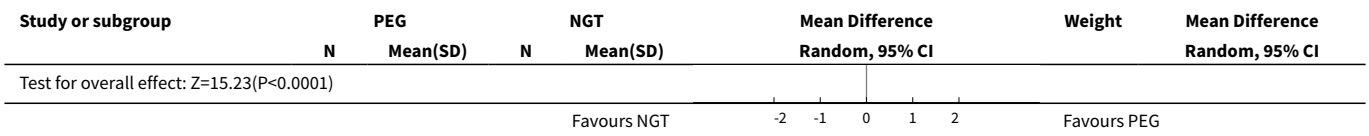
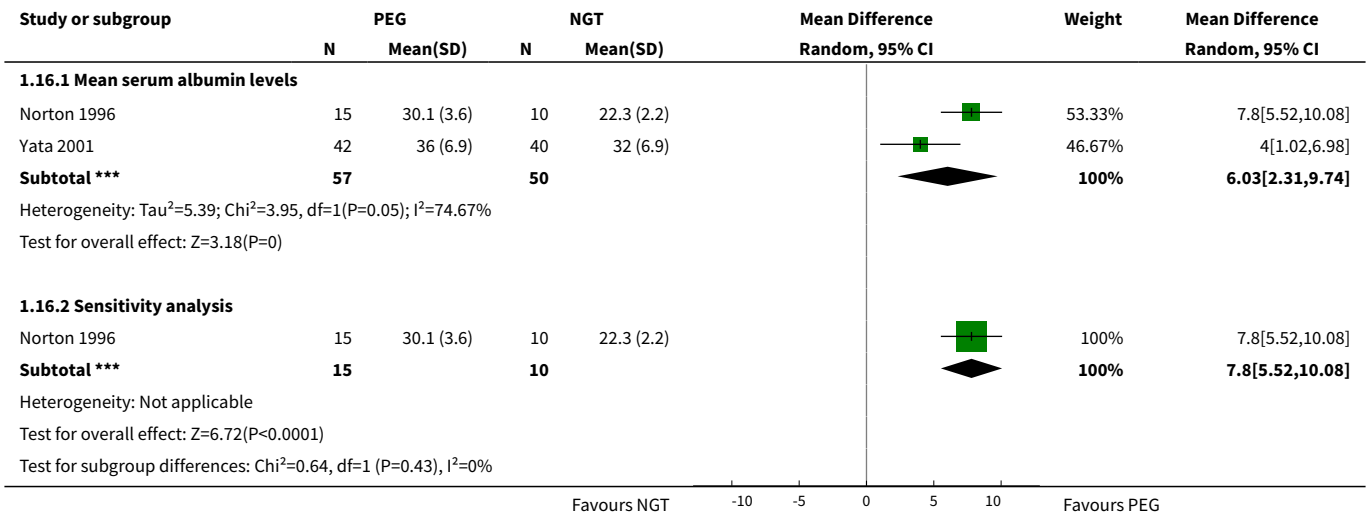
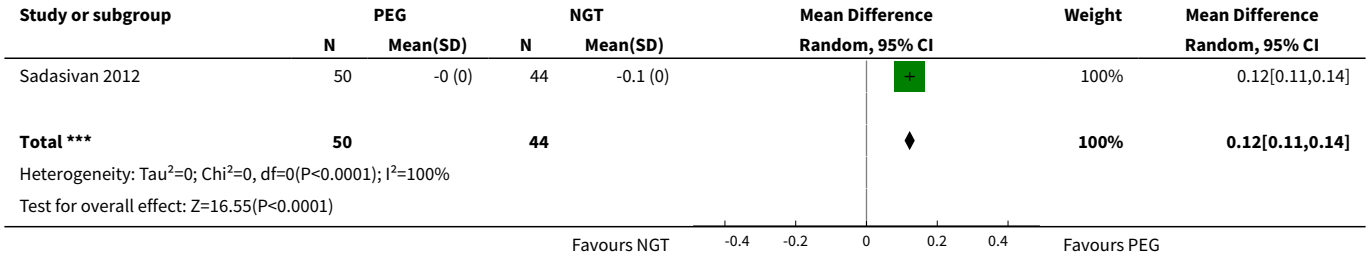


