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[Intervention Review]

Transparent Cap Colonoscopy versus Standard Colonoscopy to Improve Caecal Intubation

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ABSTRACT

Background

Colonoscopy is considered the gold-standard investigation for screening and diagnosis of colorectal cancer. It is also becoming increasingly desirable for assessment, management, diagnosis and follow-up of other colorectal diseases, such as inflammatory bowel diseases and acute diverticulitis. Hence, due to the increasing demand for colonoscopy, devices to advance examination techniques are highly sought-after and the colonoscope with the transparent cap could be one of these.

Objectives

To identify and review all relevant data in order to determine whether colonoscopy with a transparent cap is a more effective diagnostic tool than colonoscopy.

Search methods

We searched the MEDLINE, EMBASE and CINAHL databases, and the Cochrane Central Register of Controlled Trials for all randomised controlled trials (RCTs) comparing the use of colonoscopy with a transparent cap with standard colonoscopy.

Selection criteria

Studies were included if they were randomised controlled trials which compared the use of colonoscopy with a transparent cap with standard colonoscopy.

Data collection and analysis

Data on study methods, participants, interventions used and outcomes measured was extracted from each study. Data was entered into the Cochrane Review Manager software (RevMan 5.0, 2008) and analysed using Cochrane MetaView.

Main results

In the present meta-analysis, we considered 14 randomised controlled trials so far published. The findings of our work indicate that colonoscopy with transparent cap has a faster caecal intubation time when compared with standard colonoscopy. Reviewing studies individually would also seem to favour colonoscopy with transparent cap for polyp detection rate and pain during procedure but due to lack of comparable data meta-analysis was not feasible.

Authors' conclusions

This review suggests that a transparent cap on the end of the colonoscope may give a marginally faster caecal intubation time compared with standard colonoscopy. It also suggests that there is a better polyp detection rate and less pain with the cap. However, the authors feel that further randomised controlled trials in this area would provide more clinically significant information on this adjunct to colonoscopy.

PLAIN LANGUAGE SUMMARY**[Transparent Cap Colonoscopy versus Standard Colonoscopy to Improve Caecal Intubation]**

Fourteen randomised controlled trials were included in the review comparing Colonoscopy with the Transparent Cap with Standard Colonoscopy in the investigation of gastrointestinal tract conditions. The findings of our work suggest that there is improvement in time to caecal intubation (which indicates that the colonoscopy is complete) when using the transparent cap compared with standard colonoscopy, although this is not statistically significant. We conclude that further research is required to assess the clinical significance of this result, especially considering that there have been no adverse events noted.]

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Caecal Intubation Rate for

Caecal Intubation Rate for

Patient or population: patients with

Settings:

Intervention: Caecal Intubation Rate

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of Participants (studies) | Quality of the evidence (GRADE) | Comments |
|---|--|-------------------------------------|----------------------------------|------------------------------|--------------------------------------|----------|
| | Assumed risk | Corresponding risk | | | | |
| | Control | Caecal Intubation Rate | | | | |
| Total Successful Intubation Rate | Study population | | OR 1.36 (0.95 to 1.93) | 5932 (12 studies) | ⊕⊕⊕⊖ moderate ¹ | |
| | 975 per 1000 | 981 per 1000 (974 to 987) | | | | |
| | Medium risk population | | | | | |
| | 982 per 1000 | 987 per 1000 (981 to 991) | | | | |

*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; **OR:** Odds 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 related to blinding of the patients and endoscopists - some trials did attempt to overcome this difficulty, whilst others did not. With regards randomisation, some studies chose an inadequate randomisation method.

BACKGROUND

Description of the condition

Colorectal Cancer is one of the commonest malignancies worldwide and in the UK, colorectal cancer is the 2nd leading cause of death from malignancy (Quinn 2001). Up to 90% of colorectal cancers are thought to arise from adenomas (Benson 2007) via the adenoma-carcinoma sequence (Muto 1975). Small cancers with invasive properties are becoming increasingly recognised and account for up to 22% of early colorectal cancer (Ishii 1992; Kudo 1995). Many of these small cancers and adenomas are flat or depressed (Matsumoto 1995; Kanamori 1995; Stolte 1995; Axelrad 1996; Goto 2006), and can be difficult to detect because of their lack of protrusion (Rex 1997a; Bressler 2004). They can be detected as advanced cancers after a few years.

Evidence suggests that mortality from colorectal cancer can be reduced with early diagnosis. This is achieved by screening for early-stage cancers or pre-cancerous adenomas (Mandel 1993; Thiis-Evensen 1999; Newcomb 2003). Faecal Occult Blood test (FOBT) has been used to detect colorectal cancer at an early stage (Mandel 1993; Hardcastle 1996; Kronborg 1996), and screening colonoscopy has been recommended to detect both early cancers and pre-cancerous adenomas (Imperiale 2000; Leiberman 2000; Rex 2000; Baxter 2009). At present colonoscopy is considered the gold-standard investigation for screening and diagnosis (Benson 2007) of colorectal cancer. It is valuable in removal of potentially pre-cancerous lesions by polypectomy (Wolfe 1975; Winawer 1993b; Conso 2008), which has been shown to be the most effective way of preventing colorectal cancer (Muto 1975; Winawer 1993a; Winawer 1993b; Rex 1997b).

It is not only used in the context of screening for malignant disease, but also assessment, diagnosis and follow-up of inflammatory bowel diseases (Friedman 2001; Hurlstone 2007; Ando 2008), and evaluating the bowel after an attack of acute diverticulitis (Lahat 2008).

Description of the intervention

Colonoscopy is becoming increasingly desirable for management of colorectal disease (Matsushita 1998). Despite colonoscopy being introduced over four decades ago and many progressions in equipment and techniques, there remain limitations with the procedure. International screening programmes and improved therapeutic abilities has resulted in increasing demand for colonoscopy, and therefore the need for development of methods to improve patient acceptance and diagnostic yield. Rates of patient acceptance of the investigation vary, with problems including pre-procedure bowel preparation (Lichenstein 2006) and discomfort during procedure (Svensson 2002). Regarding diagnostic yield, even experienced endoscopists leave a small percentage of the mucosa unexamined (Matsushita 1998; Dafnis 2000). Adenoma detection rates vary greatly between countries, from between 5% and 37.5% in diagnostic and screening procedures (Leiberman 2000; Rainis 2007). Using current technology, miss rates for polyps less than 1cm in diameter are reported to be up to 26% (Rex 1997a; Hixson 1990; van Rijn 2006) especially for de novo cancers in the right colon due to their inconspicuous protrusion (Rex 1997a; Bressler 2004). In spite of scrupulous inspection of colonic mucosa, due to the semilunar folds, small lesions can be located behind these in

blind spots, where they are easily overlooked (Matsushita 1998). Techniques that aim to improve polyp detection rates include high resolution colonoscopy (Le Rhun 2006), wide angle colonoscopy (Deenadayalu 2004), chromo-endoscopy (Hurlstone 2004; Lapalus 2004), narrowband imaging colonoscopy (Chiu 2007) and FUJI intelligent chromo-endoscopy (Rex 2006), but unfortunately mostly these techniques increase the length of the procedure, decreasing patient acceptance. Techniques that aim to improve patient acceptance by decreasing pain and the time taken to caecal intubation, include using a variable stiffness (Yoshikawa 2004), or narrower scopes (Bat 1991; Marshall 1996; Han 2000), carbon dioxide insufflation (Church 2003) and using scope guides (Suzuki 2004), but these have little effect on polyp detection. Transparent colonoscopy caps aim to improve both these aspects (Tada 1997; Matsushita 1998; Kondon 2007; Horiuchi 2008; Shida 2008).

A transparent cap attached to the tip of the colonoscope has been reported to shorten time to caecal intubation (Tada 1997; Matsushita 1998; Dafnis 2000; Kondon 2007; Horiuchi 2008; Shida 2008; Choi 2009; De Wijkerslooth 2011; Lee 2009; Rastogi 2012), reduce pain (Shida 2008), improve polyp detection and removal (Tada 1997; Matsushita 1998; Dafnis 2000; Kondon 2007; Horiuchi 2008; Shida 2008).

How the intervention might work

One of the reported main advantages of colonoscopy with the cap is the continuous good visual fields and easy recognition of the luminal continuity at bends (Matsushita 1997; Matsushita 2007). It is stated that the colonic lumen is always clearly seen since the mucosa is never in direct contact with the lens and this helps to reduce loop formation (Lee 2006). Also, it is described that with use of pressure from the cap, depressing the semilunar folds, blind areas behind the folds can be well observed (Tada 1997; Kobayashi 1998; Matsushita 1998; Cotton 1990; Dafnis 2000; Lee 2006), assisting in finding lesions hidden behind colonic folds (Tada 1997), and also increasing the number of flat adenomas/de novo carcinomas found (Kobayashi 1998). The cap is reputed to reduce the percentage of unexamined colonic mucosal surface, in spite of a colonoscopy being deemed "complete" (Cotton 1990).

Some studies reported a significantly higher detection rate of colorectal polyps when using a transparent hood than when using no hood (Tada 1997; Matsushita 1998; Kondon 2007).

The colonoscope with hood is well tolerated by patients (Tada 1997; Dafnis 2000). The transparent hood is commonly available, reusable, and inexpensive as it fits standard colonoscopies (Lee 2006).

Hood-assisted colonoscopy has also been used as a rescue method to improve the success rate of colonoscopy when failure is encountered (Lee 2006).

Why it is important to do this review

Due to the increasing demand for colonoscopy, devices to advance examination techniques are highly sought-after. The colonoscope with the transparent cap could be one of these.

OBJECTIVES

To identify and review all relevant data in order to determine whether colonoscopy with a transparent hood is a more effective diagnostic tool than colonoscopy without as measured by:

- successful caecal intubation rate
- caecal intubation time
- polyp detection rate

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) comparing the use of colonoscopy with a transparent hood against standard colonoscopy.

Types of participants

Both adults and children investigated using colonoscopy as a diagnostic tool were included.

Types of interventions

Colonoscopy with a transparent hood as compared to standard colonoscopy.

Types of outcome measures

Primary outcomes

- successful caecal intubation rate
- caecal intubation time
- polyp detection rate

Secondary outcomes

- pain during procedure
- analgesia/sedation used
- adverse events

Search methods for identification of studies

We searched the MEDLINE, EMBASE and CINAHL databases, and the Cochrane Central Register of Controlled Trials. There was no limitation based on language or date of publication. Bibliographies of all retrieved and relevant publications identified by these strategies were searched for further studies.

Electronic searches

We searched the MEDLINE, EMBASE and CINAHL databases, and the Cochrane Central Register of Controlled Trials as above.

For comprehensive search strategies, see [Appendix 1](#) (Medline); [Appendix 2](#) (EMBASE).

Searching other resources

In addition, we searched additional trials through scanning of reference lists in relevant papers and conference proceedings and through correspondence with experts and pharmaceutical companies. The customized search strategy for systematic reviews was used to identify relevant articles.

Data collection and analysis

Data from the selected studies was extracted using a paper data extraction form (see attached table). Data was entered into the Cochrane Review Manager software (RevMan 5) and analysed using Cochrane MetaView.

Selection of studies

The reviewers (JM, KT, SB, HLR) independently assessed titles and abstracts of the references identified by the search strategy according to the selection criteria. Full text copies of those articles and studies that appeared to satisfy these criteria were obtained.

When it was unclear from the title or abstract whether the paper fulfilled the criteria, or when there was disparity between reviewers, a full text copy was obtained. Obtained studies were individually assessed by two of the three reviewers (JM, KT, SB, HLR) and then agreement obtained as to whether include or exclude a study. Any dispute was resolved by requesting a third independent review (JM, KT, SB, HLR, RLN).

Studies were assessed for quality, with respect to methods of randomisation, allocation concealment, blinding of outcomes and drop-out rate.

