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# Trocar types in laparoscopy (Review)

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[Intervention Review]

# Trocar types in laparoscopy

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## ABSTRACT

### Background

Laparoscopic surgery has led to great clinical improvements in many fields of surgery; however, it requires the use of trocars, which may lead to complications as well as postoperative pain. The complications include intra-abdominal vascular and visceral injury, trocar site bleeding, herniation and infection. Many of these are extremely rare, such as vascular and visceral injury, but may be life-threatening; therefore, it is important to determine how these types of complications may be prevented. It is hypothesised that trocar-related complications and pain may be attributable to certain types of trocars. This systematic review was designed to improve patient safety by determining which, if any, specific trocar types are less likely to result in complications and postoperative pain.

### Objectives

To analyse the rates of trocar-related complications and postoperative pain for different trocar types used in people undergoing laparoscopy, regardless of the condition.

### Search methods

Two experienced librarians conducted a comprehensive search for randomised controlled trials (RCTs) in the Menstrual Disorders and Subfertility Group Specialised Register, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, PsycINFO, CINAHL, CDSR and DARE (up to 26 May 2015). We checked trial registers and reference lists from trial and review articles, and approached content experts.

### Selection criteria

RCTs that compared rates of trocar-related complications and postoperative pain for different trocar types used in people undergoing laparoscopy. The primary outcomes were major trocar-related complications, such as mortality, conversion due to any trocar-related adverse event, visceral injury, vascular injury and other injuries that required intensive care unit (ICU) management or a subsequent surgical, endoscopic or radiological intervention. Secondary outcomes were minor trocar-related complications and postoperative pain. We excluded trials that studied non-conventional laparoscopic incisions.

**Data collection and analysis**

Two review authors independently conducted the study selection, risk of bias assessment and data extraction. We used GRADE to assess the overall quality of the evidence. We performed sensitivity analyses and investigation of heterogeneity, where possible.

**Main results**

We included seven RCTs (654 participants). One RCT studied four different trocar types, while the remaining six RCTs studied two different types. The following trocar types were examined: radially expanding versus cutting (six studies; 604 participants), conical blunt-tipped versus cutting (two studies; 72 participants), radially expanding versus conical blunt-tipped (one study; 28 participants) and single-bladed versus pyramidal-bladed (one study; 28 participants). The evidence was very low quality: limitations were insufficient power, very serious imprecision and incomplete outcome data.

**Primary outcomes**

Four of the included studies reported on visceral and vascular injury (571 participants), which are two of our primary outcomes. These RCTs examined 473 participants where radially expanding versus cutting trocars were used. We found no evidence of a difference in the incidence of visceral (Peto odds ratio (OR) 0.95, 95% confidence interval (CI) 0.06 to 15.32) and vascular injury (Peto OR 0.14, 95% CI 0.0 to 7.16), both very low quality evidence. However, the incidence of these types of injuries were extremely low (i.e. two cases of visceral and one case of vascular injury for all of the included studies). There were no cases of either visceral or vascular injury for any of the other trocar type comparisons. No studies reported on any other primary outcomes, such as mortality, conversion to laparotomy, intensive care admission or any re-intervention.

**Secondary outcomes**

For trocar site bleeding, the use of radially expanding trocars was associated with a lower risk of trocar site bleeding compared to cutting trocars (Peto OR 0.28, 95% CI 0.14 to 0.54, five studies, 553 participants, very low quality evidence). This suggests that if the risk of trocar site bleeding with the use of cutting trocars is assumed to be 11.5%, the risk with the use of radially expanding trocars would be 3.5%. There was insufficient evidence to reach a conclusion regarding other trocar types, their related complications and postoperative pain, as no studies reported data suitable for analysis.

**Authors' conclusions**

Data were lacking on the incidence of major trocar-related complications, such as visceral or vascular injury, when comparing different trocar types with one another. However, caution is urged when interpreting these results because the incidence of serious complications following the use of a trocar was extremely low. There was very low quality evidence for minor trocar-related complications suggesting that the use of radially expanding trocars compared to cutting trocars leads to reduced incidence of trocar site bleeding. These secondary outcomes are viewed to be of less clinical importance.

Large, well-conducted observational studies are necessary to answer the questions addressed in this review because serious complications, such as visceral or vascular injury, are extremely rare. However, for other outcomes, such as trocar site herniation, bleeding or infection, large observational studies may be needed as well. In order to answer these questions, it is advisable to establish an international network for recording these types of complications following laparoscopic surgery.

## PLAIN LANGUAGE SUMMARY

**Complications of trocar types for laparoscopic surgery**

**Review question**

Laparoscopy is a modern operative technique to perform abdominal (belly) surgery through small incisions in the skin. Specific instruments, called trocars, are used to gain access to the abdominal organs through the skin. We reviewed the evidence to find out whether the use of different types of trocar for laparoscopic surgery leads to fewer complications and less pain in the first month following surgery.

**Background**

In laparoscopic surgery, trocars are needed to seal the skin openings, while permitting entry and removal of the surgical instruments. The introduction of trocars through the skin into the abdominal cavity is usually safe, yet, in a small minority of people, life-threatening

complications can occur. The two most serious complications are puncture into a large blood vessel (occurs 0.9 times per 1000 operations) and puncture into abdominal organs (e.g. the intestine, stomach or liver) (occurs 1.8 times per 1000 operations). Less serious but more frequent complications include bleeding or infection of the skin at the trocar insertion site. Also, the degree of pain following laparoscopy could depend on the type of trocar used. It is unclear whether specific trocar types are less likely to be associated with complications and postoperative pain.

**Study characteristics**

We identified seven randomised controlled studies (clinical studies where people are randomly put into one of two or more treatment groups) that compared two or more different trocar types in 654 people undergoing laparoscopy. The evidence is current to May 2015.

**Key results**

From the data available in these studies, there appears to be no advantage from one trocar type over another for serious complications, which include visceral and vascular injury. However, caution is urged when interpreting these results because very few cases were identified for these types of complications.

**Quality of the evidence**

Most of our results are based on very low quality evidence, mostly due to the limited number of studies identified and low number of complications. Therefore, no specific trocar type can be recommended over another for laparoscopic surgery.

## SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

**Radially expanding trocars compared to cutting trocars for laparoscopy**

**Patient or population:** people undergoing laparoscopy
**Settings:** surgical
**Intervention:** radially expanding trocars
**Comparison:** cutting trocars

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Assumed risk | Corresponding risk | | | | |
| | Cutting trocars | Radially expanding trocars | | | | |
| **Visceral injury** | **4 per 1000** | **4 per 1000** (0 to 60) | **OR 0.95** (0.06 to 15.32) | 473 (4 studies) | ⊕◯◯◯ **very low**[1,2] | - |
| **Vascular injury** | **4 per 1000** | **1 per 1000** (0 to 28) | **OR 0.14** (0.00 to 7.16) | 473 (4 studies) | ⊕◯◯◯ **very low**[1,2] | - |
| **Trocar site herniation** Follow-up: 6-46 months | No events reported | No events reported | Not estimable[3] | 463 (4 studies) | ⊕◯◯◯ **very low**[2,4] | - |
| **Trocar site bleeding** | **115 per 1000** | **35 per 1000** (18 to 66) | **OR 0.28** (0.14 to 0.54) | 553 (5 studies) | ⊕◯◯◯ **very low**[2,4] | - |
| **Trocar site haematoma**[5] | See comment[5] | See comment[5] | Not estimable[5] | 238 (2 studies) | ⊕◯◯◯ **very low**[2,4] | - |
| **Postoperative pain**[6] | See comment[6] | See comment[6] | Not estimable[6] | 306 (4 studies) | See comment[6] | - |

*The basis for the **assumed risk** is the *mean control group risk* across studies. 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] Downgraded one level due to high risk of attrition bias.
[2] Downgraded two levels due to imprecision: the number of events was fewer than 300 (the threshold rule-of-thumb value).
[3] No events reported.
[4] Downgraded one level due to risk of bias: in all included studies, high risk of performance bias, due to differences between groups for fascial closure or other types of port manipulation. Method of assessment mostly unclear.
[5] Data could not be pooled because of clinical heterogeneity.
[6] All studies provided insufficient statistical data, making it inappropriate to pool the data.