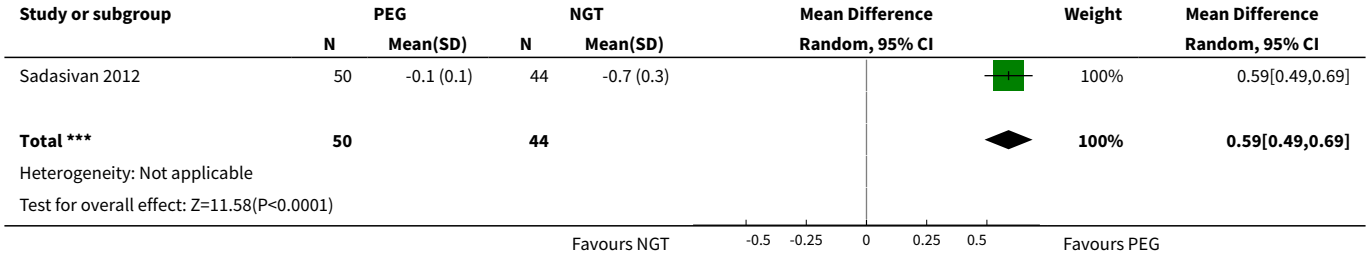
Analysis 1.16. Comparison 1 PEG versus NGT, Outcome 16 Albumin.



Analysis 1.17. Comparison 1 PEG versus NGT, Outcome 17 Albumin (change from baseline).



Analysis 1.18. Comparison 1 PEG versus NGT, Outcome 18 Haemoglobin g/dL (change from baseline).



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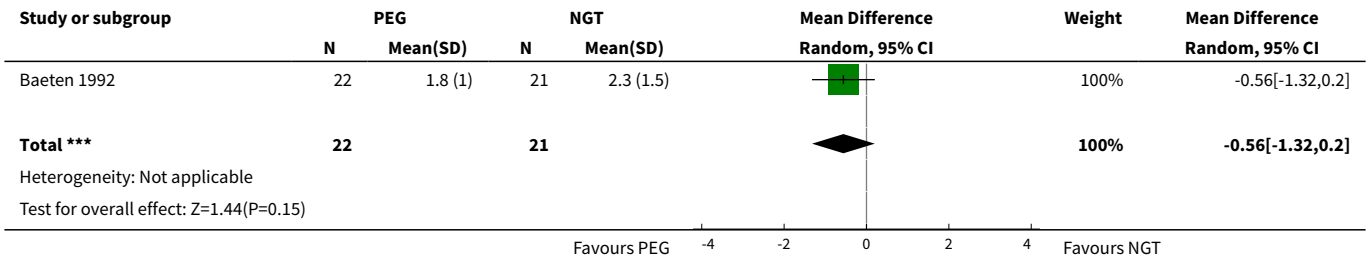
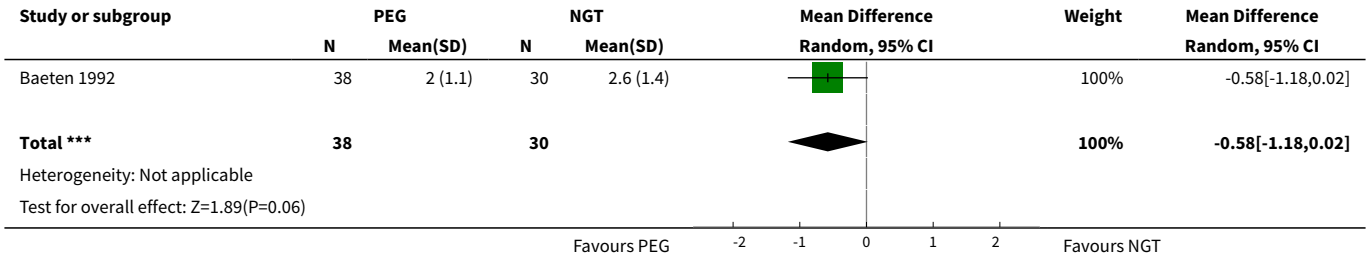
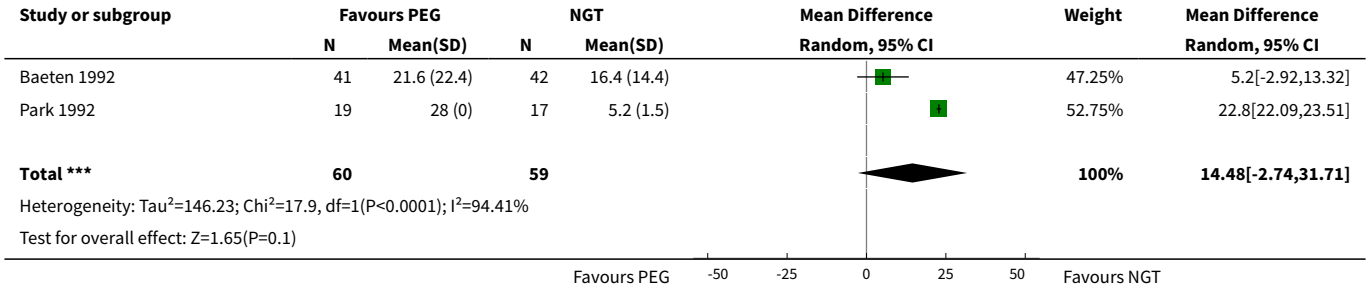
Analysis 1.19. Comparison 1 PEG versus NGT, Outcome 19 Score of patients satisfaction.