Data extraction and management

Reviewers used a piloted data extraction sheet to summarise details of the studies. Data extraction was undertaken independently by the two reviewers and compared, with any dispute being resolved by the third independent reviewer.

The following data was extracted from each study:

- Study methods
 - * Definition and diagnostic criteria
- Participants
 - * Number, source, age, gender, inclusion and exclusion criteria, duration of symptoms, previous investigations and treatments, underlying conditions
- Interventions
 - * Type of colonoscopy
- Outcomes
 - * Completion rate
 - * Time to caecal intubation
 - * Polyp detection rate
 - * Associated complications (e.g. abdominal pain - e.g. use of pain medication, sedation)

Unit of analysis issues - Completion rate and polyp detection rate are dichotomous variables. Time to caecal intubation and associated complications were continuous variables.

Assessment of risk of bias in included studies

See risk of bias tables in [Characteristics of included studies](#) section.

The quality of the included trials was evaluated independently by the reviewers. It was assessed following the four types of bias: Selection bias; Performance bias; Attrition bias and Detection bias. Criteria for quality assessment included:

(1) Selection bias:

Allocation concealment:

A. Adequate: Use of randomisation method that did not allow investigator and participant to know or influence the allocation of treatment before eligible participants entered the studies.

B. Unclear: Randomization stated but not information on method used is available.

C. Inadequate: Use of alternate medical record numbers or unsealed envelopes as randomisation method, and/or there is information in the study indicating that investigators or participants could have influenced the allocation of treatment.

(2) Performance bias:

Blinding of care providers: Due to the nature of the intervention, the studies in this review cannot be blinded to the endoscopists.

Blinding of participants: Yes/No/Unclear

Care providers and participants are considered not blinded if the intervention group can be identified in >20% of participants because of the side effects of treatment.

(3) Detection bias: Blinding of outcome assessors: again, due to the nature of the intervention, the studies in this review cannot be blinded to the endoscopists.

(4) Attrition bias:

Intention-to-treat analysis:

A: Yes: All participants are analysed in the treatment group to which they were allocated, regardless of whether or not they received the allocated intervention.

B: No: Some participants (<5%, 5-10%, 10-20 %, > 20%) are not analysed in the treatment group to which they were randomised because they did not receive study intervention; they withdraw from the study, or because of protocol violation.

C: Unclear: Inability to determine if patients were analysed according to the intention-to-treat principle after contact with the authors.

Clarification from the author was sought if the published data provided inadequate information for the review. Discrepancies were resolved by consensus. From the quality assessment of the trials the potential risk of bias were summarized into three categories as described in the Cochrane handbook:

Risk of bias interpretation relationships to individual criteria

A: Low risk of bias: plausible bias unlikely. All of the criteria met therefore unlikely to seriously alter the results.

B: Moderate risk of bias: plausible bias. One or more criteria partly met, or one not met, which therefore raise some doubt about the results.

C: High risk of bias: plausible bias. Two or more criteria not met. Seriously weakens confidence in the results.

Measures of treatment effect

The outcomes with continuous variables were assessed using weighted mean difference with 95% confidence intervals.

The outcomes with dichotomous variables were assessed by calculating the odds ratios (OR) with 95% confidence intervals. OR greater than 1.0 favoured the intervention group, indicating that colonoscopy with the cap is superior to colonoscopy without the cap in the measured outcomes.

Unit of analysis issues

The primary outcome of caecal intubation time is a continuous outcome (measured as the time taken to achieve caecal intubation in minutes). The primary outcome of polyp detection rate is also a continuous outcome (measured as the number of polyps detected per patient or patient sample). The analysis of continuous data used the weighted mean difference + 95% confidence intervals. The primary outcome of successful caecal intubation rate is dichotomous (yes or no). The secondary outcomes of pain during the procedure used the amount of sedation/analgesia required and was continuous and analysed as for the continuous outcomes above.

Dealing with missing data

The authors of included published studies were contacted to supply missing data for two studies, we received a reply from Yutaka Yamanji, co-author of [Kondo 2007](#) but received no reply from [Shida 2008](#). Additionally, there were several conference abstracts ([Hyun 2010](#); [Hyun 2010a](#); [Jeong 2010](#); [Jung 2011](#); [Lee 2011](#); [Moon 2008](#); [Park SH 2011](#); [Sato 2009](#); [Takano 2008](#)) and an attempt was made to contact all authors to obtain data for inclusion in this review, however no responses were received. Missing data and drop-outs/attrition was assessed for each included study, and the extent to which the result/conclusion of the review could be altered by the missing data was assessed and discussed.

Assessment of heterogeneity

As trials are conducted by different groups of investigators at different periods of time, they may be heterogeneous. We explored heterogeneity between trial results using multi-step process including: (1) Forest plots were examined and the presence or absence of overlap in the confidence intervals noted. Lack of overlap of confidence intervals indicates heterogeneity; (2) We looked at the I^2 statistic to describe the proportion of the variability in the results that was due to heterogeneity ([Higgins 2008](#)); (3) Chi-Squared test for heterogeneity was performed and data considered heterogenous if $P < 0.1$; (4) If significant heterogeneity was detected, possible explanations were sought.

Assessment of reporting biases

All studies reported appropriate outcomes and only two studies ([Dai 2010](#); [Tada 1997](#)) didn't report on caecal intubation rate, however both reported on caecal intubation time.

Data synthesis

The analyses was performed in RevMan version 5.1. Results were shown using the approach recommended in the Cochrane Handbook ([Higgins 2008](#)). Dichotomous data was presented as odds ratios (OR) with 95% confidence intervals. All randomised patients included were analysed using the intention-to-treat principle. We assessed heterogeneity between the trials using I^2 . Where the interventions were the same or similar enough, we synthesized results in meta-analysis if there was not important clinical heterogeneity. In the case of the absence of heterogeneity,

data was analysed using fixed-effects model. Random-effects models was used where there was unexplained heterogeneity.

Subgroup analysis and investigation of heterogeneity

We did not perform any subgroup analyses.

RESULTS

Description of studies

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

Results of the search

We assessed 1200 references from the primary search and additional search methods described, until 20/12/2011. From their abstracts, 29 of these were felt to potentially meet our inclusion criteria and the full papers were obtained. Meta-analyses that were identified were also obtained and a further two randomised controlled trials were identified from hand-searching the references. After reviewing each of the full papers, we excluded 17 of these trials (see [Characteristics of excluded studies](#)), which included conference abstracts that were lacking substantial data to warrant inclusion. A total of fourteen trials were included in the review. The fourteen trials enrolled a total of 6713 participants (range 24 - 1339), of which all were adults. Thirteen of the fourteen trials were reported in English, with one study being published in Korean and translated with the help of Kim Je Young, Jo Youngjin and Professor Roman Lach (Department of German Language and Literature, Keimyung University, Daegu, Korea). The trials included in the review were published between 1997 and 2012.

Location:

Six trials were conducted in Japan, two in Korea, two in China, two in the USA, one in Netherlands and one in Australia. The trials were all conducted in a hospital setting.

Funding:

Two trials stated funding, [De Wijckerslooth 2011](#) who received funding from the Netherlands Organisation for Health Research and Development and the Center for Translational Molecular Medicine; and [Rastogi 2012](#) who received funding via an Endoscopic Research Center for Development Award (A. Rastogi) from the American Society for Gastrointestinal Endoscopy. The remaining trials did not state their source of funding.

Inclusion Criteria:

Trials used different inclusion criteria for the participants. Twelve studies included patients referred for colonoscopy. One study ([Matsushita 1998](#)) recruited patients that had colorectal polyps detected on barium enema and one ([Park 2011](#)) recruited those who were scheduled to undergo Endoscopic Mucosal Resection (EMR).

Participant Age:

The mean participant age ranged from 46.1 to 64.6 years. Ages of included participants ranged from 18 to 88 years.

Included studies

From 1997 to 2011, fourteen randomised controlled trials were conducted that examined the use of colonoscopy with a transparent cap compared with colonoscopy without the cap and allowed data analysis.

Excluded studies

Five trials were excluded as they were not randomised controlled trials ([Dafnis 2000](#); [Inoue 2008](#); [Mamula 2011](#); [Nakamura 2011](#); [Yeung 2011](#)), one of these ([Dafnis 2000](#)) was a pilot study. Twelve trials were excluded as they were conference abstracts and did not contain enough data for analysis and quality assessment ([Horiuchi 2010](#); [Hyun 2010](#); [Hyun 2010a](#); [Jeong 2010](#); [Jung 2011](#); [Lee 2011](#); [Moon 2008](#); [Park SH 2011](#); [Sato 2009](#); [Takano 2008](#); [Tee 2009](#); [Thomas 2011](#)).

Risk of bias in included studies

See [Figure 1](#) and [Figure 2](#)

Figure 1. Methodological quality graph: review authors' judgments about each methodological quality item presented as percentages across all included studies.

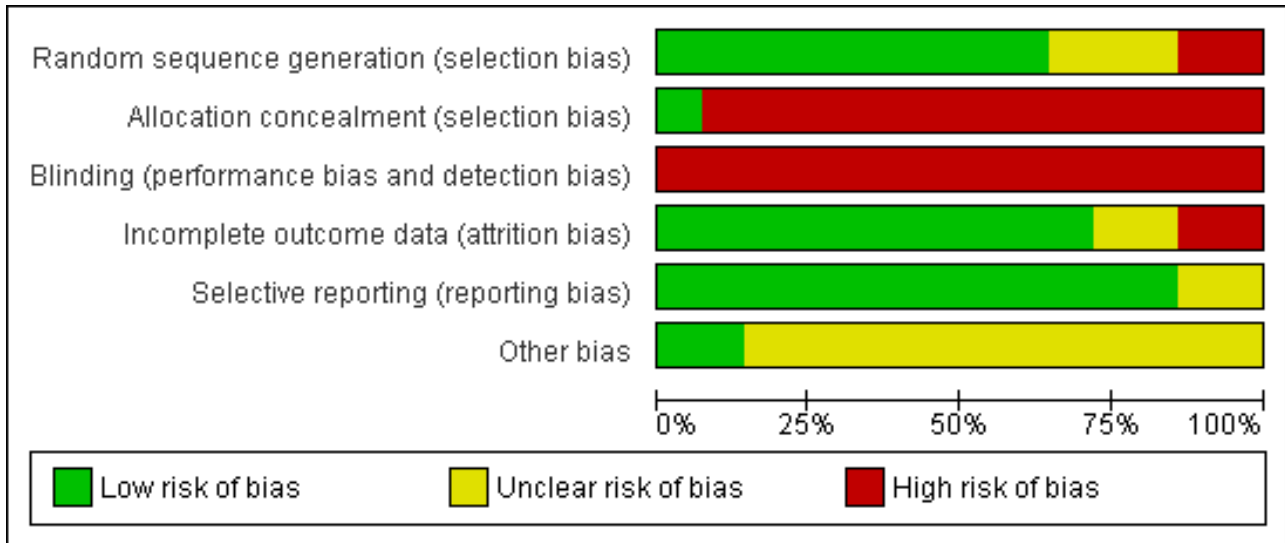


Figure 2. Methodological quality summary: review authors' judgments about each methodological quality item for each included study.

| | Random sequence generation (selection bias) | Allocation concealment (selection bias) | Blinding (performance bias and detection bias) | Incomplete outcome data (attrition bias) | Selective reporting (reporting bias) | Other bias |
|----------------------|---|---|--|--|--------------------------------------|------------|
| Choi 2009 | - | - | - | + | + | ? |
| Dai 2010 | ? | - | - | + | + | ? |
| De Wijkerslooth 2011 | + | + | - | - | + | + |
| Harada 2009 | + | - | - | + | + | ? |
| Hewett 2010 | + | - | - | + | + | ? |
| Horiuchi 2008 | - | - | - | + | + | ? |
| Kondo 2007 | + | - | - | + | + | ? |
| Lee 2009 | + | - | - | + | + | ? |
| Matsushita 1998 | + | - | - | + | + | ? |
| Park 2011 | + | - | - | ? | + | ? |
| Rastogi 2012 | + | - | - | ? | ? | + |
| Shida 2008 | ? | - | - | - | + | ? |
| Tada 1997 | ? | - | - | + | ? | ? |
| Tee 2010 | + | - | - | + | + | ? |

Allocation

Eleven of the fourteen trials reported on the generation of their allocation sequence. [De Wijkerslooth 2011](#), [Hewett 2010](#), [Kondo 2007](#), [Park 2011](#) and [Tee 2010](#) all used computer-generated random numbers. [Matsushita 1998](#), [Horiuchi 2008](#), [Harada 2009](#), [Lee 2009](#) and [Rastogi 2012](#) all used sealed envelopes. [Choi 2009](#) used the date of presentation which was deemed as inadequate. Three trials, [Dai 2010](#), [Tada 1997](#) and [Shida 2008](#) didn't specify their randomisation process but did state they "randomly allocated".