# BACKGROUND

## Description of the condition

Surgery is by nature invasive and inevitably associated with complications and trauma. Laparoscopic surgery, also known as minimally invasive surgery, was developed to minimise surgical trauma as opposed to the open abdominal surgical technique (i.e. laparotomy). A laparoscopic procedure is an abdominal or pelvic operation conducted through small incisions in the abdominal wall. In gynaecology, laparoscopy began in the late 1970s and was primarily used for diagnostic procedures. The first widely accepted laparoscopic procedure was tubal ligation (Hulka 1977). Thereafter, gynaecological surgeons began to explore other applications, including diagnostic procedures for pelvic pain and ectopic pregnancy. In the early 1980s, additional operative procedures were introduced including adnexal surgery, uterine myomectomy and hysterectomy (DeSimone 2008). Less visible scarring, less postoperative pain and rapid recovery have fuelled patient advocacy and enabled an increasing use of laparoscopy. For healthcare providers, laparoscopy has the benefit of shorter hospital stays and thus reduced inpatient costs. The benefits for the surgeon include the magnified optics and no-touch operative technique (Ahmad 2015; DeSimone 2008). There is indeed evidence that laparoscopy has advantages compared to laparotomy, which include fewer surgical injuries, fewer postoperative complications, less postoperative pain and shorter hospital stays (Kulier 2004; Medeiros 2009; Metwally 2012). At present, with advanced laparoscopic operations for pelvic organ prolapse, urinary incontinence and gynaecological cancers, laparoscopy has become completely integrated into the field of gynaecologic surgery. In general surgery and urology, laparoscopy is increasingly being used for different purposes as well.

## Description of the intervention

The first step in a laparoscopic procedure involves the introduction of a primary instrument (i.e. a Veress needle or trocar) followed by the insufflation of carbon dioxide into the peritoneal cavity. This is called the primary entry, which is applied to create a pneumoperitoneum. Different primary entry techniques are used in practice. Ahmad et al. performed a Cochrane review on laparoscopic entry techniques and compared the different techniques in terms of their influence on intraoperative and postoperative complications (Ahmad 2015). They found no evidence of benefit in terms of safety of one technique over another.

Intraperitoneal access for laparoscopic instruments is provided via 'ports'. Specific cannulas, called trocars, are introduced through the abdominal wall to create these ports. A distinction needs to be made between primary and secondary trocar ports. The first port for primary entry is located in or near the umbilicus. This port is used for the introduction of the laparoscope. Secondary or ancillary ports are intended for the introduction of laparoscopic instruments. The secondary port locations depend upon the location in the abdomen where the surgical procedure is to take place. In general, a minimum of two secondary ports are created. The trocars are placed to facilitate operating in line with the camera while maintaining a comfortable operating position for the surgeon with triangulation of the instruments around the surgical focal point within the abdomen.

The rapid evolution of instrumentation has led to the development of new minimally invasive techniques such as natural orifice transluminal endoscopic surgery (NOTES), laparo-endoscopic single-site surgery (LESS) and mini laparoscopy. NOTES refers to surgery via natural orifices, where procedures are performed with transluminally placed instruments to gain access to the abdominal cavity. Transvaginal, transanal, transvesical, transoesophageal, transgastric and transoral approaches for NOTES are described (Moris 2012). LESS surgery is an advanced minimally invasive approach that allows laparoscopic operations to be undertaken through a single small (12 mm to 15 mm) incision, typically placed at the person's umbilicus (Rao 2011). Mini laparoscopy involves the use of smaller incisions, smaller instruments and fewer ports to reduce perioperative morbidity further and enhance cosmesis. Other terms for mini laparoscopic surgery include mini port or micro laparoscopic surgery (Thakur 2011). NOTES, LESS and mini laparoscopy are in their early stages of development. NOTES, LESS and mini laparoscopy are not included in this review since these techniques are different from traditional laparoscopy.

## How the intervention might work

Trocar designs include a myriad of device designs, including over 100 brands from more than 20 manufacturers (Fuller 2003). There is a distinction between reusable and disposable trocars. Reusable trocars are made of metal and have a perforator tip. Completely blunt trocars, with a cone-shaped perforator tip, and sharp or cutting trocars with a conical, pyramidal, triflanged or excentric tip can be differentiated. Disposable trocars are made of plastic materials and are provided with bladed or blade-less tips. Shielded disposable trocars have a retractable shield that covers the tip before and after insertion. Dilatation systems represent yet another technical alternative in trocar techniques. These trocars are equipped with a radially expanding sleeve that can be dilated from 5 mm to 12 mm in diameter. This radially expanding access (REA) trocar was developed to minimise tissue trauma and, in theory, its use would result in fewer vascular and visceral injuries. Optical access trocars allow laparoscopists to view the cutting tip as it penetrates the tissues. Many other different trocar designs are described, for example trocars with a threaded sleeve or an expandable arm (Fuller 2005; Leibl 2001; Ternamian 1998; Vilos 2007). The diameters of trocars vary from 2 mm to 12 mm, depending on the largest instrument needed for a particular port. For exceptional indica-

tions (e.g. extirpation of large cysts) larger or modified trocars are available (Leibl 2001).

## Why it is important to do this review

Laparoscopic trocars are the most common device named in malpractice injury claims associated with laparoscopic procedures, representing one-third of all claims (Fuller 2005). The incidence is estimated to be 3 to 4 per 1000 procedures (Cardin 2011; Champault 1996). Trocar-related complications represent all types of complications due to the contribution of the trocar, including intra-abdominal vascular injury, intra-abdominal visceral injury, trocar site bleeding, trocar site herniation and trocar site infection. Of all trocar-related complications, vascular and visceral injuries are associated with the highest morbidity and mortality (Jansen 1997). By inserting a trocar, the trocar tip can damage abdominal wall vessels (e.g. the epigastric artery), intra-abdominal vessels (e.g. the aorta, vena cava, iliac artery or iliac vein) or visceral organs (e.g. bowel, stomach and bladder). Although vascular injury is often noticed directly during laparoscopy, bowel injuries are more likely to go undetected during the procedure (Fuller 2005). When vascular or visceral injury occurs, additional surgical intervention is often required. Cardin et al. reported vascular and visceral injuries in 51 out of 4007 (1.3%) people undergoing a laparoscopic procedure. At least 14 (27.5%) of these people required a subsequent surgical, endoscopic or radiological intervention under general anaesthesia (Cardin 2011). Mortality is reported occasionally after vascular or visceral injury (Cardin 2011; Jansen 2004).

An important postoperative trocar-related complication is trocar site herniation. A trocar site hernia (TSH) is a protrusion of intestine or omentum through a remaining defect in the peritoneum, abdominal fascia or musculature at the trocar insertion site. TSHs occur postoperatively, which can vary from shortly following surgery to several years postoperation. Whereas TSH is uncommon, with an estimated prevalence of 0.5% in people operated on laparoscopically, it is a potentially serious complication. People with TSH may require emergency re-operation for bowel obstruction or strangulation (Swank 2012). Less severe trocar-related complications are trocar site bleeding, trocar site infection and pain. Although pain is not always classified as a complication, it is considered clinically important and is an indicator for recovery.

The use of trocars inevitably leads to risks of trocar-related complications. Major complications such as vascular and visceral injury can have serious consequences including conversion from laparoscopy to laparotomy, other invasive interventions, medical therapies and prolonged hospitalisation. When discovered postoperatively, occasionally emergency or revision surgery is required, resulting in longer hospital stay or re-admission and additional costs. Minor complications might also result in the need for additional pharmacological treatment and compromise postoperative recovery. All these deviations from a normal intra- and postoperative course after laparoscopy potentially have a negative effect on people's quality of life and satisfaction.