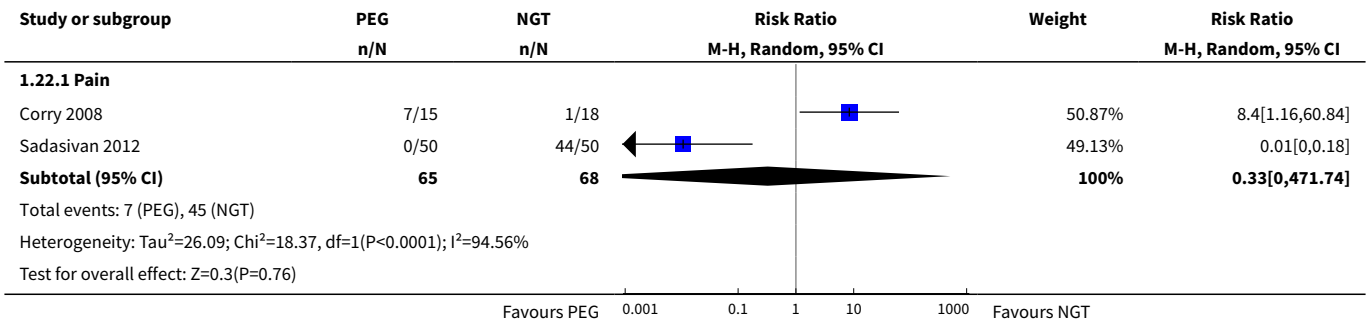
Analysis 1.20. Comparison 1 PEG versus NGT, Outcome 20 Score of inconvenience by nurses.



Analysis 1.21. Comparison 1 PEG versus NGT, Outcome 21 Time on enteral nutrition (days).



Analysis 1.22. Comparison 1 PEG versus NGT, Outcome 22 Quality of life measures EORTC QLQ-H&N35 number scoring 3 or 4 (worst).