Blinding

Due to the nature of the study, it is not possible to blind the endoscopists to the interventions. However, two trials, [Shida 2008](#) and [Tada 1997](#), reported single blinded (of the patients).

Incomplete outcome data

The following studies reported the outcomes below, however due to the use of incomparable scales or incomplete raw data, they could not be included in the meta-analysis.

Caecal intubation rate

Two of the trials ([Dai 2010](#) and [Tada 1997](#)) do not specifically report on caecal intubation rate, however they do report on

caecal intubation time and make no comment about unsuccessful intubations or exclusions due to this. It is, therefore, appropriate to assume that their caecal intubation rate was 100% in both groups which has no impact on the meta-analysis.

Caecal intubation time

[Kondo 2007](#) reported caecal intubation time as an average in minutes with a range but no standard deviation or raw data. We contacted the authors and they have provided us with this raw data to use in the meta-analysis.

[Shida 2008](#) reported caecal intubation time as a mean average in minutes with a range but no standard deviation or raw data. We were unable to obtain the raw data.

Polyp detection rate

Twelve of the studies reported polyp detection, however there was no standardised presentation of data between studies and so we were unable to use this outcome in the meta-analysis.

[Horiuchi 2008](#) reported polyp detection as total of patients with at least one polyp.

[Kondo 2007](#) reported polyp detection as total number of polyps found for the total number of patients in each category.

[Matsushita 1998](#) was a tandem study and reported polyp detection as a percentage miss rate.

[Tada 1997](#) reported polyp detection as a mean +/- standard deviation.

[Choi 2009](#) reported polyp detection as total number of polyps detected, number (and percentage) of patients with 1 or more polyps, number of patients (and percentage) with one or more adenoma and the total number of adenomas (no./patient).

[De Wijkerslooth 2011](#) reported polyp detection as total number of polyps detected, the total number of adenomas detected and the number of subjects with one or more adenoma.

[Harada 2009](#) reported polyp detection as total number of patients with polyps and the total number of polyps.

[Hewett 2010](#) was a tandems study and reported polyp detection as the number of polyps found on first and second examinations, as well as a percentage miss rate.

[Lee 2009](#) reported polyp detection as subjects with adenomas as a percentage, as well as the number of adenomas/screened subject. They also analysed the number of subjects with advanced lesions and those with colorectal cancer.

[Park 2011](#) was a tandem study and reported polyp detection as the mean number of polyps found (per patient) on the first examination, as well as the mean number of missed polyps per patient.

[Rastogi 2012](#) reported polyp detection as the total number of subjects (and percentage) with adenomas, the total number of adenomas found and the mean number of adenomas per subject.

[Tee 2010](#) reported polyp detection as the number of subjects with polyps, the total number of polyps and the total number of adenomas.

Pain during procedure

[Shida 2008](#) reported pain using a visual analogue scale (between 1 and 100).

[Tada 1997](#) reported pain during the procedure using a scale of 1-4.

[Choi 2009](#) reported pain using a visual analogue scale (between 1 and 10).

[De Wijkerslooth 2011](#) reported pain using Gloucester Comfort Scores.

[Harada 2009](#) reported pain using a questionnaire with the following responses: comfortable, acceptable, and intolerable.

[Lee 2009](#) reported pain using a visual analogue scale (between 1 and 10).

Selective reporting

Our primary outcome of caecal intubation rate was reported by all authors except for [Tada 1997](#) and [Dai 2010](#). Both report caecal intubation time and do not comment on failed caecal intubation or exclusions, therefore it could be surmised that as they reported caecal intubation time that all colonoscopies reached the caecum, however this is not stated.

Other potential sources of bias

Twelve of the fourteen of the trials did not state whether they received funding - this could be considered a potential source of bias but the authors are unable to comment further.

Effects of interventions

See: [Summary of findings for the main comparison Caecal Intubation Rate for](#)

All trials compared the used of transparent cap colonoscopy and standard colonoscopy using a combination of outcomes to assess this.

Caecal Intubation Rate:

Twelve of the fourteen trials, [Choi 2009](#); [De Wijkerslooth 2011](#); [Harada 2009](#); [Hewett 2010](#); [Horiuchi 2008](#); [Kondo 2007](#); [Lee 2009](#); [Matsushita 1998](#); [Park 2011](#); [Rastogi 2012](#); [Shida 2008](#); [Tee 2010](#), reported caecal intubation rate and all were assessed in the metanalysis. Singularly taken, five trials, [De Wijkerslooth 2011](#); [Harada 2009](#); [Kondo 2007](#); [Lee 2009](#); and [Rastogi 2012](#), showed colonoscopy with the transparent cap to have a better caecal intubation rate than standard colonoscopy. Two trials, [Shida 2008](#) and [Tee 2010](#), showed standard colonoscopy to have a better caecal intubation rate than colonoscopy with the transparent cap. Five trials, [Choi 2009](#); [Hewett 2010](#); [Horiuchi 2008](#); [Matsushita 1998](#); [Park 2011](#), showed no difference between the standard colonoscopy and colonoscopy with the transparent cap, all having a 100% caecal intubation rate. On meta-analysis there was no significant difference between the two [Analysis 1.1](#), however our results favoured colonoscopy with the transparent cap. We found

no significant heterogeneity (Heterogeneity: $\text{Chi}^2 = 3.25$, $\text{df} = 6$ ($P = 0.78$); $I^2 = 0\%$)

[Shida 2008](#) also compared caecal intubation rate using a paediatric scope with a transparent cap versus a paediatric scope without. However they describe no statistical difference in this instance.

[Kondo 2007](#) also compared the use of a "short hood" versus standard colonoscopy, however this demonstrated no significant difference in caecal intubation rate.

Caecal Intubation Time:

All trials reported on this outcome, however only thirteen of the fourteen trials, [Choi 2009](#); [Dai 2010](#); [De Wijkerslooth 2011](#); [Harada 2009](#); [Hewett 2010](#); [Horiuchi 2008](#); [Kondo 2007](#); [Lee 2009](#); [Matsushita 1998](#); [Park 2011](#); [Rastogi 2012](#); [Tada 1997](#); [Tee 2010](#), reported caecal intubation time using comparable data for meta-analysis. Singularly taken, nine trials, [Choi 2009](#); [De Wijkerslooth 2011](#); [Harada 2009](#); [Horiuchi 2008](#); [Kondo 2007](#); [Lee 2009](#); [Park 2011](#); [Rastogi 2012](#); [Tee 2010](#) showed that colonoscopy with the transparent cap had a faster caecal intubation time than standard colonoscopy, with the data from [Choi 2009](#); [De Wijkerslooth 2011](#); [Harada 2009](#); [Horiuchi 2008](#); [Kondo 2007](#); [Lee 2009](#); and [Park 2011](#) being statistically significant. Three trials, [Dai 2010](#); [Hewett 2010](#) and [Tada 1997](#), showed that standard colonoscopy had a faster caecal intubation time than colonoscopy with the transparent cap. One trial, [Matsushita 1998](#), showed absolutely no difference in time taken for caecal intubation between standard colonoscopy and colonoscopy with the transparent cap. Meta-analysis of this data favours colonoscopy with transparent cap (-0.80 ; $\text{CI} -1.31, -0.30$), although only by a mean of 48 seconds, [Analysis 2.1](#). There was significant heterogeneity between this data: $\text{Tau}^2 = 0.60$; $\text{Chi}^2 = 93.09$, $\text{df} = 12$ ($P < 0.00001$); $I^2 = 87\%$.

[Shida 2008](#) also reported caecal intubation time, however they used non-comparable data, but showed that colonoscopy with the transparent cap had a significantly faster time to caecal intubation than standard colonoscopy. They also compared caecal intubation time using a paediatric scope with a transparent cap versus a paediatric scope without, which again demonstrated that colonoscopy with the transparent cap had a significantly faster time to caecal intubation than standard colonoscopy.

[Kondo 2007](#) also compared the use of a "short hood" versus standard colonoscopy, however this demonstrated no significant difference in caecal intubation time.

Polyp Detection Rate:

Twelve of the fourteen trials, [Choi 2009](#); [De Wijkerslooth 2011](#); [Harada 2009](#); [Hewett 2010](#); [Horiuchi 2008](#); [Kondo 2007](#); [Lee 2009](#); [Matsushita 1998](#); [Park 2011](#); [Rastogi 2012](#); [Tada 1997](#); and [Tee 2010](#), reported polyp detection, however due to the variable reporting methods we were unable to use this outcome in the meta-analysis. Singularly taken, seven of these twelve trials [Hewett 2010](#); [Horiuchi 2008](#); [Kondo 2007](#); [Lee 2009](#); [Matsushita 1998](#); [Park 2011](#); and [Rastogi 2012](#) showed a significantly improved polyp detection rate using the transparent cap.

[Horiuchi 2008](#) reported polyp detection as total number of patients with at least one polyp CAC 123 (29%) vs RC 99 (24.1%) $P = 0.11$ as well as the total number of adenomas CAC 205 vs RC 150 and this

was significantly higher in the colonoscopy with the cap compared with standard colonoscopy ($P = 0.04$).

[Kondo 2007](#) reported polyp detection as total number of polyps found for the total number of patients in each category CAC 49.3% vs RC 39.1% and this was significantly higher in the colonoscopy with the cap compared to standard colonoscopy ($P = 0.04$).

[Matsushita 1998](#) was a tandem study and reported polyp detection as a percentage miss rate (with-without 0% vs without-with 15%). They reported that standard colonoscopy had a higher polyp miss rate than colonoscopy with the transparent cap ($P = 0.0125$).

[Tada 1997](#) reported polyp detection as a mean +/- standard deviation CAC 0.86 +/- 0.96 vs RC 0.58 +/- 0.81 ($P < 0.05$) demonstrating a significant difference in the average number of lesions found between standard colonoscopy and colonoscopy with the transparent cap.

[Choi 2009](#) reported polyp detection as total number of polyps detected CAC 75 vs RC 71 ($P =$ not significant), number (and percentage) of patients with 1 or more polyps CAC 44 (38.6%) vs RC 38 (33.3%) (not significant), number of patients (and percentage) with one or more adenoma CAC 32 (28.1) vs RC 29 (25.4) ($P =$ not significant) and the total number of adenomas (no./patient) 51 (0.45) vs 49 (0.43) ($P =$ not significant).

[De Wijkerslooth 2011](#) reported polyp detection as total number of polyps detected CAC 665 vs RC 682 ($P = 0.71$), the total number of adenomas detected CAC 339 vs RC 341 ($P = 0.92$) and the number of subjects with one or more adenoma CAC 196 (29) vs RC 189 (29) ($P = 0.96$).