A difference in trocar-related complications may be attributable to different types of trocars and the experience of the surgeon according to the trocar type. The Cochrane review from Ahmad et al. studied different trocar systems. They found eight randomised controlled trials (RCTs) where different trocar designs were compared. In four RCTs, REA trocars were compared with standard trocars. One meta-analysis demonstrated fewer trocar site bleeding episodes when using REA trocars compared to standard trocars for the primary laparoscopic entry (Ahmad 2015). Two RCTs compared cutting trocars to blunt trocars for primary and secondary port insertion, and there was no difference in any type of complication. Two RCTs compared the REA trocar to a conventional cutting tip trocar for secondary port entry. REA trocars were associated with lower rates of trocar site bleeding compared to standard secondary port trocars. Our review differs from Ahmad et al. in that we searched for differences in the outcome of postoperative pain. Specific types of trocars could relate to higher or lower risks on any of the trocar-related complications or for postoperative pain. The sharpness of disposable cutting trocars is usually better compared to that of reusable cutting trocars. This sharpness of disposable trocars facilitates smooth insertion. Reusable trocars do lose their sharpness through repetitive insertion. Reusable trocars require a relatively high puncture force for penetration through the abdominal wall. Increased entry force could result in an abrupt and uncontrolled introduction of the trocar that may result in a deeper penetration and potential serious visceral and vascular injury (Tansatit 2006). The cutting trocar mechanism of sharp trocars may result in occasional bleeding from the trocar port. Conical blunt-tipped trocars are designed to stretch, rather than cut, the abdominal wall to enable port placement. The use of conical reusable trocars compared to sharp cutting disposable trocars was associated with fewer trocar-related bleeding events and TSHs in one non-randomised prospective study (Leibl 1999). A larger trocar diameter creates a larger defect in the abdominal wall and potentially results in an increased risk of trocar site herniation. In 1993, one retrospective study demonstrated an increased risk of trocar site herniation when trocars with a diameter of 12 mm were used compared to 10 mm (Kadar 1993).

This Cochrane review aimed to determine whether specific trocar designs can be recommended for use in people undergoing laparoscopy, with a goal to minimise trocar-related complications and postoperative pain.

# OBJECTIVES

To analyse the rates of trocar-related complications and postoperative pain for different trocar types used in people undergoing laparoscopy, regardless of the condition.

# METHODS

## Criteria for considering studies for this review

### Types of studies

We included only RCTs. We excluded quasi-randomised (e.g. randomised by birth date, chart number, alternating inclusion), cluster randomised studies and studies with a 'split-mouth design'.

### Types of participants

#### Inclusion criteria

We included adults (aged 18 years and older) who underwent elective or emergency diagnostic, therapeutic or mixed laparoscopy for surgical, gynaecological or urological conditions.

#### Exclusion criteria

We excluded animal studies.

### Types of interventions

#### Inclusion criteria

- Studies on different trocar designs used in laparoscopy, performed by surgeons, gynaecologists or urologists.
- Studies on trocars used for both primary and for secondary entry.
- All variations of trocar types, for example, sharp-tipped trocars, blunt-tipped trocars, pyramidal-tipped or conical-tipped trocars, disposable (plastic) trocars, reusable (metal) trocars, trocars with a shielded tip, radially expanding trocars, trocars with a threaded sleeve, an expandable arm or an optical view.

#### Exclusion criteria

- Studies wherein other (than conventional) laparoscopic incisions were made (e.g. single port surgery (single-incision laparoscopic surgery (SILS), LESS), natural orifice surgery (NOTES) and mini laparoscopy).

### Types of outcome measures

#### Primary outcomes

- Major trocar-related complications:
    - mortality;
    - conversion to laparotomy due to any trocar-related adverse event;
    - visceral injury (such as perforation of the intestines or stomach, or injury of the bladder or liver);
    - vascular injury (such as perforation of the aorta, vena cava, iliac artery or iliac vein); and
    - other injuries that required intensive care (IC) or intensive care unit (ICU) management or a subsequent surgical, endoscopic or radiological intervention.

#### Secondary outcomes

- Minor trocar-related complications, such as trocar site herniation, trocar site bleeding or postoperative wound haematoma, trocar site infection, extraperitoneal insufflation and other injuries that did not require IC or ICU management or a subsequent surgical, endoscopic or radiological intervention under general anaesthesia.
- Postoperative pain, expressed on a self reported scale (e.g. visual analogue scale (VAS), numerical rating scale (NRS)).

## Search methods for identification of studies

### Electronic searches

#### Search methods for identification of studies

The clinical librarian (MW) developed a comprehensive literature search strategy in consultation with the Trials Search Co-ordinator of the Cochrane Gynaecology and Fertility Group (formerly Cochrane Menstrual Disorders and Subfertility Group). We based the search strategy on that in the Cochrane Gynaecology and Fertility Group module. We identified the relevant subject indexing terms used within individual databases and added them to the strategy as appropriate. Where databases offered facilities such as truncation, explosion and proximity searching, we used these as appropriate. We focused the searches to the study designs of interest by using RCT search filters. We used no publication or language restrictions.

We searched the following databases:

- Gynaecology and Fertility Group Specialised Register (inception to 26 May 2015) (Appendix 1);
- Ovid Cochrane Central Register of Controlled Trials (CENTRAL) (inception to 26 May 2015) (Appendix 2);
- Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE® (1950 to 26 May 2015) (Appendix 3);
- Ovid EMBASE (January 2010 to 26 May 2015) (Appendix 4);
- Ovid PsycINFO (inception to 26 May 2015) (Appendix 5);

- CINAHL via EBSCO (inception to 26 May 2015) (Appendix 6);
- Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE, Wiley) (inception to 26 May 2015) (Appendix 7).

We used both indexed and free-text terms. The MEDLINE search was combined with the Cochrane highly sensitive search strategy to identify randomised trials (Higgins 2011). The EMBASE and CINAHL searches were combined with trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) (www.sign.ac.uk/mehodology/filters.html#random).

### Searching other resources

We also:

- screened the reference lists of all included studies and systematic reviews pertinent to this topic;
- searched the main electronic sources of ongoing trials, World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch/), Current Controlled Trials ( www.controlled-trials.com/), Clinicaltrials.gov (federally and privately supported clinical trials conducted in the US) and European Clinical Trials database (EudraCT) ( www.clinicaltrialsregister.eu/ctr-search/); and
- searched the US Food and Drug Administration (FDA) website (www.fda.gov/MedicalDevices) and contacted the US FDA by email for regulatory trial data.

## Data collection and analysis

Two review authors (HS and CC) independently performed the selection of studies, risk of bias assessment, and extraction of qualitative and quantitative data. They had a background in surgery (HS), gynaecology and clinical epidemiology (CC). A third review author (FWJ or SMR) acted as arbiter when necessary.

### Selection of studies

We screened the titles and abstracts from the search results and obtained potentially relevant studies in full text and independently assessed them for inclusion. We evaluated full papers, abstracts, proceedings from congresses and any other 'grey literature'. A third review author (FWJ or SMR) resolved disagreements by discussion.

### Data extraction and management

Two review authors (HS and CC) independently extracted data, applying the inclusion and exclusion criteria. We used a pre-defined and tested data selection list. We extracted the methodological details (concealed assignment, technique of randomisation, time of randomisation (pre- or intraoperatively), number of randomised participants, number of participants not randomised with explanation, the presence of blinding) and descriptive study characteristics (e.g. country where the study was conducted, recruitment modality, source of funding), characteristics of the participants (e.g. age, gender, body mass index (BMI), previous abdominal surgery), description of the trocar type and size (diameter), description of the entry method, description of the port creation and closure (desufflation, closure of peritoneum, fascia and skin), co-interventions (e.g. local anaesthetics at trocar sites), and outcomes (types of outcomes, documentation of drop-outs, follow-up, standardisation of outcome assessment, and whether an intention-to-treat analysis was employed), and the authors' results and conclusions. We discussed disagreements and consulted an arbiter (FWJ or SMR) when necessary. We summarised key findings in a narrative format. We extracted the outcome per study. We made a differentiation of outcomes regarding primary trocar ports and secondary trocar ports and differentiated primary port outcomes for open, Veress needle and direct entry methods. We assessed data relating to the defined outcomes for inclusion in the meta-analyses. We extracted final scores for means and measures of variance for continuous outcomes (e.g. VAS) while we extracted the number of participants experiencing an event and the number randomised for adverse events (e.g. incidence of trocar site bleeding).