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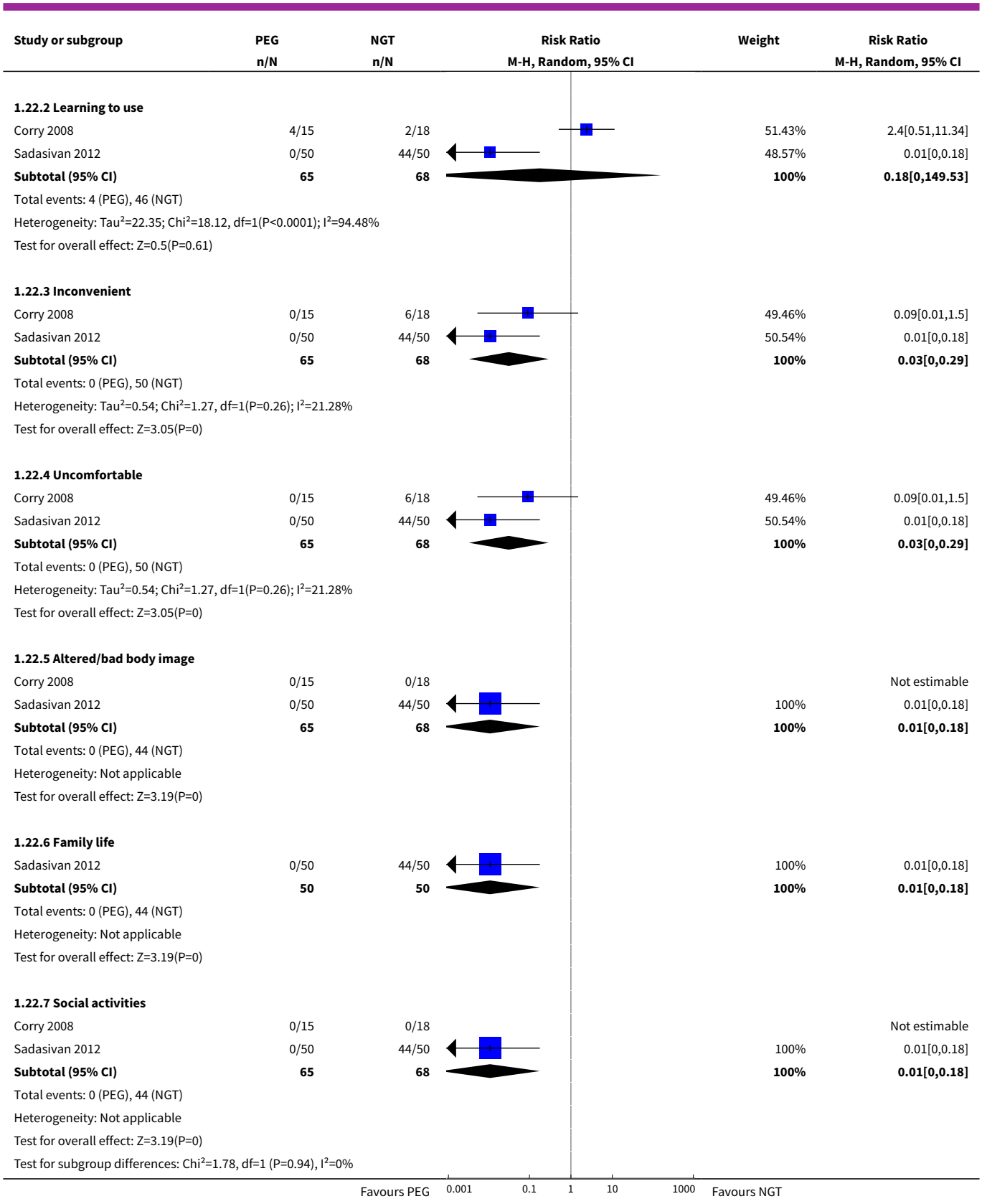

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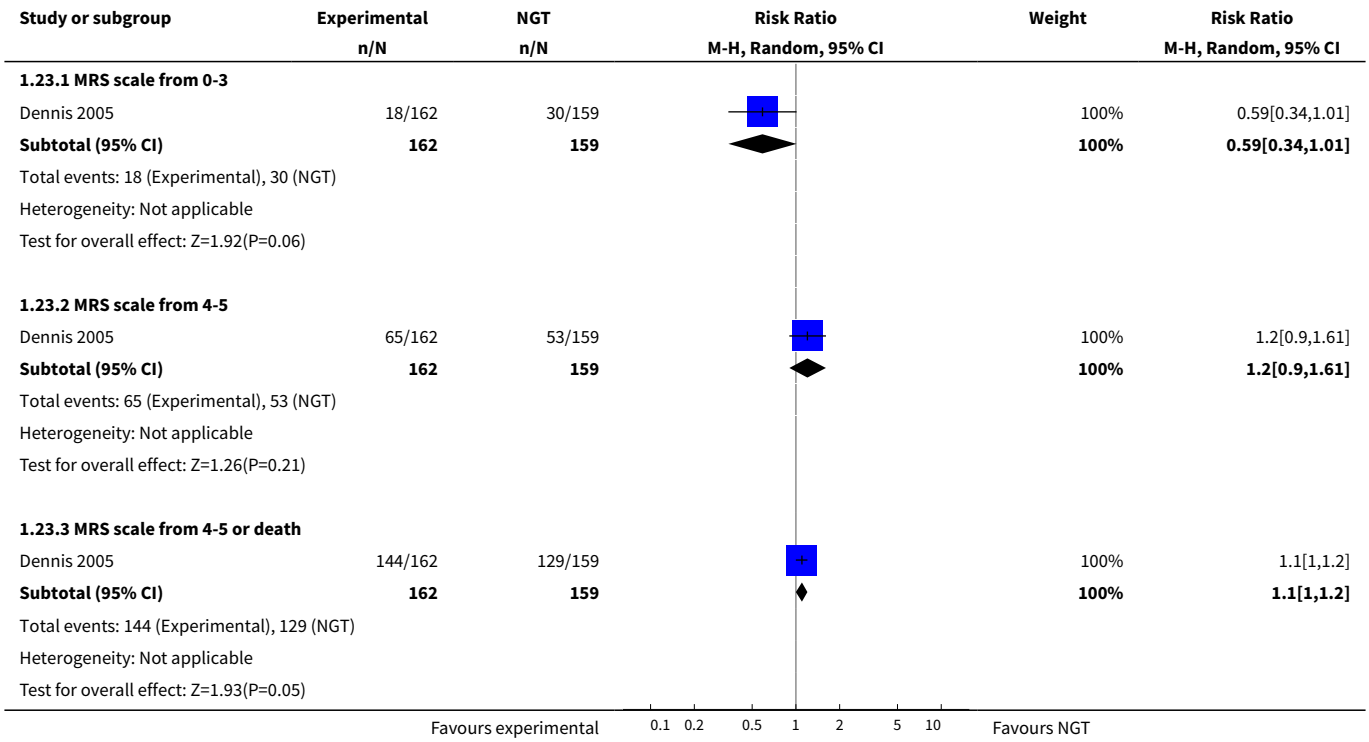
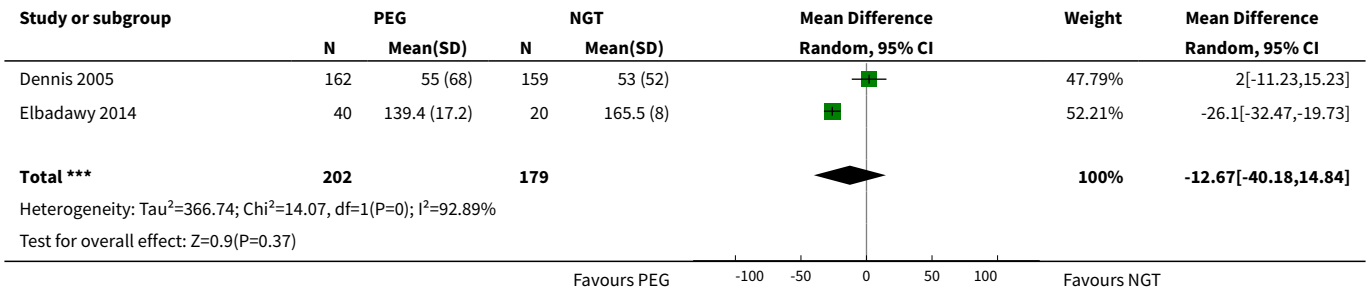
Analysis 1.23. Comparison 1 PEG versus NGT, Outcome 23 Functional ability (MRS).