[Harada 2009](#) reported polyp detection as total number of patients with polyps CAC 120 vs RC 122 and the total number of polyps CAC 432 vs RC 456 ($P = 0.8757$).

[Hewett 2010](#) was a tandems study and reported polyp detection as a percentage miss rate CAC 21% vs RC 33% ($P = 0.037$).

[Lee 2009](#) reported polyp detection as subjects with adenomas as a percentage CAC 30.5% vs RC 37.5% ($P = 0.018$), as well as the number of adenomas/screened subject CAC 0.63 +/- 1.47 vs RC 0.96 +/- 2.86 ($P = 0.023$). They also analysed the number of subjects with advanced lesions and those with colorectal cancer.

[Park 2011](#) was a tandem study and reported polyp detection as the mean number of polyps found (per patient) on the first examination CAC 2.2 +/- 1.7 vs RC 2.0 +/- 1.8 ($P = 0.221$), as well as the mean number of missed polyps per patient CAC 1.1 +/- 1.5 vs RC 0.8 +/- 0.9 ($P = 0.024$).

[Rastogi 2012](#) reported polyp detection as the total number of subjects (and percentage) with adenomas CAC 144/210 vs RC 117/210 ($P = 0.009$), the total number of adenomas found CAC 474 vs RC 298 ($P < 0.001$) and the mean number of adenomas per subject CAC 2.3 vs RC 1.4 ($P < 0.001$).

[Tee 2010](#) reported polyp detection as the number of subjects with polyps CAC 63/192 vs RC 61/195 ($P = 0.75$), the total number of polyps CAC 147 vs RC 107 ($P = 0.59$) and the total number of adenomas CAC 75 vs RC 55 ($P = 0.26$).

Pain During Procedure:

Six of the trials, [Choi 2009](#); [De Wijkerslooth 2011](#); [Harada 2009](#); [Lee 2009](#); [Shida 2008](#); and [Tada 1997](#), reported patient pain levels. However there was no standard method of presenting the results and so it was not included in the meta-analysis. Singularly taken, three of these six [De Wijkerslooth 2011](#); [Harada 2009](#); and [Shida 2008](#) showed a significantly reduced reported pain level in the colonoscopy with the transparent cap.

[Shida 2008](#) reported pain using a visual analogue scale (between 1 and 100). Colonoscopy with the transparent cap had a significantly lower mean visual analogue score for pain than standard colonoscopy ($P=0.01$).

[Tada 1997](#) reported pain during the procedure using a scale of 1-4. They reported no significant difference in patients' discomfort when using the transparent cap compared to without it.

[Choi 2009](#) reported pain using a visual analogue scale (between 1 and 10). CAC 2.48 vs RC 2.74 $P=0.353$

[De Wijkerslooth 2011](#) reported pain using Gloucester Comfort Scores. Overall scores were lower in the CAC group 2.0 +/- 1.0 vs 2.2 +/- 1.0 ($P=0.03$).

[Harada 2009](#) reported pain using a questionnaire with the following responses: comfortable, acceptable, and intolerable. They reported that the number of patients answering comfortable was significantly higher in the hood group ($P=0.0398$) and the number of patients answering intolerable was significantly lower in the hood group ($P=0.0369$).

[Lee 2009](#) reported pain using a visual analogue scale (between 1 and 10). No significant differences in scores (CAC 3.5 +/- 2.9 vs 3.6 +/- 2.9; $P=0.71$)

DISCUSSION

Due to the increasing demand for colonoscopy, devices to advance examination techniques are highly sought-after. The colonoscope with the transparent cap could be one of these. Fourteen randomised studies have been conducted comparing the use of a transparent cap compared with conventional colonoscopy, [Choi 2009](#); [Dai 2010](#); [De Wijkerslooth 2011](#); [Harada 2009](#); [Hewett 2010](#); [Horiuchi 2008](#); [Kondo 2007](#); [Lee 2009](#); [Matsushita 1998](#); [Park 2011](#); [Rastogi 2012](#); [Shida 2008](#); [Tada 1997](#); [Tee 2010](#) providing enough information for a systematic review comparing these for efficacy.

Summary of main results

In the present meta-analysis, we considered for the all fourteen randomised controlled trials so far performed. The findings of our work indicate that colonoscopy with transparent cap has a significantly faster caecal intubation time when compared with standard colonoscopy. Reviewing studies individually would also seem to favour colonoscopy with transparent cap for polyp detection rate and pain during procedure but due to lack of comparable data meta-analysis was not feasible.

Overall completeness and applicability of evidence

In the light of the faster caecal intubation time when using colonoscopy with transparent cap, the findings of the present meta-analysis must be taken into consideration in the investigation

of colonic pathology. We would recommend that this adjunct to colonoscopy is further investigated as to its clinical significance.

Quality of the evidence

There was no significant heterogeneity. We assessed each study individually for quality.

[Choi 2009](#) had a poor method of randomisation, using alternate days of study period to allocate participants to each group. There was also no description as to whether all randomised patients were included in the analysis. However, appropriate outcomes were reported (including caecal intubation rate and time, polyp detection rate, pain during procedure, adverse events) and the study size was reasonable. Groups were comparable at baseline. Endoscopists had experience of more than 3000 colonoscopies.

[Dai 2010](#) did not state the method of allocation or whether all randomised patients were included in the analysis. However appropriate outcomes were reported (including caecal intubation time, pain during procedure, distension, total procedure time) and the study size was reasonable. Groups were comparable at baseline. Two subgroups of endoscopists were included: those with at least 5 years experience and those with at least 1 year experience.

[De Wijkerslooth 2011](#) was a large study that compared standard colonoscopy with transparent cap colonoscopy in a screening population. It used computer-generated randomisation methods and appeared to be a well-designed and carried-out study. Appropriate outcomes were reported (including caecal intubation rate, caecal intubation time, polyp detection rate, pain during procedure, perceived burden of colonoscopy, size of adenoma analysis). Patients who did not undergo the procedure were excluded and exclusion reasons were documented. Groups were comparable at baseline. Endoscopists were considered experienced, having performed more than 1000 colonoscopies.

[Harada 2009](#) was a large study in a screening/surveillance population. It used sealed envelope randomisation and appeared to be a well-designed and well carried-out study. Appropriate outcomes were reported (including caecal intubation rate, caecal intubation time, polyp detection rate, pain during procedure, withdrawal time, sedation/analgesia requirements). All patients were included in the study analysis. There were nearly twice as many men compared with women in the study, however groups were comparable at baseline. Six endoscopists were involved in the study 3 with >5000 caecal intubations, 1 with >3000 caecal intubations and 2 with <1000 caecal intubations.

[Hewett 2010](#) was a fairly small study with 100 participants. It used computer-generated randomisation and all patients were included in data analysis. Groups were comparable at baseline. The study was not blinded. Appropriate outcomes were reported (including caecal intubation time, polyp detection rate, propofol dose, missed adenomas). Endoscopists were described as experienced.

[Horiuchi 2008](#) had an unnecessarily complex design with a small proportion of patients being allocated to a second colonoscopy. We wonder if the RCT protocol was altered during the 17 months of recruitment. The outcome of the first colonoscopy was blinded to the second investigator. The generation of their allocation sequence was inadequate, using date of presentation for randomisation, or sealed envelopes. The study was not blinded. They estimated, using historical data, the number of patients

required to be at least 800 and exceeded this. Both groups were comparable at baseline. All procedures were carried out by a single endoscopist. Appropriate outcomes were reported (including caecal intubation rate, caecal intubation time and polyp detection rate), although patients factors, such as pain during procedure, were not studied. We felt the design of this study was weak.

Kondo 2007 appeared to be a well-designed and carried-out study. Generation of allocation sequence was adequate but the study was not blinded. A calculation of study size was carried out requiring 200 patients in each arm, which was exceeded. Recruitment to the study was open for eleven months. Groups were comparable at baseline. Appropriate outcomes were reported (including caecal intubation rate, caecal intubation time, polyp detection rate, trainee intubation rate, complications). We do note however that patient tolerance was not discussed, even though this may have been a reason for the attending Colonoscopist replacing the trainee.

Lee 2009 was a large study across two regional centres. A priori calculation was performed and met. Generation of allocation sequence was adequate with sealed envelopes and randomisation blocks of 10. All participants were included in the analysis and groups were comparable at baseline. There were two groups of endoscopists: 8 with at least 5 years experience and >3000 cases. 3 with at least 2 years experience and >1000 cases. Appropriate outcomes were reported (including caecal intubation rate, caecal intubation time, polyp detection, pain during procedure, analgesia/sedation requirements).

Matsushita 1998 was a small study. Tandem colonoscopies were carried out and recruitment and ethics for such a design may be a reason for the small numbers, particularly as these patients had already undergone barium enema which originally diagnosed their polyps. Generation of allocation sequence was adequate but the study was not blinded. No priori calculation of sample size was described. This was a cross-over design, therefore groups were comparable. All procedures were carried out by a single endoscopist. Appropriate outcomes were reported (included caecal intubation rate, caecal intubation time, polyp detection rate, terminal ileal intubation rate, rectal retroflexion rate, polyp miss rate).

Park 2011 used a computer generated allocation sequence and was single blinded (to the patient) with allocation concealment using sealed envelopes. Patients were scheduled for elective colonoscopic EMR. There were more than twice as many men than women in the study but groups were comparable at baseline. A priori calculation was performed and met. 25 patients were excluded from analysis due to poor bowel prep. Endoscopists were described as experienced with more than 3000 colonoscopies between them. Appropriate outcomes were reported (including caecal intubation time, polyp detection rate, total procedure time, withdrawal time, polyp miss rate, time required for EMR).

Rastogi 2012 was a fairly large study in a screening/surveillance population and participants were stratified according to indication. Generation of allocation sequence was acceptable, using sealed envelopes. Patient groups were comparable at baseline. Patients were excluded from analysis when there was poor bowel prep or when the endoscopist did not reach the caecum for whatever reason. All endoscopists were considered experienced with more

than 3000 colonoscopies each. Appropriate outcomes were reported (including caecal intubation rate, caecal intubation time, polyp detection rate, use of sedation/analgesia, polyp analysis, withdrawal time).

Shida 2008 compared two different colonoscope types and therefore multiple different caps. Generation of allocation sequence was unclear and the study was unblinded. A priori calculation of sample size was not described. We feel that comparing four interventions in a relatively small study (372 patients) may mean that this was underpowered. Groups were comparable at baseline. All procedures were carried out by a single experienced endoscopist. Appropriate outcomes were reported (including caecal intubation rate, caecal intubation time, level of pain during procedure). Difficulty of insertion was also reported, despite being operator-dependent in an unblinded study.

Tada 1997 compared standard colonoscopy with colonoscopy with a transparent cap in a screening population. Generation of the allocation sequence was unclear and the study was unblinded. A priori calculation of sample size was not described. This was a small study (140 patients) we question why when this was recruited from a "screening population". Groups were comparable at baseline. All procedures were carried out by a single experienced endoscopist. Appropriate outcomes were reported (including caecal intubation time, level of pain during procedure and polyp detection rate). However, caecal intubation rate was not reported.

Tee 2010 used computer-generated randomisation and patients were blinded to allocation. This was a moderate sized study and a priori calculation was performed and met. Groups were comparable at baseline and the withdrawal rate was less than 10%. Procedures were carried out by a mixture of consultant gastroenterologists (five) and trainees (ten). Appropriate outcomes were reported (including caecal intubation rate, caecal intubation time, polyp detection and complications).

Potential biases in the review process

The difficulty with blinding the endoscopist may have lead to bias, however we do not see a way to overcome this due the nature of the intervention.

Agreements and disagreements with other studies or reviews

A previous meta-analysis performed by **Westwood 2012** et al, did demonstrate a significant difference in favour of the cap, although not in time. **Ng 2011** et al have shown results comparable to our own.