### Assessment of risk of bias in included studies

We used Cochrane's tool for assessing risk of bias (Higgins 2011, Section 8.5) and produced a 'Risk of bias' summary. We evaluated: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, intention to treat analysis, selective reporting, group similarity at baseline, co-interventions and timing of outcome assessment. We judged for the presence of a 'high', 'low' or 'unclear' risk of bias. When trials appeared to meet the eligibility criteria but aspects of the methodology were unclear or unsuitable for statistical analysis, we contacted the authors of those trials and asked for the additional information. We resolved any disagreements of opinion by discussion, and when necessary we included the input from a third independent review author (FWJ or SMR).

### Measures of treatment effect

We conducted the review using the standard Cochrane software Review Manager 5 (RevMan 2014). For dichotomous data (rates of trocar-related complications), we used the number of events in the control and intervention groups of each study to calculate Peto estimated odds ratios (ORs). The Peto method, which uses an inverse variance approach but utilises an approximate method of estimating the log OR, and uses different weight, works well when intervention effects are small (OR are close to one), events

are not particularly common and the studies have similar numbers in experimental and control groups (Higgins 2011). We expected this would match our findings. For continuous data (pain scales), we planned to calculate mean difference (MDs) between treatment groups. We allowed pain scales other than VAS if we thought that the construct measured was consistent with the evaluated outcome. We would have used standardised mean difference (SMD) instead of MD if studies used multiple scales to measure the same outcome (e.g. VAS and verbal scale). We presented 95% confidence intervals (CIs) for all outcomes.

### Unit of analysis issues

Analysis was per person randomised. We excluded trials where body parts or sites were randomised for trocar introduction.

### Dealing with missing data

To deal with missing data, we planned to use the strategies described in Chapter 16, Section 16.1 (missing data) and Section 16.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). When summary data were missing, we attempted to contact the author. In the absence of additional information, we looked for statistics that allowed calculation or estimation of the standard deviation (e.g. test statistics, P values). When these were not available, we planned that imputation could be reasonable for a small proportion of studies comprising a small proportion of the data if it enabled the data to be combined with other studies for which full data were available, but that was not the case.

We collected and reported drop-out rates in the 'Risk of bias' table. For dichotomous data, we assumed that all missing participants did not experience the event (based on clinical judgement). We could not perform sensitivity analyses to assess how sensitive results were to changes in the drop-out rates since there were too few study data.

### Assessment of heterogeneity

We identified and qualified statistical heterogeneity among the results informally by visual inspection (eye-ball test) and formally by calculating the $I^2$ statistic. The decision regarding heterogeneity was dependent upon the $I^2$ statistic, with a value of 50% or greater indicating substantial heterogeneity. Where $I^2$ was 50% or greater, we did not pool results, but described the effect of the interventions.

### Assessment of reporting biases

We used online trial registers to investigate trials that had not been published. There were not sufficient studies to construct funnel plots to investigate possible publication bias.

### Data synthesis

If studies were sufficiently similar, we planned to combine the data using Peto's method in a fixed-effect model, for the dichotomous outcomes of trocar-related complications. For the continuous outcome pain, we planned to combine data for meta-analysis using a random-effects model. An increase in the odds of a particular outcome, which may be beneficial (e.g. live birth) or detrimental (e.g. adverse effects), is displayed graphically in the meta-analyses to the right of the centre-line and a decrease in the odds of an outcome to the left of the centre-line.

### Subgroup analysis and investigation of heterogeneity

We intended to perform subgroup analyses for type of surgery (e.g. general versus gynaecological versus urological surgery), age groups, gender, obesity, presence of co-morbidities, primary entry technique, secondary entry technique and differing trocar diameters. However, there were insufficient details to extract data about separate participant types.

### Sensitivity analysis

We planned the following sensitivity analyses a priori to determine whether the conclusions were robust to arbitrary decisions made regarding the eligibility of studies and analysis. We considered if conclusions would have differed if:

- eligibility were restricted to studies without high risk of bias: this analysis was not possible because of insufficient data;
- eligibility were restricted to studies with blinded outcome assessment; this analysis was not possible because of insufficient data;
- alternative imputation strategies had been adopted; this analysis was not possible since we could not impute any data;
- a random-effects model had been adopted for meta-analysis of dichotomous data.

### Overall quality of the body of evidence: 'Summary of findings' table

We generated 'Summary of findings' tables for analyses of all primary and secondary outcome measures. When statistical heterogeneity was present, we noted this. We used GRADEpro to prepare the tables (GRADEpro).

We used GRADE (Grading of Recommendations Assessment, Development and Evaluation) to evaluate the overall quality of the evidence and strength of recommendations (Guyatt 2008). We based the quality of evidence for a specific outcome upon performance against five principal domains:

- limitations in design (downgraded when more than 25% of the participants were from studies with a high risk of bias);
- inconsistency of results (downgraded in the presence of substantial statistical heterogeneity ($I^2$ greater than 50%) and

inconsistent findings (in the presence of widely differing estimates of a specific trocar type A versus type B);

- indirectness (i.e. generalisability of the findings; downgraded when a participant-important outcome is represented by a surrogate);
- imprecision (downgraded when the total number of participants was insufficient to determine any significant statistical difference. The required power of a study depended on the questioned outcome);
- other (e.g. publication bias).

The quality of the evidence was defined as:

- high quality: further research is very unlikely to change the estimate of effect or our confidence in it. There were sufficient data with narrow CIs. There were no known or suspected reporting biases;
- moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate; one of the domains was not met;
- 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 it; two of the domains were not met;
- very low quality: great uncertainty about the estimate, three of the domains were not met;
- no evidence: no evidence for this outcome from RCTs.