Analysis 1.24. Comparison 1 PEG versus NGT, Outcome 24 Length of hospital stay (days).



ADDITIONAL TABLES

Table 1. Continuous data unsuitable for inclusion in meta-analyses

Outcome	PEG		NGT		P value	Mean difference (95% CI)
		n		n		
mean albumin (at 3 months) (Yata 2001 abstract)	3.6	42	3.2	40	< 0.01	

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Table 1. Continuous data unsuitable for inclusion in meta-analyses *(Continued)*

mean albumin (at 6 months) (Yata 2001 abstract)	3.9	42	3.1	40	< 0.01	
mean haemoglobin (at 3 months) (Yata 2001 abstract)	11.9	42	11.7	40	no significant difference	
mean haemoglobin (at 6 months) (Yata 2001 abstract)	12.4	42	11.1	40	no significant difference	
median length of stay (days) (Dennis 2005)	34.0 (IQR 17 to 66)	162	37.0 (IQR 17 to 76)	159	not reported	
utility mean difference between comparison groups (endpoint) Derived from EuroQol between comparison groups (endpoint) favouring NGT group, no statistically significant difference (Dennis 2005)					0.12	0.035 (-0.024 to 0.093)
median patient overall quality of life at first week (endpoint) (Corry 2008)	4.0 (R 2.0 to 7.0)	15	4.0 (R 2.0 to 7.0)	18	0.89	
anthropometric parameters (endpoint medians) (Hamidon 2006)		8		10		
median TSFT (mm)	20.1 (R 9.6 to 34)		12.7 (R 9.8 to 32)		0.076	
median BSFT (mm)	0.3 (R 4.8 to 13)		7.4 (R 4.4 to 15)		0.533	
median MAC (cm)	31.4 (R 22 to 36)		27.8 (R 21 to 37)		0.182	
median serum albumin (g/L)	39.5 (R 36 to 44)		36.0 (R 31 to 45)		0.045	
median change in gastro-oesophageal reflux (%, endpoint) on day 7 (Douzinas 2006)	2.7 (R 0 to 10.4)		10.8 (R 6.3 to 36.6)		< 0.01	
anthropometric parameters (endpoint medians) (6 weeks) Corry 2008						
upper-arm circumference (mm) at endpoint	302.5 (R 270 to 370)	15	300.0 (R 240 to 352)	18	0.69	Mean values stated in text (Page 506) to be 295 vs. 283 mm P = 0.25
median TSFT (mm)	13 (R 10 to 20)	15	12 (R 10 to 23)	18	0.65	The NGT patients had significantly

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Table 1. Continuous data unsuitable for inclusion in meta-analyses *(Continued)*

				lower triceps skin fold thickness (9.5 vs 13.5 mm; P = 0.03) than the PEG patients at 6 weeks post-treatment.