AUTHORS' CONCLUSIONS

Implications for practice

We have a demonstrated statistically significant difference between colonoscopy with the transparent cap and standard colonoscopy with regards caecal intubation time, with the time to caecal intubation being shorter by approximately 48 seconds. The clinical significance of these results remains debatable as it reduces the overall procedure time by less than a minute. We have not demonstrated any worse outcomes when using the transparent cap. We do not feel that this can recommend the introduction of transparent caps into regular clinical practice but suggest that

further research into their use in routine practice and in training Colonoscopists may be beneficial and does not appear to be harmful.

Implications for research

For the outcomes of caecal intubation rate and time, further studies looking at the effects on both experienced endoscopists and trainees would be helpful in the evaluation of this intervention. In these cases a large-scale randomised controlled trial, with patients randomised simply to one arm or the other, would best assess this. By undertaking this type of study, overall clinical implications, such as patient satisfaction and complication rates, could be looked at if the study numbers were large enough.

To assess polyp detection, a cross-over design may be more appropriate but careful ethical consideration would be required. Such a study may enable investigation of whether the cap has wider application as an adjunct to therapeutic procedures, such as EMR.

It has been suggested that the outcomes assessed within this review are surrogate markers for the cap having a clinical rather than a procedural advantage. A study looking at this, with outcomes such as improved survival, would need to be large with very lengthy follow-up in the context of an internationally funded study. However, in view of the fact the basic science of this has already been thoroughly investigated and widely accepted (adenoma-carcinoma sequence) and as such this may be deemed unnecessary.

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CHARACTERISTICS OF STUDIES
Characteristics of included studies [ordered by study ID]
Choi 2009

| | |
|---------------|---|
| Methods | Generation of allocation sequence: Randomised according to date of endoscopy. Allocation concealment: Not stated. Blinding: Not applicable. Inclusion of all randomised patients: Not stated. |
| Participants | Number: 228 (108M:120F) Age: Cap group mean 46.1 +/- 11.1 years. Standard group mean 48.5 +/- 10.9 years. Source: Yang Hospital, Seoul. Inclusion criteria: All patients undergoing colonoscopy. Exclusion criteria: Prior colonic surgery, colonic obstruction or obstructing tumour. |
| Interventions | Colonoscope: not stated. Bowel Preparation: 4L polyethylene glycol/ or 50mg sodium phosphate. Intra-procedure medication: Midazolam, Propofol, Oxygen. Colonoscopists: Experienced colonoscopists having performed >3000 colonoscopies. Cap: D-201-13404 (Olympus, Tokyo, Japan) transparent plastic cap: 13.7mm outer diameter, 11.7mm inner diameter, depth 8mm, protruding 4mm ahead of scope. |
| Outcomes | Included in review: Caecal intubation rate and time, polyp detection rate, pain during procedure, adverse events. |
| Notes | Location: Korea. Source of funding: Not stated. Attempts to clarify information: Translation from Korean. Language of Publication: Korean. |

Risk of bias

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

Choi 2009 (Continued)

| | | |
|--|--------------|---|
| Random sequence generation (selection bias) | High risk | Inadequate method - randomised by alternate days. |
| Allocation concealment (selection bias) | High risk | Not blinded. |
| Blinding (performance bias and detection bias) All outcomes | High risk | Not blinded. |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | All data appears complete. |
| Selective reporting (reporting bias) | Low risk | Appropriate outcomes reported. |
| Other bias | Unclear risk | Source of funding not stated. |

Dai 2010

| | |
|---------------|---|
| Methods | <p>Generation of allocation sequence: Not stated.</p> <p>Allocation concealment: Not stated.</p> <p>Blinding: Not stated.</p> <p>Inclusion of all randomised patients: Not stated.</p> |
| Participants | <p>Number: 250 (134M:116F)</p> <p>Age: Cap group mean 49.4 years (range 22-77). Regular group mean 53.3 years (range 18-78).</p> <p>Source: Renji Hospital, Shanghai.</p> <p>Inclusion criteria: Patients undergoing outpatient colonoscopy.</p> <p>Exclusion criteria: Prior colonic surgery, IBD, colonic stricture or tumour, poor bowel preparation.</p> |
| Interventions | <p>Colonoscope: CF-240 (Olympus, Tokyo, Japan).</p> <p>Bowel Preparation: 2L polyethylene glycol/electrolyte lavage solution (Shenzhen Wanhe, Shenzhen, China) 6hours before.</p> <p>Intra-procedure medication: 10mg Scopolamine, 10mg Diazepam I.M.</p> <p>Colonoscopists: 2 subgroups - experienced (at least 5 years experience) and inexperienced (1 year experience).</p> <p>Caps: D-201-13404 (Olympus, Tokyo, Japan) transparent plastic cap: 13.7mm outer diameter, 11.7mm inner diameter, depth 8mm, protruding 4mm ahead of scope.</p> |
| Outcomes | <p>Included in review: Caecal intubation time, pain during procedure</p> <p>Excluded from review: Distension, total procedure time.</p> |
| Notes | <p>Location: China</p> <p>Source of funding: Not stated</p> |

Dai 2010 (Continued)

Attempts to clarify information: Not required.

Language of Publication: English

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | Not stated |
| Allocation concealment (selection bias) | High risk | Not blinded to endoscopist |
| Blinding (performance bias and detection bias) All outcomes | High risk | Not stated but not blinded to endoscopist. |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | All data appears complete. |
| Selective reporting (reporting bias) | Low risk | Appropriate outcomes reported. |
| Other bias | Unclear risk | Source of funding not stated. |

De Wijkerslooth 2011

| | |
|---------------|--|
| Methods | <p>Generation of allocation sequence: Computer randomisation program. Patients stratified by age, sex and screening center using random block sizes of maximum 6 per block.</p> <p>Allocation concealment: Unclear.</p> <p>Blinding: Single blinded.</p> <p>Inclusion of all randomised patients: No. Did not include data for patients who did not undergo the intervention (reasons included withdrawal (26), absence of trained endoscopist (13) and technical problem (2).</p> |
| Participants | <p>Number: 1339 (685M:654F)</p> <p>Age: 60 (50-65) in CC group; 60 (55-65) in CAC group (years; median (IQR)).</p> <p>Source: Academic Medical Center, Amsterdam & Erasmus Medical Center, Rotterdam.</p> <p>Inclusion criteria: All patients undergoing screening colonoscopy.</p> <p>Exclusion criteria: Full colonoscopic examination within the previous 5 years, surveillance colonoscopy, subjects with end-stage disease and previous colonic resection.</p> |
| Interventions | <p>Colonoscopes used: CF-Q160, CF-Q180, PCF-Q180 variable stiffness (Olympus Medical Systems, Tokyo, Japan).</p> <p>Bowel Preparation: low fibre diet, 2litres transparent fluid, 2litred polyethylene glycol (Moviprep; Norgine, Amsterdam).</p> <p>Intra-procedure medications: IV midazolam, IV fentanyl as required.</p> |

De Wijkerslooth 2011 (Continued)

Endoscopist: "Experienced" (at least 1000 colonoscopies and at least 20 CAC procedures).

Caps: Transparent cap protruding 4mm: D-201-12704 (13.4mm diameter) or D-201-14304 (15mm diameter) (Olympus Medical Systems, Tokyo, Japan).

| | |
|----------|--|
| Outcomes | Included in review: Caecal intubation rate, caecal intubation time, Polyp detection rate, Pain during procedure Excluded from review: perceived burden of colonoscopy, Size of adenoma analysis. |
| Notes | Location: Netherlands. Source of funding: The Netherlands Organisation for Health Research and Development; Center for Translational Molecular Medicine. Attempts to clarify information: Not required. Language of Publication: English. |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Computer generated |
| Allocation concealment (selection bias) | Low risk | Participants and Endoscopists were blinded to randomisation until start of procedure. |
| Blinding (performance bias and detection bias) All outcomes | High risk | Not blinded to endoscopist. |
| Incomplete outcome data (attrition bias) All outcomes | High risk | Patients excluded from data analysis if did not have procedure. |
| Selective reporting (reporting bias) | Low risk | All outcomes reported. |
| Other bias | Low risk | None found. |

Harada 2009

| | |
|--------------|---|
| Methods | Generation of allocation sequence: Sealed envelopes Allocation concealment: Not applicable as not blinded. Blinding: Not stated but unblinded to endoscopists Inclusion of all randomised patients: Yes |
| Participants | Number: 592 (391M:201F) Age: Hood group - 62.6 years +/- 63.7. No Hood - 62.7 years +/- 64.0 (mean) Source: A single Japanese tertiary referral centre Inclusion criteria: Screening/surveillance total colonoscopy. |

Harada 2009 (Continued)

Exclusion criteria: Emergency, therapeutic or EUS procedures. Poor bowel preparation.

Interventions

Colonoscope: PCF-Q240ZI, PCF-Q260AI, PCF-P240AI (Olympus Optical Co, Ltd, Japan).

Bowel Preparation: Colonic lavage with polyethylene glycol.

Intra-procedure medication: 2-5mg midazolam as required for pain IV, Scopolamine butyl bromide or glucagon as antispasmodic.

Endoscopists: 3 with >5000 caecal intubations, 1 with >3000 caecal intubations and 2 with <1000 caecal intubations.

Cap: D-201-13404, D-201-012704, D-201-11804 (Olympus Medical Systems, Tokyo, Japan).

Outcomes

Included in review: Caecal intubation rate, caecal intubation time, polyp detection rate, Pain during procedure

Excluded from review: Withdrawal time (?sedation/analgesia requirements)

Notes

Location: Japan

Source of funding: Not stated

Attempts to clarify information: Not required

Language of Publication: English

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Sealed envelopes. |
| Allocation concealment (selection bias) | High risk | Not blinded |
| Blinding (performance bias and detection bias) All outcomes | High risk | Not blinded to endoscopist. |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | All patients included in data analysis. |
| Selective reporting (reporting bias) | Low risk | Appropriate outcomes reported. |
| Other bias | Unclear risk | Source of funding not stated. |

Hewett 2010
Methods

Generation of allocation sequence: computer generated.