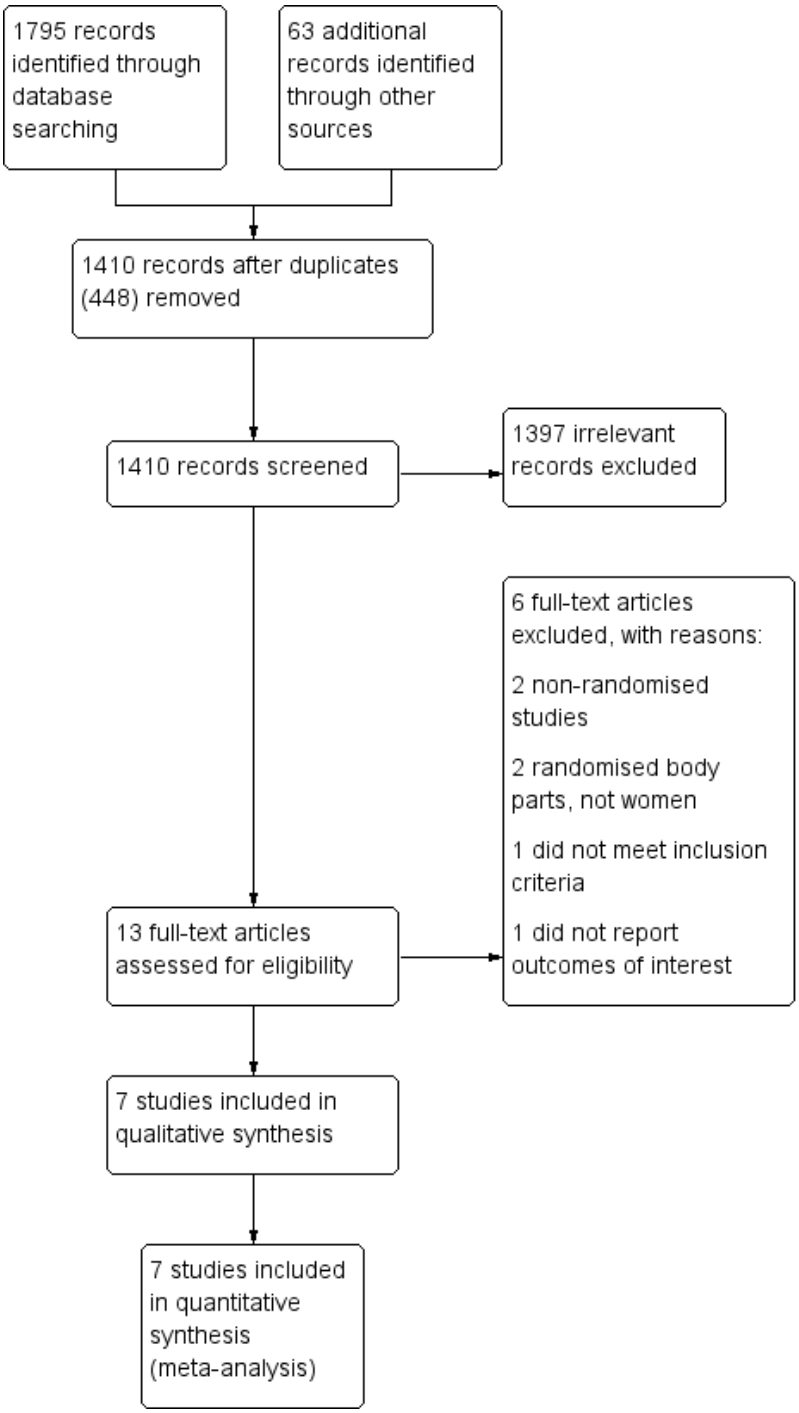
# RESULTS

## Description of studies

### Results of the search

We identified 1858 references of possible interest by searching the Menstrual Disorders and Subfertility Group Specialised Register (31 references), CENTRAL (552 references), MEDLINE (540 references), EMBASE (434 references), PsycINFO (10 references), CINAHL (135 references), Cochrane Database of Systematic Reviews (69 references), DARE (24 references) and other sources (63 references). We excluded 448 duplicates and 1397 clearly irrelevant references by reading the abstracts. Accordingly, we retrieved 13 references for further assessment. Of these, we excluded six references because they were not RCTs or did not fulfil our review protocol inclusion criteria. In total, seven RCTs fulfilled our inclusion criteria (Figure 1).

**Figure 1. Study flow diagram.**



We contacted four study authors to ask for the missing information and received answers from two authors.

## Included studies

The characteristics of the trials are described in detail in the Characteristics of included studies table.

### Trial characteristics

All the included trials randomly assigned participants individually. Three trials were multicentre (Bhoyrul 2000; Feste 2000; Mettler 2000), and four were single centre (Bisgaard 2007; Hamade 2007; Lam 2000; Venkatesh 2007). The trials were published from 2000 to 2007. The trials were conducted in the US (Feste 2000; Venkatesh 2007), Australia (Mettler 2000), China (Lam 2000), the UK (Hamade 2007), Denmark (Bisgaard 2007), and Germany (Feste 2000; Mettler 2000). In one trial the study location was not specified (Bhoyrul 2000). In two trials, the study trocars were supplied free of charge by a pharmaceutical company (Lam 2000; Venkatesh 2007). The other five trials did not report funding.

### Participants

The trials included 654 participants. Sample size ranged from 30 to 250. The age range of participants was from 18 to 80 years. A total of 314 women and 90 men were included; one study did not report sex of the 250 participants (Bhoyrul 2000). Three studies reported a mean or median BMI (Bisgaard 2007; Hamade 2007; Venkatesh 2007), while the other four other studies did not report any data on body mass (Bhoyrul 2000; Feste 2000; Lam 2000; Mettler 2000). Laparoscopic procedures included surgical (405 procedures), gynaecological (187 procedures) and urological (56 procedures). Three studies did not refer to exclusion criteria (Feste 2000; Hamade 2007; Venkatesh 2007). The other trials excluded people on the presence of acute inflammatory conditions (Bhoyrul 2000; Lam 2000; Mettler 2000), and conversion to laparotomy (Bhoyrul 2000; Bisgaard 2007). Exclusion was also based on gallbladder malignancy (Lam 2000), American Society of Anaesthesiologists (ASA) physical class 4, pregnancy, participant age, chronic pain diseases, use of opioids or tranquillisers, foreign language, mental disorder and history of alcoholism or drug abuse (Bisgaard 2007).

### Interventions

Trials compared the following trocar types:

- radially expanding trocar versus cutting trocar: two studies used reusable cutting trocars (Lam 2000; Mettler 2000), three studies used disposable cutting trocars (Bhoyrul 2000; Bisgaard 2007; Venkatesh 2007), and one study used both reusable and disposable cutting trocars were used (Feste 2000);
- conical blunt-tipped versus cutting trocar (Hamade 2007; Venkatesh 2007);
- radially expanding trocar versus conical blunt-tipped trocar (also called axially dilating) (Venkatesh 2007);
- single-bladed trocar versus pyramidal-bladed trocar (Venkatesh 2007).

Three studies did not refer to the diameter of the trocars (Bhoyrul 2000; Feste 2000; Mettler 2000), two studies evaluated 5 mm and 10 mm trocars (Bisgaard 2007; Hamade 2007), one study evaluated 10 mm trocars (Lam 2000) and one study evaluated 12 mm trocars (Venkatesh 2007).

Four studies examined primary entry and secondary entry ports (Bisgaard 2007; Feste 2000; Mettler 2000; Venkatesh 2007), two studies examined secondary ports only (Hamade 2007; Lam 2000), and one study examined primary ports only (Bhoyrul 2000). Primary entry used the Veress needle technique.

### Co-interventions

Two studies reported gallbladder extraction through a port (Bhoyrul 2000; Lam 2000), one study documented the morcellation site, specimen extraction, and hand-assist device site location (Venkatesh 2007). The other studies did not report specimen extraction or other mechanisms of port manipulation. The indications for fascial closure were specified in five studies (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Mettler 2000; Venkatesh 2007), two studies did not report on fascial closure (Hamade 2007; Lam 2000). Intraoperative anaesthesia was not described in five studies (Bhoyrul 2000; Feste 2000; Hamade 2007; Mettler 2000; Venkatesh 2007), two studies reported that the participants received general anaesthesia (Bisgaard 2007; Lam 2000). A standardised postoperative analgesics regimen was mentioned in two studies (Bisgaard 2007; Lam 2000) and in Bisgaard 2007 the amount of postoperative analgesics was clearly specified. Other studies did not report the use of postoperative analgesics.

### Outcomes

Studies reported the following outcome measures.

#### Primary outcomes: major trocar-related complications

- Visceral injury (e.g. perforation of the intestines or stomach, or injury of the bladder or liver) (571 participants) (Bhoyrul 2000; Feste 2000; Mettler 2000; Venkatesh 2007).
- Vascular injury (e.g. perforation of the aorta, vena cava, iliac artery or iliac vein) (571 participants) (Bhoyrul 2000; Feste 2000; Mettler 2000; Venkatesh 2007).

No studies reported mortality, conversion to laparotomy and other injuries that required IC or ICU management or a subsequent surgical, endoscopic or radiological intervention.

**Secondary outcomes: minor trocar-related complications**

- Minor trocar-related complications (trocar site herniation (533 participants), trocar site bleeding (583 participants) or postoperative wound haematoma (161 participants) and trocar site infection (56 participants) (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Hamade 2007; Lam 2000; Mettler 2000; Venkatesh 2007).

- Postoperative pain, expressed on a self reported scale (e.g. VAS, NRS (348 participants) (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Mettler 2000; Venkatesh 2007).

No studies reported measures for extraperitoneal insufflation and other injuries that did not require IC or ICU management or a subsequent surgical, endoscopic or radiological intervention under general anaesthesia.

### Excluded studies

We excluded five studies from the review, for the following reasons (see Characteristics of excluded studies table):

- two were not RCTs (Herati 2011; Huang 2012);
- two had randomised different sites of the abdomen to different trocars ('Split-mouth' design) (Stephanian 2007; Yim 2001);
- one study did not examine the types of outcome measures defined for this review (Tchartchian 2010).

## Risk of bias in included studies

Further quality details about the included studies are provided in the Characteristics of included studies table; the results for risk of bias for the individual studies are summarised in Figure 2, for assessment with GRADE see the 'Summary of findings' tables. See also Figure 3.

**Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

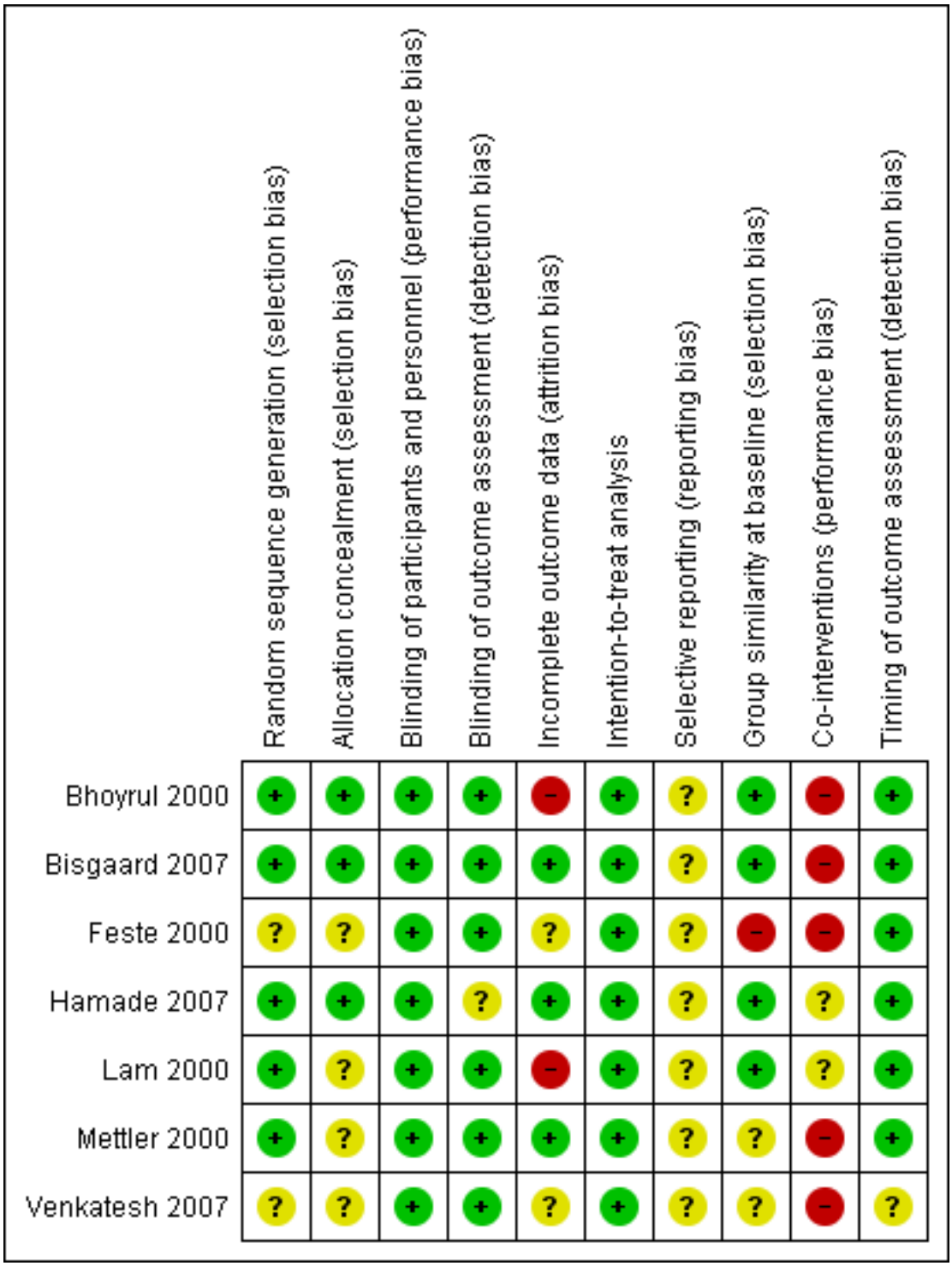
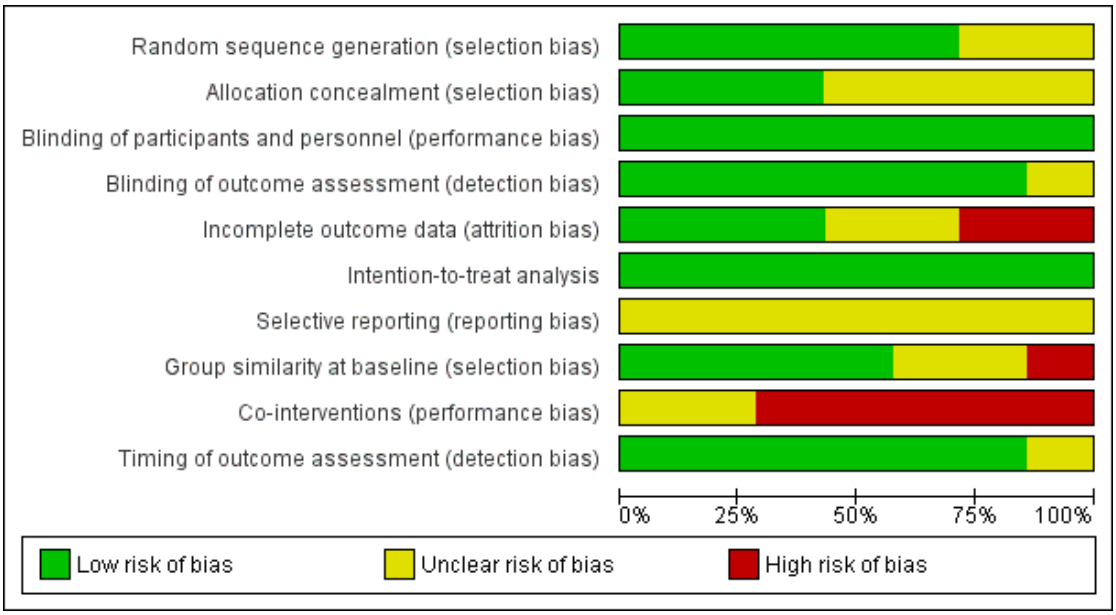


**Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**




## Allocation

### Sequence generation

Five RCTs reported that they used randomisation tables or lists (Bhoyrul 2000; Bisgaard 2007; Hamade 2007; Lam 2000; Mettler 2000). Two RCTs did not describe the method used for sequence generation (Feste 2000; Venkatesh 2007).

### Allocation concealment

Three studies described that their allocation concealment was performed by independent investigators using sealed envelopes (Bhoyrul 2000; Bisgaard 2007; Hamade 2007). The other four studies did not report their method of concealment (Feste 2000; Lam 2000; Mettler 2000; Venkatesh 2007).

## Blinding

There was a low risk of performance bias through blinding issues. Six studies reported that blinding of participants and outcome assessors was well performed. Six studies blinded the participants for the type of trocars used (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Lam 2000; Mettler 2000; Venkatesh 2007). One study did not report details on blinding of participants. This study did not have subjective outcomes that could be influenced by the participant (Hamade 2007). Blinding of the surgical personnel was not applicable in any of the studies. Blinding of the outcome assessors was reported in the six studies that performed participant blinding (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Lam 2000; Mettler 2000; Venkatesh 2007). One study did not report the use of a blinded outcome observer. This study measured objective outcomes only (Hamade 2007).

There was a substantial risk of performance bias through variance in co-interventions in all studies. None of the studies specified the applied degree of port manipulation during the operation, for example for morcellation or extraction of a surgical specimen. Only two authors reported the intra- or postoperatively applied standard analgesics (Bisgaard 2007; Lam 2000). We judged there to be a high risk of performance bias in five of the studies, because of significant differences between study groups in the application of fascial closure (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Mettler 2000; Venkatesh 2007). Two other studies did not provide details

on the application of fascial closure (Hamade 2007; Lam 2000). There was a low risk of detection bias for short-term outcomes. These were all equally assessed between the groups. We rated three studies that performed a long-term assessment of TSH at high risk on detection bias: the duration and completeness of follow-up was unclear or uneven between the studied groups (Bhoyrul 2000; Bisgaard 2007; Venkatesh 2007).