BSTF: biceps skin fold thickness
CI: confidence interval
IQR: interquartile range
MAC: mid-arm circumference
R: range
TSFT: triceps skin fold thickness

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Table 2. Additional data of adverse events

Adverse events from Elbadawy 2014	Group I (NGT + intubation)		Group II (PEG + intubation)		Group III (PEG + tracheostomy)		P1	P2	P3
	No.	%	No.	%	No.	%			
Infection of tracheostomy wound	0	0.0	0	0.0	16	80.00	-	-	-
Bleeding from tracheostomy	0	0.0	0	0.0	0	0.00	-	-	-
Pneumothorax	0	0.0	0	0.0	3	15.00	-	-	-
Tracheo-oesophageal fistula	0	0.0	0	0.0	5	25.00	-	-	-
Infection of gastrostomy wound	0	0.0	10	50.00	9	45.00	-	-	0.635
Leakage around gastrostomy tube	0	0.0	11	55.00	10	50	-	-	0.732
Dislodgement of gastrostomy tube	0	0.0	10	50.00	9	45.00	-	-	0.751
GIT Fistula	0	0.0	0	0.00	0	0.00	-	-	-
GIT Perforation	0	0.0	0	0.00	0	0.00	-	-	-
Buried Pumper syndrome	0	0.0	0	0.00	0	0.00	-	-	-
Obstruction	0	0.0	1	5.00	1	0.00	-	-	0.742
Paransal sinusitis	12	60.0	0	0.0	0	0.0	-	-	-

P1 is the comparison between group I and group II
P2 is the comparison between group I and group III
P3 is comparison between group II and group III

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APPENDICES

Appendix 1. CENTRAL search strategy

1. esophag*
2. oesophag*
3. 1 or 2
4. disease*
5. Neoplasms/
6. cancer*
7. Adenocarcinoma/
8. or/4-7
9. 3 and 8
10. Pathologic Constriction
11. stenosis
12. stenoses
13. dysmotilit*
14. stricture
15. or/10-14
16. 3 and 15
17. (Esophageal Motility Disorders) or (Esophageal Diverticulum) or (Esophageal Diverticulosis) or (Esophageal Stenosis) or (Esophageal Achalasia)
18. Deglutition Disorders/
19. dysphagia
20. swallowing disorder*
21. swallowing disturbance*
22. Esophageal Diseases/
23. or/16-22
24. Enteral Nutrition/
25. Gastrointestinal Intubation/
26. tube feeding
27. gastroenteral tube
28. nasoenteral tube
29. nasojejunal feeding tube
30. nasojejunal tube
31. enteral feeding
32. gastric feeding tube*
33. Feeding Apparatus/ or Nutritional Support/ or Enteric Feeding/ or Tube Feeding/
34. force feeding*
35. Nasogastric Tube/
36. post-pyloric feeding
37. postpyloric feeding
38. Enteric Feeding/
39. trans-pyloric feeding
40. nasoduodenal tube
41. Gastrointestinal Endoscopy/ or Digestive System Endoscopy/
42. endoscop*
43. Endoscopic Surgical Procedure*
44. Gastrostom*
45. Gastrostomy/
46. percutaneous endoscopic gastrostomy
47. or/24-46