Allocation concealment: Not applicable as not blinded

Blinding: Not stated but not blinded to endoscopist

Inclusion of all randomised patients: Yes

Hewett 2010 (Continued)

| | |
|---------------|--|
| Participants | <p>Number: 100 (57M:43F)</p> <p>Age: group 1: mean age 61.0 years +/- 1.0. Group 2: 62.9 +/-1.2.</p> <p>Source:Indiana University Hospital, USA.</p> <p>Inclusion criteria: Patients 50 years of age or older and able to give informed consent, scheduled for elective colonoscopy.</p> <p>Exclusion criteria: ASA III or more, previous surgical resection of colon or rectum, IBD, current anticoagulant use.</p> |
| Interventions | <p>Colonoscope: High-definition videocolonoscopes CF-H180AL (Olympus, America).</p> <p>Bowel preparation: not stated.</p> <p>Intra-procedure medication: propofol sedation "endoscopist-directed".</p> <p>Endoscopist: "experienced".</p> <p>Caps: Soft, transparent plastic cap 13.4mm outer diameter, 4mm protrusion. (D-201-12704, Olympus).</p> |
| Outcomes | <p>Included in review: Caecal intubation time, Polyp detection rate</p> <p>Excluded from review: propofol dose, missed adenomas</p> |
| Notes | <p>Location: USA</p> <p>Source of funding: Not stated</p> <p>Attempts to clarify information: Not required</p> <p>Language of Publication: English</p> |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|-------------------------------|
| Random sequence generation (selection bias) | Low risk | Computer generated |
| Allocation concealment (selection bias) | High risk | Not blinded |
| Blinding (performance bias and detection bias) All outcomes | High risk | Not blinded to endoscopist. |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | All data used for analysis |
| Selective reporting (reporting bias) | Low risk | Appropriate outcomes measured |
| Other bias | Unclear risk | Source of funding not stated. |

Horiuchi 2008

| | |
|---------------|---|
| Methods | <p>Generation of allocation sequence: For first colonoscopy randomised by date of presentation, for second colonoscopy randomised by sealed opaque envelopes.</p> <p>Allocation concealment: not applicable as not blinded.</p> <p>Blinding: the endoscopist was not blinded to the intervention itself (transparent retractable extension) but the endoscopist in the second colonoscopy was blinded to the findings from the first colonoscopy.</p> <p>Inclusion of all randomised patients: All randomised patients were included in data analysis.</p> |
| Participants | <p>Number: 835</p> <p>Age: 63.7 +/- 11 in group 1 and 64.6 +/-13 in group 2</p> <p>Source: Showa Inan General Hospital, Komagane, Japan.</p> <p>Inclusion criteria: consecutive patients undergoing screening colonoscopy in whom the endoscopist evaluated greater than 90% of mucosa seen during endoscopy.</p> <p>Exclusion criteria: previous colorectal surgical resection, less than 20 years of age, pregnancy, ASA class 3 or 4, overweight (body weight >100kg) and allergy to the drugs used.</p> |
| Interventions | <p>7mm Olympus PCF Q260A1 transparent retractable extension (TRE) device fitted onto a paediatric, variable stiffness, colonoscope. Bowel preparation using polyethylene glycol electrolyte solution. All procedures were conducted under nurse-administered propofol sedation. Between August 2005 and December 2006, consecutive patients were enrolled. Colonoscopy with or without transparent retractable extension was then undertaken by one endoscopist. A subset of patients with colonic adenomas were randomised to a repeat colonoscopy with or without the TRE. Adenoma removal was performed at the second colonoscopy.</p> |
| Outcomes | <p>Included in review: Caecal intubation time, caecal intubation rate, polyp detection rate</p> <p>Excluded from review: none</p> |
| Notes | <p>Location: Showa Inan General Hospital, Komagane, Japan.</p> <p>Source of funding: Not stated</p> <p>Attempts to clarify information: not required</p> <p>Language of Publication: English</p> |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | High risk | For first colonoscopy randomised by date of presentation, for second colonoscopy randomised by sealed opaque envelopes. |
| Allocation concealment (selection bias) | High risk | Not concealed to endoscopist. |
| Blinding (performance bias and detection bias) All outcomes | High risk | Not blinded to endoscopist. |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | All randomised patients were included in data analysis. |

Horiuchi 2008 (Continued)

| | | |
|--------------------------------------|--------------|-------------------------------|
| Selective reporting (reporting bias) | Low risk | All outcomes reported. |
| Other bias | Unclear risk | Source of funding not stated. |

Kondo 2007

| | |
|---------------|--|
| Methods | <p>Generation of allocation sequence: Patients were randomly assigned to transparent hood, short hood or no hood on the basis of computer-generated random numbers.</p> <p>Allocation concealment: Although the allocation was concealed until each examination, the Colonoscopists and possibly the patients, noticed the allocation.</p> <p>Blinding: Unblinded</p> <p>Inclusion of all randomised patients: All randomised patients were included in data analysis.</p> |
| Participants | <p>Number: 684</p> <p>Age: 62.0 (19-88) years</p> <p>Source: Patients referred for total colonoscopy at University of Tokyo Hospital between July 2004 and May 2005.</p> <p>Inclusion criteria: Consecutive patients referred for total colonoscopy giving written, informed consent.</p> <p>Exclusion criteria: Prior colonic resection, known fulminant colitis, severe hematochezia.</p> |
| Interventions | <p>All patients underwent bowel preparation with sodium pico sulphate the day before the examination and two litres of polyethylene glycol-containing lavage solution on the day of examination. Scopolamine butyl bromide 20mg or glucagon 1IU, was administered intra-muscularly. No sedatives were used. Either Olympus PCF 230 or PCF 240I colonoscopes were used for all examinations. Each colonoscopic examination was started by one of fourteen trainees with less than 1000 cases of colonoscopy experience. They performed colonoscopy under supervision of attending Colonoscopist. If the trainee failed to reach the caecum within 15 minutes, or the patient complained of intolerable pain, the attending Colonoscopist replaced the trainee and continued the examination. In all cases examinations during withdrawal of the scope were performed by trainees.</p> <p>The patients were randomly assigned to the:</p> <p>Transparent Hood (Olympus D-201-12704) made of thermoplastic elastomer. The hood has an outer diameter of 12.6mm and an inner diameter of 10.6mm. The portion of the hood that sticks out from the tip is 4mm. The edge of this hood comes into the field of vision of the colonoscope but objects can be seen through the transparent wall.</p> <p>Short Hood (Olympus MB46) made of fluorine rubber. The hood has a distal end with an outer diameter of 12mm and an inner diameter of 10.6mm. The length is 2mm. The hood does not come into the field of vision of the colonoscope.</p> <p>No hood.</p> |
| Outcomes | <p>Included in review: Caecal intubation rate, caecal intubation time and polyp detection rate</p> <p>Excluded from review: Complications, trainee intubation rate</p> |
| Notes | <p>Location: University of Tokyo Hospital, Japan</p> <p>Source of funding: Not stated</p> |

Kondo 2007 (Continued)

Attempts to clarify information: attempts made to contact authors for raw data on caecal intubation time.

Language of Publication: English

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Patients were randomly assigned to transparent hood, short hood or no hood on the basis of computer-generated random numbers. |
| Allocation concealment (selection bias) | High risk | Not concealed as unblinded |
| Blinding (performance bias and detection bias) All outcomes | High risk | Unblinded |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | None |
| Selective reporting (reporting bias) | Low risk | All outcomes reported |
| Other bias | Unclear risk | Source of funding not stated |

Lee 2009

| | |
|---------------|---|
| Methods | <p>Generation of allocation sequence: Sealed opaque envelopes, randomisation blocks of 10</p> <p>Allocation concealment: No stated.</p> <p>Blinding: Not stated.</p> <p>Inclusion of all randomised patients: Yes</p> |
| Participants | <p>Number: 1000 (460M: 540F)</p> <p>Age: CAC group: 52.6 +/- 14.0 years. RC group 52.6 +/- 13.8 years</p> <p>Source: 2 regional endoscopy centres.</p> <p>Inclusion criteria: Aged 18 years or over, undergoing first colonoscopy and could provide written consent.</p> <p>Exclusion criteria: Prior colonoscopy or prior colonic surgery (except appendicectomy), having colonic stricture or obstructing tumour. Acute surgical conditions or acute GI bleeding.</p> |
| Interventions | <p>Colonoscope: Regular colonoscopes without variable stiffness: CF-240 or CF-Q240 (Olympus Medical Systems, Tokyo, Japan).</p> <p>Bowel preparation: 3 day of low-residue diet. Either 4L polyethylene glycol (Klean-Pred, Harefield, UK) or 90ml phosphosoda (Fleet, CB Fleet, Virginia, USA).</p> <p>Intra-procedure medication: Diazepam 0.05mg/kg IV, pethidine 0.25mg/kg IV.</p> |

Lee 2009 (Continued)

Endoscopist experience: 8 had at least 5 years experience and >3000 cases. 3 had at least 2 years experience and >1000 cases.

Caps: Mucosectomy cap MAJ-665 or MH-596 (Olympus Medical Systems Corp).

| | |
|----------|---|
| Outcomes | Included in review: Caecal intubation rate, caecal intubation time, Polyp detection, Pain during procedure Excluded from review: Analgesia/sedation requirements? Complications. |
| Notes | Location: China Source of funding: Not stated Attempts to clarify information: Not necessary Language of Publication: English |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Low risk | Sealed envelopes |
| Allocation concealment (selection bias) | High risk | Not concealed as not blinded |
| Blinding (performance bias and detection bias) All outcomes | High risk | Not stated but endoscopist not blinded |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | All randomised patients included in analysis |
| Selective reporting (reporting bias) | Low risk | Appropriate outcomes reported |
| Other bias | Unclear risk | Source of funding not stated. |

Matsushita 1998

| | |
|--------------|---|
| Methods | Generation of allocation sequence: randomisation was carried out using closed envelopes. Allocation concealment: not applicable as not blinded. Blinding: Unblinded. Inclusion of all randomised patients: All randomised patients were included in data analysis. |
| Participants | Number: 24 Age: 58.6 (42-77) years Source: 24 patients with colorectal polyps detected at previous barium enema examination in Tenri Hospital, Nara, Japan. Inclusion criteria: Previous polyps detected at barium enema examination. |

Matsushita 1998 (Continued)

Exclusion criteria: Previous abdominal or pelvic surgery, or if it was considered their general medical condition was poor.

| | |
|---------------|--|
| Interventions | Tandem colonoscopies were carried out, randomly either first without a transparent cap (Obliclear, Top, Tokyo, Japan) and then with the cap (without-to-with) or first with the cap and then without (with-to-without) in the 24 patients. All patients were initially prepared with Polyethylene glycol solution and they received no pre-medications. The Olympus CF2001 scope was used for all procedures. All polyps were removed whilst removing the colonoscope, intubation of the terminal ileum was attempted in all cases, as was retroflexion in the rectum. |
| Outcomes | Included in review: Caecal intubation rate, caecal intubation time, polyp detection rate. Excluded from review: polyp miss rate, retroflexion within rectum, and terminal ileal intubation rates. |
| Notes | Location: Department of gastroenterology, Tenri Hospital, Nara, Japan Source of funding: Not stated Attempts to clarify information: not required Language of Publication: English |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|-------------------------------|
| Random sequence generation (selection bias) | Low risk | Closed envelopes |
| Allocation concealment (selection bias) | High risk | Not concealed as not blinded |
| Blinding (performance bias and detection bias) All outcomes | High risk | Unblinded |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | None |
| Selective reporting (reporting bias) | Low risk | Appropriate outcomes assessed |
| Other bias | Unclear risk | Source of funding not stated |

Park 2011

| | |
|--------------|---|
| Methods | Generation of allocation sequence: Computer generated Allocation concealment: Sealed envelopes Blinding: Single blinded (patient only) Inclusion of all randomised patients: No (25 excluded due to poor bowel prep) |
| Participants | Number: 329 (235M:94F) Age: CAC group 61.3 +/- 10.3 years. RC 59.3 +/- 10.2 years. |

Park 2011 (Continued)

Source: Chonnam National University Hospital

Inclusion criteria: Patients 18 years or older who were able to give informed consent and were scheduled for elective colonoscopic EMR.

Exclusion criteria: Previous colorectal surgery, colonic stricture, obstructing tumour, other acute surgical conditions (such as severe colitis, toxic megacolon, Ischaemic colitis or acute GI bleed).

| | |
|---------------|--|
| Interventions | <p>Colonoscope: Regular colonoscopes without variable stiffness function: CF-240 or CF-Q240 (Olympus Medical Systems, Tokyo, Japan).</p> <p>Bowel Preparation: 3 day low residue diet, followed by 4L polyethylene glycol solution.</p> <p>Intra-procedure medications: not stated.</p> <p>Endoscopist experience: "Experienced" >3000 procedures between them.</p> <p>Caps: Soft, transparent plastic cap, 14mm outer diameter and protrudes 4mm. D-201-12704 (Olympus).</p> |
| Outcomes | <p>Included in review: Caecal intubation time, polyp detection rate</p> <p>Excluded from review: Total procedure time, withdrawal time, polyp miss rate, time required for EMR.</p> |
| Notes | <p>Location: South Korea</p> <p>Source of funding: Not stated</p> <p>Attempts to clarify information: Not necessary</p> <p>Language of Publication: English</p> |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Computer generated |
| Allocation concealment (selection bias) | High risk | Not concealed as not blinded |
| Blinding (performance bias and detection bias) All outcomes | High risk | Endoscopist not blinded |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | 25 excluded from analysis due to poor bowel prep. |
| Selective reporting (reporting bias) | Low risk | Appropriate outcomes reported. |
| Other bias | Unclear risk | Source of funding not stated. |

Rastogi 2012

| | |
|---------|--|
| Methods | Generation of allocation sequence: Opaque, sealed envelopes. Stratified by indication (screening or surveillance). |
|---------|--|

Rastogi 2012 (Continued)

Allocation concealment: Not stated

Blinding: Not stated

Inclusion of all randomised patients: No - patients with inadequate bowel prep or where they could not reach the caecum were excluded from analysis.