### Incomplete outcome data

We rated two studies at a substantial risk of attrition bias (Bhoyrul 2000; Lam 2000). In one of these studies, data on intraoperative complications, postoperative pain and wound complications (trocar site bleeding and haematoma) were either missing or unclear (Bhoyrul 2000). In the second of these studies, approximately 10% of the laparoscopies in both groups were converted to open surgery and a substantial percentage of outcome data from the radially trocar group was missing (Lam 2000). It remained unclear how they dealt with the missing data and data of converted procedures. We rated two studies at unclear risk of attrition bias, because they did not present the numbers of participants that were excluded for participation (Feste 2000) or analysis (Venkatesh 2007). No loss of data or participants was apparent in the remaining studies and we judged them at a low risk of attrition bias (Bisgaard 2007; Hamade 2007; Mettler 2000). However, loss to follow-up was unclear and thus resulted in a high risk for attrition bias on long-term outcomes (Bisgaard 2007; Mettler 2000).

Six studies applied an intention-to-treat analysis, and analysed all data according to the randomisation result (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Hamade 2007; Lam 2000; Mettler 2000). In one study, unit-of-analysis issues were evident: the trocar sites rather than the participants were analysed (Venkatesh 2007).

### Selective reporting

We judged all included studies at unclear risk of selective reporting. One study had published a study protocol; however, they published it after finishing the study (Hamade 2007). All studies analysed their outcomes as they planned in the methods sections.

### Other potential sources of bias

#### Surgeon's experience

Two trials described the surgeon's as "experienced" (Bisgaard 2007) and "well trained" (Feste 2000). Only one study reported that the surgeons were equally distributed between the two study groups (Bisgaard 2007). The other five studies were unclear about the experience of the surgeons (Bhoyrul 2000; Hamade 2007; Lam 2000; Mettler 2000; Venkatesh 2007). Two studies provided the number of surgeons that had performed the laparoscopies: seven (Feste 2000) and 16 (Bhoyrul 2000). The remaining studies did not report the number of surgeons. This substantial lack of clarity of the number and experience of surgeons created a potential risk of bias. This limits the external validity of the included studies.

#### Source of funding

Two studies reported their sources of funding. Lam 2000 received all radially trocars from Kojima Healthcare Asia Ltd; Venkatesh 2007 received all the trocars used in the study from manufacturing companies.

## Effects of interventions

See: **Summary of findings for the main comparison** Radially expanding trocars compared to cutting trocars for laparoscopy; **Summary of findings 2** Conical blunt-tipped trocar compared to cutting trocar for laparoscopy; **Summary of findings 3** Radially expanding trocar compared to conical blunt-tipped trocar for laparoscopy; **Summary of findings 4** Single-bladed trocar compared to pyramidal-bladed trocar for laparoscopy

### 1. Radially expanding trocar versus cutting trocar

#### Primary outcomes: major trocar-related complications

##### 1.1 Visceral injury

Four studies with 473 participants provided data for analysis of visceral injury (Bhoyrul 2000; Feste 2000; Mettler 2000; Venkatesh 2007). One study reported two cases of visceral injury, one in each group (Bhoyrul 2000). The combined results from the four trials showed no evidence of a difference in visceral injury between the use of the two trocars (Peto OR 0.95, 95% CI 0.06 to 15.32; Analysis 1.1).

##### 1.2 Vascular injury

Vascular injuries were infrequent in the four studies that reported them (473 participants) (Bhoyrul 2000; Feste 2000; Mettler 2000; Venkatesh 2007). There was only one case of vascular injury in a participant where a disposable cutting trocar was used for primary entry (Bhoyrul 2000). The combined results from the four trials showed no evidence of a difference in vascular injury (Peto OR 0.14, 95% CI 0.00 to 7.16; Analysis 1.2).

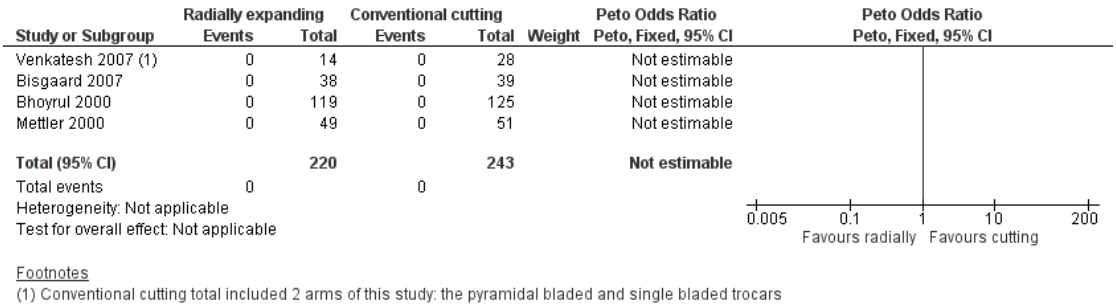
#### Secondary outcomes: minor trocar-related complications

Six studies provided data for analysis of minor trocar-related complications (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Lam 2000; Mettler 2000; Venkatesh 2007).

### 1.3 Trocar site herniation

See Figure 4. There was no trocar site herniation in four studies (463 participants) (Bhoyrul 2000; Bisgaard 2007; Mettler 2000; Venkatesh 2007).

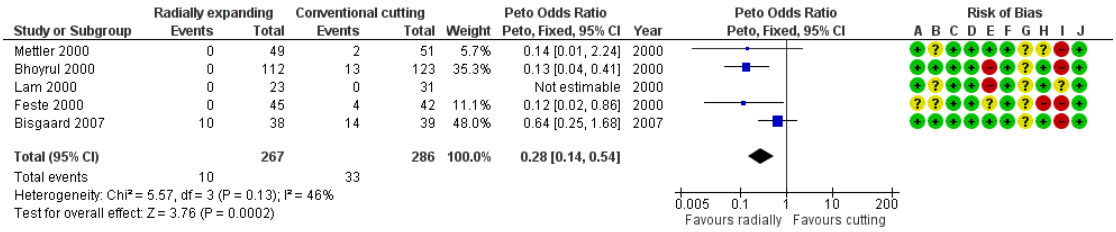
**Figure 4. Forest plot of comparison: 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry, outcome: 1.3 Trocar site herniation.**




### 1.4 Trocar site bleeding

See Figure 5. Five trials (553 participants) reported trocar site bleeding within radially expanding versus cutting trocar use (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Lam 2000; Mettler 2000). There was a decreased risk for trocar site bleeding in the radially expanding trocar group (Peto OR 0.28, 95% CI 0.14 to 0.54; Analysis 1.4) without substantial heterogeneity ($I^2$ = 46%). Subgroup analyses for surgical and gynaecological participants revealed a beneficial effect for the use of radially expanding trocars in people undergoing general surgery (Peto OR 0.29, 95% CI 0.15 to 0.58) but not for people undergoing gynaecological surgery (Peto OR 0.14, 95% CI 0.01 to 2.24). We could not perform a subgroup analysis for primary entry, secondary entry or trocar diameter because there were too few data. One included study reported a remarkably high incidence of bleeding at radially expanding trocar sites. More participants in the radially expanding trocar group had needed an additional incision to retract the gallbladder compared to the cutting group. One study reported one single trocar site bleeding at 43 radially trocar sites versus five at 84 cutting trocar sites. Because of unit-of-analysis issues, we could not use these data for statistical analysis (Venkatesh 2007).

**Figure 5. Forest plot of comparison: 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry, outcome: 1.4 Trocar site bleeding.**

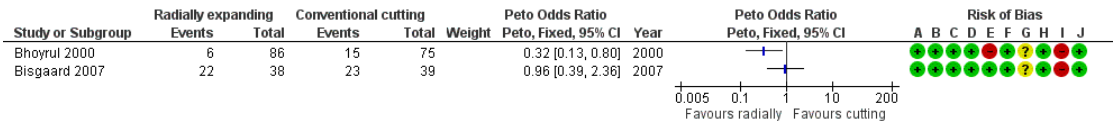



Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Intention-to-treat analysis
(**G**) Selective reporting (reporting bias)
(**H**) Group similarity at baseline (selection bias)
(**I**) Co-interventions (performance bias)
(**J**) Timing of outcome assessment (detection bias)

### 1.5 Trocar site haematoma

See Figure 6. Two studies described trocar site haematoma (Bhoyrul 2000; Bisgaard 2007). One study (77 participants) reported no evidence of a difference between radially expanding trocars and cutting trocars in the occurrence of trocar site haematoma at two days postoperative (Peto OR 0.96, 95% CI 0.39 to 2.36; Analysis 1.5) (Bisgaard 2007). However, in this study, more participants in the radially expanding group needed an additional incision to retract the gallbladder compared to the cutting group. The other study (161 participants) reported no evidence of a difference four hours postoperative, but at 24 hours postoperative fewer participants in the radially expanding trocar group compared to the cutting trocar group, had haematomas (Peto OR 0.32, CI 0.13 to 0.80) (Bhoyrul 2000). We could not pool these data because of the clinical heterogeneity.