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48.(9 or 23) and 47

Appendix 2. MEDLINE search strategy

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. clinical trials as topic.sh.
6. randomly.ab.
7. trial.ti.
8. or/1-7
9. (animals not (humans and animals)).sh.
10. 8 not 9
11. esophag$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
12. oesophag$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
13. 11 or 12
14. disease$.ab,ti.
15. exp Neoplasms/
16. cancer$.mp.
17. exp Adenocarcinoma/
18. or/14-17
19. 13 and 18
20. exp Constriction, Pathologic/
21. stenosis.mp.
22. stenoses.mp.
23. dysmotilit$.mp.
24. stricture.mp.
25. or/20-24
26. 13 and 25
27. Esophageal Motility Disorders/ or Diverticulum, Esophageal/ or Diverticulosis, Esophageal/ or Esophageal Stenosis/ or Esophageal Achalasia/
28. exp Deglutition Disorders/
29. dysphagia.ab,ti.
30. swallowing disorder$.ab,ti.
31. swallowing disturbance$.ab,ti.
32. Esophageal Diseases/
33. or/26-32
34. exp Enteral Nutrition/
35. exp Intubation, Gastrointestinal/
36. tube feeding.ab,ti.
37. gastroenteral tube.ab,ti.
38. nasoenteral tube.ab,ti.
39. nasojejunal feeding tube.ab,ti.
40. nasojejunal tube.ab,ti.
41. enteral feeding.ab,ti.
42. gastric feeding tube$.ab,ti.
43. exp Feeding Apparatus/ or exp Nutritional Support/ or exp Enteric Feeding/ or exp Tube Feeding/
44. force feeding$.ab,ti.
45. Nasogastric Tube/
46. post-pyloric feeding.ab,ti.
47. postpyloric feeding.ab,ti.
48. Enteric Feeding/

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49. trans-pyloric feeding.ab,ti.
50. nasoduodenal tube.ab,ti.
51. exp Endoscopy, Gastrointestinal/ or exp Endoscopy, Digestive System/
52. endoscop$.ab,ti.
53. Endoscopic Surgical Procedure$.mp.
54. Gastrostom$.mp.
55. exp Gastrostomy/
56. percutaneous endoscopic gastrostomy.mp.
57. or/34-56
58. (19 or 33) and 57
59. 10 and 58

Appendix 3. EMBASE search strategy

1. (random$ or placebo$).ti,ab.
2. ((single$ or double$ or triple$ or treble$) and (blind$ or mask$)).ti,ab.
3. controlled clinical trial$.ti,ab.
4. RETRACTED ARTICLE/
5. or/1-4
6. (animal$ not human$).sh,hw.
7. 5 not 6
8. esophag$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
9. oesophag$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
10. 8 or 9
11. disease$.ab,ti.
12. exp Neoplasms/
13. cancer$.mp.
14. exp Adenocarcinoma/
15. or/11-14
16. 10 and 15
17. exp Constriction, Pathologic/
18. stenosis.mp.
19. stenoses.mp.
20. dysmotilit$.mp.
21. stricture.mp.
22. or/17-21
23. 10 and 22
24. Esophageal Motility Disorders/ or Diverticulum, Esophageal/ or Diverticulosis, Esophageal/ or Esophageal Stenosis/ or Esophageal Achalasia/
25. exp Deglutition Disorders/
26. dysphagia.ab,ti.
27. swallowing disorder$.ab,ti.
28. swallowing disturbance$.ab,ti.
29. Esophageal Diseases/
30. or/23-29
31. exp Enteral Nutrition/
32. exp Intubation, Gastrointestinal/
33. tube feeding.ab,ti.
34. gastroenteral tube.ab,ti.
35. nasoenteral tube.ab,ti.
36. nasojejunal feeding tube.ab,ti.
37. nasojejunal tube.ab,ti.

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38.enteral feeding.ab,ti.
39.gastric feeding tube$.ab,ti.
40.exp Feeding Apparatus/ or exp Nutritional Support/ or exp Enteric Feeding/ or exp Tube Feeding/
41.force feeding$.ab,ti.
42.Nasogastric Tube/
43.post-pyloric feeding.ab,ti.
44.postpyloric feeding.ab,ti.
45.Enteric Feeding/
46.trans-pyloric feeding.ab,ti.
47.nasoduodenal tube.ab,ti
48.exp Endoscopy, Gastrointestinal/ or exp Endoscopy, Digestive System/
49.endoscop$.ab,ti.
50.Endoscopic Surgical Procedure$.mp.
51.Gastrostom$.mp.
52.exp Gastrostomy/
53.percutaneous endoscopic gastrostomy.mp.
54.or/31-53
55.(16 or 30) and 54
56.7 and 5

Appendix 4. LILACS search strategy

1. pt ensaio controlado aleatorio
2. pt ensaio clinico controlado
3. mh ensaios controlados aleatorios
4. mh distribuicao aleatoria
5. mh método duplo-cego
6. mh método simples-cego
7. pt estudo multicentrico
8. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
9. tw ensaio
10.tw ensayo
11.tw trial
12.#9 OR #10 OR #11
13.tw azar
14.tw acaso
15.tw placebo
16.tw control$
17.tw aleat$
18.tw random$
19.#13 OR #14 OR #15 OR #16 OR #17 OR #18
20.tw duplo
21.tw cego
22.#20 AND #21
23.tw doble
24.tw ciego
25.#23 AND #24
26.tw double
27.tw blind
28.#26 AND #27
29.#19 OR #22 OR #25 OR #28
30.tw clinic$
31.#12 AND #29 AND #30

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32.#8 OR #31

WHAT'S NEW

Date	Event	Description
11 January 2017	Amended	Data in Table 1 from Yata 2001 corrected.