Participants

Number: 427 randomised, 420 analysed (398M:22F)

Age: CAC group 60.7 +/- 7.2 years. Standard group 61.3 +/- 7.3

Source: Tertiary care Veterans Affairs Medical Center, USA.

Inclusion criteria: Referral for screening or surveillance colonoscopy and the ability to provide informed consent.

Exclusion criteria: Previous surgical colonic resection, history of colorectal cancer or IBD, use of antiplatelet agents or anti-coagulants precluding removal of polyps, poor general condition or any other reason to avoid prolonged procedure time, history of polyposis syndrome or HNPCC, inability to give informed consent.

Interventions

Colonoscope: CF-H180AL (Olympus America Inc, Centerville, Pennsylvania, USA).

Bowel preparation: not stated.

Intra-procedure medication: IV midazolam +/- Meperidine or Fentanyl.

Endoscopist: "Experienced" with more than 3000 colonoscopies each and more than 20 CAC procedures.

Outcomes

Included in review: Caecal intubation rate, caecal intubation time, Polyp detection rate

Excluded from review: use of sedation/analgesia, polyp analysis, withdrawal time

Notes

Location: USA

Source of funding: Endoscopic Research Center for Development Award (A. Rastogi) from the American Society for Gastrointestinal Endoscopy.

Attempts to clarify information: Not required.

Language of Publication: English

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|---------------------------|---|
| Random sequence generation (selection bias) | Low risk | Sealed envelopes |
| Allocation concealment (selection bias) | High risk | Not concealed as not blinded |
| Blinding (performance bias and detection bias) All outcomes | High risk | Not stated but endoscopist not blinded |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Patients excluded from data analysis when caecum not reached or when bowel prep was poor. |

Rastogi 2012 (Continued)

| | | |
|--------------------------------------|--------------|------------------------------------|
| Selective reporting (reporting bias) | Unclear risk | Appropriate outcomes all reported. |
| Other bias | Low risk | None identified. |

Shida 2008

| | |
|---------------|---|
| Methods | <p>Generation of allocation sequence: "randomly assigned"</p> <p>Allocation concealment: Not stated.</p> <p>Blinding: Unblinded to endoscopist, blinded to patient - single blinded.</p> <p>Inclusion of all randomised patients: All randomised patients were included in data analysis.</p> |
| Participants | <p>Number: 372</p> <p>Age: range 28-86 years</p> <p>Source: Patients undergoing colonoscopy between April 2006 and March 2007 at Omigawa Hospital, Chiba, Japan.</p> <p>Inclusion criteria: All patients undergoing colonoscopy in the allocated time frame.</p> <p>Exclusion criteria: Patients with prior abdominal surgery, including hysterectomy, obstructing tumours of the distal colon, and poor bowel preparation.</p> |
| Interventions | All patients underwent bowel preparation with 2 litres of polyethylene glycol lavage solution. Scopolamine butyl bromide 20mg or glucagon 1IU was administered intramuscularly. No sedatives were used. Patients were examined by standard colonoscope with transparent hood (range of hoods used, depending on scope), standard colonoscope without transparent hood, small calibre colonoscope with transparent hood, and small calibre colonoscope without transparent hood. |
| Outcomes | <p>Included in review: Caecal intubation rate, caecal intubation time, Pain during procedure</p> <p>Excluded from review: Difficulty of insertion.</p> |
| Notes | <p>Location: Omigawa Hospital, Chiba, Japan</p> <p>Source of funding: Not stated</p> <p>Attempts to clarify information: attempts made to contact authors for raw data on caecal intubation time.</p> <p>Language of Publication: English</p> |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|--|
| Random sequence generation (selection bias) | Unclear risk | "randomly allocated" |
| Allocation concealment (selection bias) | High risk | Not stated |
| Blinding (performance bias and detection bias) | High risk | Single blinded (to patient) but not to endoscopist |

Shida 2008 (Continued)

All outcomes

| | | |
|--|--------------|-------------------------------|
| Incomplete outcome data (attrition bias) All outcomes | High risk | None identified |
| Selective reporting (reporting bias) | Low risk | Appropriate outcomes assessed |
| Other bias | Unclear risk | Source of funding not stated |

Tada 1997

| | |
|---------------|--|
| Methods | <p>Generation of allocation sequence: "Randomly allocated".</p> <p>Allocation concealment: Not stated.</p> <p>Blinding: Unblinded to endoscopist. Blinded to patient.</p> <p>Inclusion of all randomised patients: All randomised patients were included in data analysis.</p> |
| Participants | <p>Number: 140</p> <p>Age: 61.1 +/- 10.5 years in Group 1, 59.1 +/- 11.5 years in Group 2</p> <p>Source: Patients attending for screening colonoscopy at First Department of Surgery, Tokyo Medical and Dental University, Japan.</p> <p>Inclusion criteria: All patients recommended to undergo screening colonoscopy at this unit.</p> <p>Exclusion criteria: No previous abdominal surgery.</p> |
| Interventions | <p>Screening colonoscopy was undertaken with an Olympus optical-core colonoscope or an Olympus optical-core colonoscope with a 10mm transparent plastic cap (17mm outer diameter, 2mm wall thickness and 10mm in length).</p> |
| Outcomes | <p>Included in review: Caecal intubation time, Polyp detection rate and Pain during procedure.</p> <p>Excluded from review: Endoscopic Mucosal resection of flat lesions vs strip biopsy.</p> |
| Notes | <p>Location: First department of Surgery, Tokyo Medical and Dental University</p> <p>Source of funding: Not stated</p> <p>Attempts to clarify information: not required</p> <p>Language of Publication: English</p> |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|-----------------------|
| Random sequence generation (selection bias) | Unclear risk | "randomly assigned" |
| Allocation concealment (selection bias) | High risk | Not stated |

Tada 1997 (Continued)

| | | |
|--|--------------|---|
| Blinding (performance bias and detection bias) All outcomes | High risk | Single blinded (to patient not endoscopist) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | None |
| Selective reporting (reporting bias) | Unclear risk | Caecal intubation rate was not reported |
| Other bias | Unclear risk | Source of funding not described |

Tee 2010

| | |
|---------------|---|
| Methods | <p>Generation of allocation sequence: Computer generated</p> <p>Allocation concealment: Not stated but unblinded to endoscopists</p> <p>Blinding: Single blinding</p> <p>Inclusion of all randomised patients: Yes</p> |
| Participants | <p>Number: 400 (190M:210F)</p> <p>Age: CAC group 53.8 +/- 15.1 years. Standard group 53.6 +/- 14.8 years.</p> <p>Source: A tertiary referral hospital - Royal Prince Alfred Hospital Sydney, Australia.</p> <p>Inclusion criteria: All patients referred to the endoscopy service for colonoscopy, aged over 18 years.</p> <p>Exclusion criteria: Prior colonic resection, pregnancy, severe co-morbidities, acute surgical conditions, acute GI bleeding, inability to provide consent.</p> |
| Interventions | <p>Colonoscopes: CF-Q160AL, CF-Q180AL, PCF-180AL, PCF-160AL (Olympus Optical Co., Tokyo, Japan).</p> <p>Bowel Preparation: Clear fluid diet the day before with either sodium picosulfate (Pcioprep, Pharmatel Fresenius Kabi Pty Ltd, Hornby, Australia) or sodium-phosphate (Fleet, Ferring Pharmaceuticals, Gordon, Australia) and fasting for 8 hours.</p> <p>Intra-procedure medication: IV Midazolam (Pfizer, Bentley, Australia), Fentanyl (Mayre Pharma Ltd, Mulgrave, Australia) and Propofol (Fresofol 1%; Pharmatel Fresenius Kabi Pty Ltd.) +/- antispasmodic with hyoscine butyl bromide.</p> <p>Endoscopist: 5 consultants and 10 trainees.</p> <p>Caps: 3 sizes of cap (different diameters for each scope - 15.3mm, 14.6mm and 13.0mm) all protruding 4mm: D-201-15004, D-201-14304, D-201-12704 (Olympus Medical Systems, Tokyo, Japan).</p> |
| Outcomes | <p>Included in review: Caecal intubation rate, caecal intubation time, Polyp detection.</p> <p>Excluded from review: Complications</p> |
| Notes | <p>Location: Australia</p> <p>Source of funding: Not stated</p> <p>Attempts to clarify information: Not required</p> |

Tee 2010 (Continued)

Language of Publication: English

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|--|--------------------|---|
| Random sequence generation (selection bias) | Low risk | Computer generated |
| Allocation concealment (selection bias) | High risk | Not stated but not blinded to endoscopist |
| Blinding (performance bias and detection bias) All outcomes | High risk | Not stated but not blinded to endoscopist |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | All patients included in analysis |
| Selective reporting (reporting bias) | Low risk | All relevant outcomes reported. |
| Other bias | Unclear risk | Source of funding not stated. |

Characteristics of excluded studies [ordered by study ID]

| Study | Reason for exclusion |
|---------------|---|
| Dafnis 2000 | This was a pilot study and not a randomised controlled trial. |
| Horiuchi 2010 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Hyun 2010 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Hyun 2010a | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Inoue 2008 | Not a randomised controlled trial comparing standard colonoscopy with cap-assisted colonoscopy. |
| Jeong 2010 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Jung 2011 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |

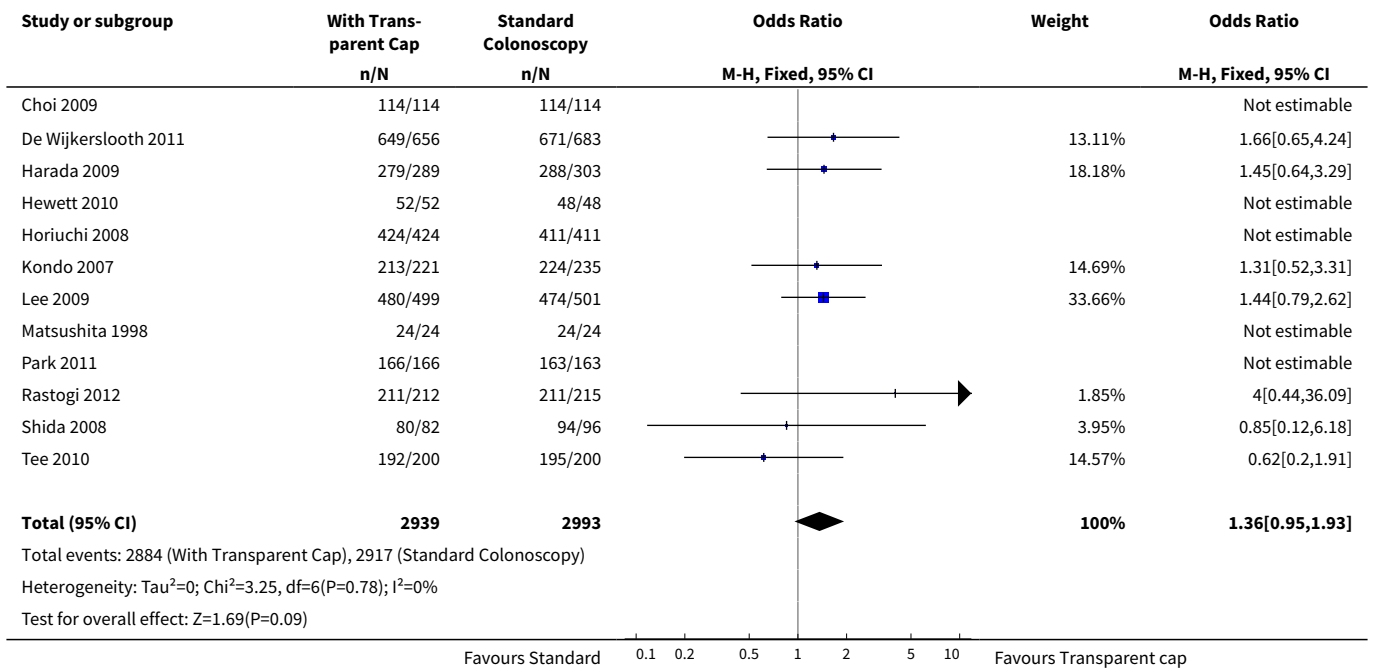
| Study | Reason for exclusion |
|-------------------------------|---|
| Lee 2011 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Mamula 2011 | Not a randomised controlled trial. |
| Moon 2008 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Nakamura 2011 | Not a randomised controlled trial comparing standard colonoscopy with transparent-cap fitted colonoscopy. |
| Park SH 2011 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Sato 2009 | Comparison between an oblique transparent cap colonoscope and magnetic endoscope imaging (MEI): not a randomised controlled trial comparing standard colonoscopy with transparent-cap fitted colonoscopy. |
| Takano 2008 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Tee 2009 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Thomas 2011 | Conference abstract only. Data not reported in full. No information regarding quality issues available in publication. Efforts made to find contact details in order to obtain further data but not found. Recommendation: await full publication of results. |
| Yeung 2011 | Not a randomised controlled trial. |

DATA AND ANALYSES

Comparison 1. Caecal Intubation Rate

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--|----------------|---------------------|---------------------------------|-------------------|
| 1 Total Successful Intubation Rate | 12 | 5932 | Odds Ratio (M-H, Fixed, 95% CI) | 1.36 [0.95, 1.93] |

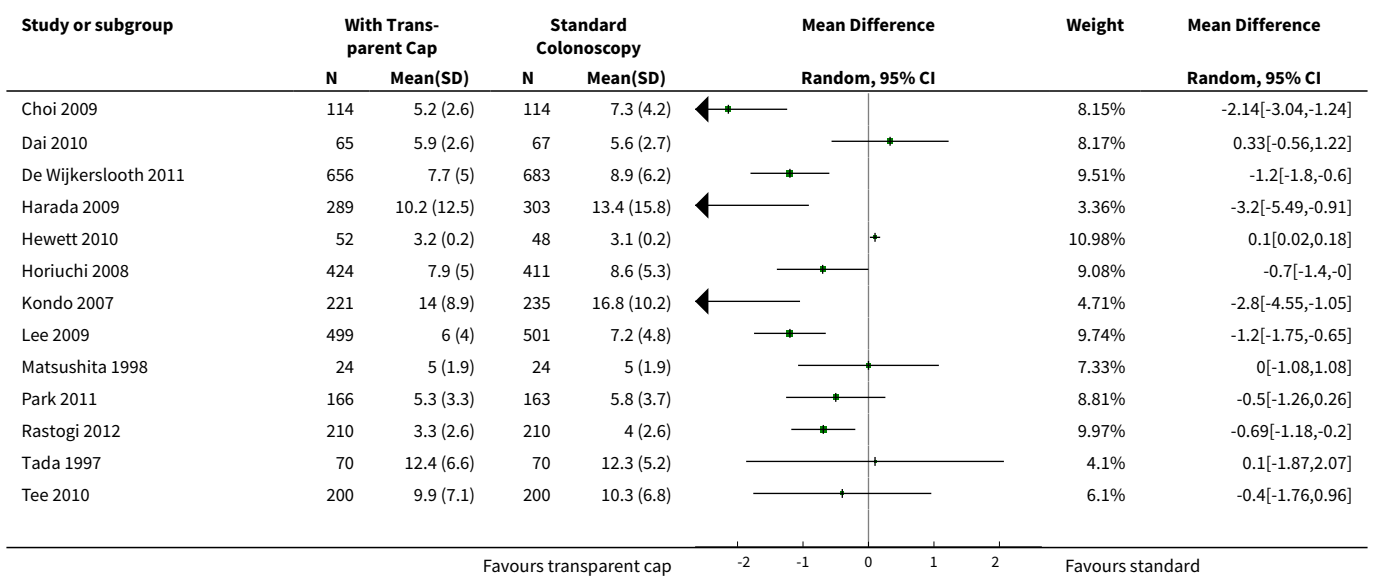
Analysis 1.1. Comparison 1 Caecal Intubation Rate, Outcome 1 Total Successful Intubation Rate.

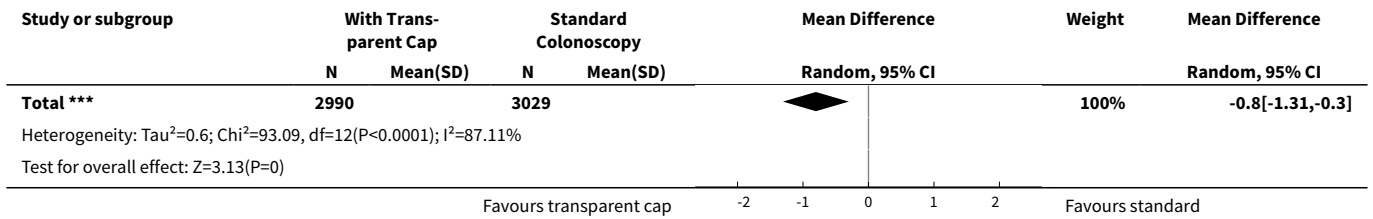


Comparison 2. Caecal Intubation Time

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--------------------------------|----------------|---------------------|--------------------------------------|----------------------|
| 1 Total Caecal Intubation Time | 13 | 6019 | Mean Difference (IV, Random, 95% CI) | -0.80 [-1.31, -0.30] |

Analysis 2.1. Comparison 2 Caecal Intubation Time, Outcome 1 Total Caecal Intubation Time.





APPENDICES

Appendix 1. Medline search strategy

JMO 078 Medline 26.11.08

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. humans.sh.
11. 10 and 9
12. ((colorectal or colonic or colon or rectal or anus) adj3 (cancer or neoplasm* or carcinom* or tumor* or tumour* or polyp* or adenom*)).tw.
13. (bowel condition* or polyp*).tw.
14. exp Colonic Neoplasms/ or exp Colorectal Neoplasms/ or exp Adenoma/ or exp Colonoscopy/ or exp Rectal Neoplasms/
15. 13 or 12 or 14
16. colorectal cancer screening.tw.
17. (video capsule endoscopy or transparent cap-fitted colonoscopy or Push enteroscopy).mp. or wireless capsule endoscopy.tw. [mp=title, original title, abstract, name of substance word, subject heading word]
18. (standard colonoscopy or conventional colonoscopy).mp. or traditional colonoscopy.tw. [mp=title, original title, abstract, name of substance word, subject heading word]
19. 18 or 16 or 17
20. 11 and 19 and 15
21. from 20 keep 1-457

MEDLINE (Ovid) 20.12.11 – 58 hits (2008-2011)

1. exp Colonoscopy/

2. exp Colonoscopes/
3. colonoscop*.mp.
4. 1 or 2 or 3
5. exp Endoscopy, Gastrointestinal/
6. exp Colon/
7. 5 and 6
8. (endoscop* and colon*).mp.
9. 4 or 7 or 8
10. (transparent or hood* or cap*).mp.
11. 9 and 10
12. randomized controlled trial.pt.
13. controlled clinical trial.pt.
14. randomized.ab.
15. placebo.ab.
16. clinical trial.sh.
17. randomly.ab.
18. trial.ti.
19. 12 or 13 or 14 or 15 or 16 or 17 or 18
20. humans.sh.
21. 19 and 20
22. 11 and 21

Appendix 2. EMBASE search strategy

JMO 078 Embase 26.11.08

1. (((((random\$ or factorial\$ or crossover\$ or cross over\$ or placebo\$ or doubl\$) adj blind\$) or singl\$) adj blind\$) or assign\$ or allocat\$ or volunteer\$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
2. crossover procedure/
3. Randomized Controlled Trial/
4. single blind procedure/
5. Double Blind Procedure/
6. 1 or 2 or 3 or 4 or 5
7. ((colorectal or colonic or colon or rectal or anus) adj3 (cancer or neoplasm* or carcinom* or tumor* or tumour* or polyp* or adenom*)).tw.
8. (bowel condition* or polyp*).tw.
9. exp colorectal cancer/ or exp colorectal carcinoma/ or exp rectum carcinoma/
10. 8 or 7 or 9
11. colorectal cancer screening.tw.

12. (video capsule endoscopy or transparent cap-fitted colonoscopy or Push enteroscopy).mp. or wireless capsule endoscopy.tw. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]

13. (standard colonoscopy or conventional colonoscopy).tw.

14. 11 or 13 or 12

15. 6 and 10 and 14

16. from 15 keep 1-129

EMBASE (Ovid) 20.12.11 – 235 hits (2008-2011)

1. exp colonoscopy/

2. exp colonoscope/

3. colonoscop*.mp.

4. 1 or 2 or 3

5. gastrointestinal endoscopy/

6. colon/

7. 5 and 6

8. (endoscop* and (colon* or colorect*)).m_titl.

9. 4 or 7 or 8

10. (transparent or hood* or cap*).mp.

11. 9 and 10

12. randomized controlled trial/

13. randomization/

14. controlled study/

15. multicenter study/

16. phase 3 clinical trial/

17. phase 4 clinical trial/

18. double blind procedure/

19. single blind procedure/

20. ((singl* or doubl* or trebl* or tripl*) adj (blind* or mask*)).ti,ab.

21. (random* or cross* over* or factorial* or placebo* or volunteer*).ti,ab.

22. 17 or 14 or 18 or 20 or 13 or 19 or 15 or 12 or 21 or 16

23. "human*".ti,ab.

24. (animal* or nonhuman*).ti,ab.

25. 24 and 23

26. 24 not 25

27. 22 not 26

28. 11 and 27

WHAT'S NEW

| Date | Event | Description |
|-----------------|--|---|
| 2 November 2012 | New citation required but conclusions have not changed | Nine more studies added this update of the review first published in 2011 issue 2 |
| 1 October 2012 | New search has been performed | Nine new RCTs were included in this updated review. |

CONTRIBUTIONS OF AUTHORS

| | |
|--------------------------------|----------------------|
| Draft the protocol | JM, KT, HLR, RLN |
| Develop a search strategy | JM, KT, HLR, RLN |
| Search for trials | JM, SB, KT, HLR, RLN |
| Select which trials to include | JM, SB, KT, HLR, RLN |
| Extract data from trials | JM, SB, KT, HLR, RLN |
| Enter data into RevMan | JM |
| Carry out the analysis | JM, KT |
| Interpret the analysis | JM, KT |
| Draft the final review | JM, SB, KT, HLR, RLN |

DECLARATIONS OF INTEREST

None

NOTES

None

INDEX TERMS

Medical Subject Headings (MeSH)

Adenoma [*diagnosis]; Cecum; Colonoscopes [*standards]; Colonoscopy [adverse effects] [*methods]; Equipment Design; Intestinal Neoplasms [*diagnosis]; Intestinal Polyps [*diagnosis]; Intubation, Gastrointestinal [*methods]; Randomized Controlled Trials as Topic; Time Factors

MeSH check words

Humans