HISTORY

Protocol first published: Issue 4, 2009
Review first published: Issue 11, 2010

Date	Event	Description
20 January 2015	New citation required but conclusions have not changed	Updated with two new studies. Conclusions not changed.
20 January 2015	New search has been performed	New review author (CB), updated with news studies and revised text to comply with current standards for systematic review reporting.
15 December 2011	New citation required but conclusions have not changed	No new studies identified and conclusions unchanged.
15 December 2011	New search has been performed	Literature searches rerun. No new studies identified and conclusions unchanged.
14 June 2011	Amended	Information about number of studies were amended in the Summary of Findings table and risk of bias terminology updated with no change to overall assessments.

CONTRIBUTIONS OF AUTHORS

Conceiving the review: CG, JW and DM
Co-ordinating the review: CG
Screening search results: CG and SL
Organising retrieval of papers: CG and DRW
Screening retrieved papers against inclusion criteria: CG, SL, DM and JW with CB
Apraising quality of papers: CG, SL, RBA and DRW with CB
Extracting data from papers: CG, DRW, SL and RBA with CB
Writing to authors of papers for additional information: CG with CB
Providing additional data about papers: CG with CB
Obtaining and screening data on unpublished studies: CG and DRW with CB
Data management for the review: CG and SL
Entering data into Review Manager (RevMan 5.0): CG and RBA, with CB
Other statistical analysis not using RevMan: RBA
Interpretation of data: CG,DM, SL,RBA and JW with CB
Statistical inferences: CG, RBA and SL
Writing the review: CG with CB

Person responsible for reading and checking review before submission: CG, DM, JW and SL

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DECLARATIONS OF INTEREST

None known.

Dr Cathy Bennett is the proprietor of Systematic Research Ltd and received a consultancy fee from the Cochrane UGPD group to assist the authors with the update of their review in 2014.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- CAPES - Ministry of Education for the postgraduate scholarship, Brazil.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Previous criteria to evaluate the risk of bias are indicated below. The criteria were modified according to the new *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011)

Selection bias

- Was the allocation sequence adequately generated?
- Was allocation adequately concealed?
- Were there systematic differences between the baseline characteristics of the groups that were compared?

Attrition bias

Were there systematic differences between groups in withdrawals from a study?

Detection bias

Were there systematic differences between groups in how outcomes were determined?

We included data in the analyses of scores of patient satisfaction and inconvenience to nursing staff from Baeten 1992, theses are five-point scales and it is unclear if these were validated scales.

In this update, for mean values of outcome data with missing standard deviations, we calculated this from the difference between means (*Cochrane Handbook for Systematic Reviews of Interventions* 7.7.3.3. Higgins 2011). We investigated the effects of making these assumptions by performing sensitivity analyses where appropriate.

Outcomes

We report outcomes as specified in the protocol and clarify the following: pneumonia in this instance occurs as a direct result of aspiration of food. Functional ability is included as an indicator of quality of life. Oesophageal reflux and reflux oesophagitis are adverse effects. We have included survival time as an additional outcome grouped with mortality.

Data synthesis

We planned to pool continuous data using SMD, but where the units of measurement were the same we used MD.

Subgroup analyses

We made a post-hoc decision to investigate the possible reasons for heterogeneity in the intervention failure meta-analysis as we assumed that the source of this statistical heterogeneity would be related to clinical heterogeneity. We categorised the studies by baseline disease, i.e. cerebrovascular event or neurological disorder versus mixed baseline disease (i.e. participants who may have had severe co-morbidities including cancer).

INDEX TERMS

Medical Subject Headings (MeSH)

Deglutition Disorders [*complications]; Enteral Nutrition [*methods] [mortality]; Gastrostomy [adverse effects] [*methods] [mortality]; Intubation, Gastrointestinal [adverse effects] [methods] [mortality]; Malnutrition [etiology] [*therapy]; Pneumonia [etiology]; Randomized Controlled Trials as Topic; Treatment Failure

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MeSH check words

Adult; Humans

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