**Figure 6. Forest plot of comparison: 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry, outcome: 1.5 Trocar site haematoma.**




Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Intention-to-treat analysis
(**G**) Selective reporting (reporting bias)
(**H**) Group similarity at baseline (selection bias)
(**I**) Co-interventions (performance bias)
(**J**) Timing of outcome assessment (detection bias)

### 1.6 Trocar site infection

One study reported indistinct findings on a single trocar site infection (Venkatesh 2007).

### 1.7 Postoperative pain

Four studies reported statistical data on postoperative pain. None of these studies provided sufficient data, making it inappropriate to pool the data (Bisgaard 2007; Feste 2000; Mettler 2000; Venkatesh 2007). Two studies found no evidence of a difference in pain at six hours, one day and two days postoperative (Bisgaard 2007), and three hours, 24 hours and one week postoperative (Venkatesh 2007). One study found no evidence of a difference four hours postoperative, but did find differences in pain eight, 12 and 24 hours postoperative (Feste 2000). The other study found differences for pain at four, eight and 12 hours, but no evidence of a difference at 24, 48 and 72 hours postoperative (Mettler 2000). The differences all favoured the participants that had received radially expanding trocars for primary and secondary ports. Another study reported no evidence of differences at four, eight, 12 and 24 hours postoperative, no statistical data were provided (Bhoyrul 2000).

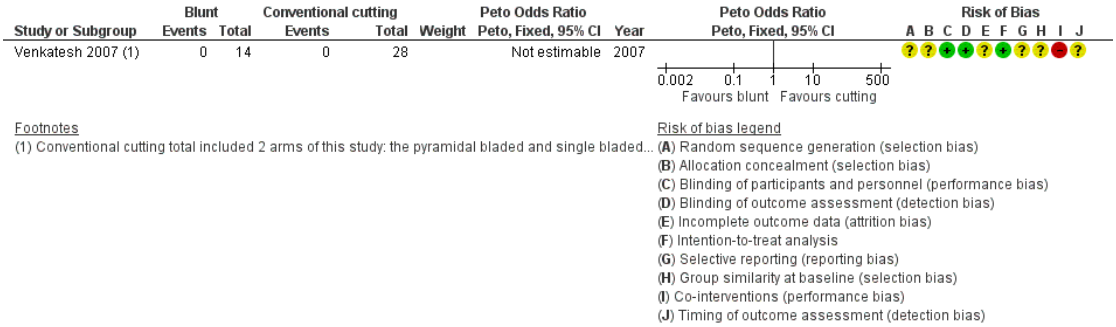
## 2. Conical blunt-tipped trocar versus cutting trocar

#### Primary outcomes: major trocar-related complications

### 2.1 Visceral injury

See Figure 7. One study provided data on visceral injury, and reported no visceral injuries in either the conical blunt-tipped trocars or cutting trocars groups (42 participants) (Venkatesh 2007).

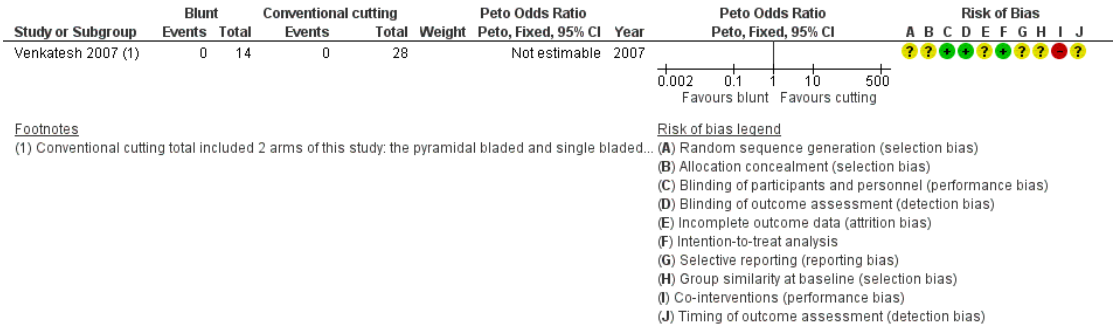
**Figure 7. Forest plot of comparison: 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry, outcome: 2.1 Visceral injury.**




### 2.2 Vascular injury

See Figure 8. One study provided data on vascular injury, and reported no vascular injuries in either the conical blunt-tipped trocars or cutting trocars groups (42 participants) (Venkatesh 2007).

**Figure 8. Forest plot of comparison: 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry, outcome: 2.2 Vascular injury.**

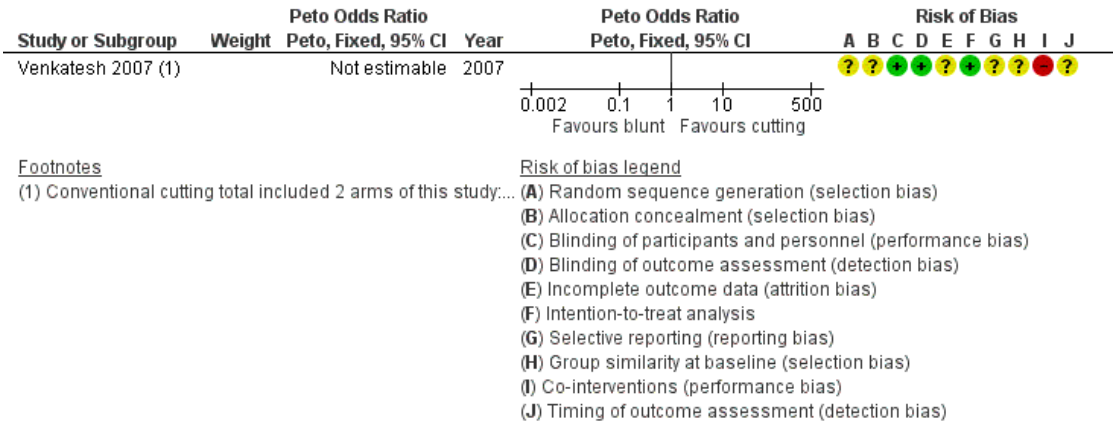



**Secondary outcomes: minor trocar-related complications**

### 2.3 Trocar site herniation

See Figure 9. One study provided data on trocar site herniation, and reported no herniations in either the conical blunt-tipped trocars or cutting trocars groups (42 participants) (Venkatesh 2007).

**Figure 9. Forest plot of comparison: 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry, outcome: 2.3 Trocar site herniation.**




### 2.4 Trocar site bleeding

Two studies reported occurrences of trocar site bleeding (Hamade 2007; Venkatesh 2007). One study with 30 participants, found no evidence of a difference between conical blunt-tipped trocars and cutting trocars (Peto OR 0.13, 95% CI 0.01 to 2.12; Analysis 2.4) (Hamade 2007). The other study reported one single trocar

site bleeding at 43 conical blunt-tipped trocar sites versus five trocar site bleedings at 84 cutting trocar sites. Because of unit-of-analysis issues, we could not use these data for statistical analysis (Venkatesh 2007). The trocar site of a single wound infection is indistinct (Venkatesh 2007).

### 2.5 Postoperative pain

One study reported mean VAS scores at three hours, 24 hours and one week postoperative (Venkatesh 2007), and found no evidence of a difference between conical blunt-tipped and cutting trocars. The data provided were insufficient for calculation of adequate measures and also unit of analysis issues are present.

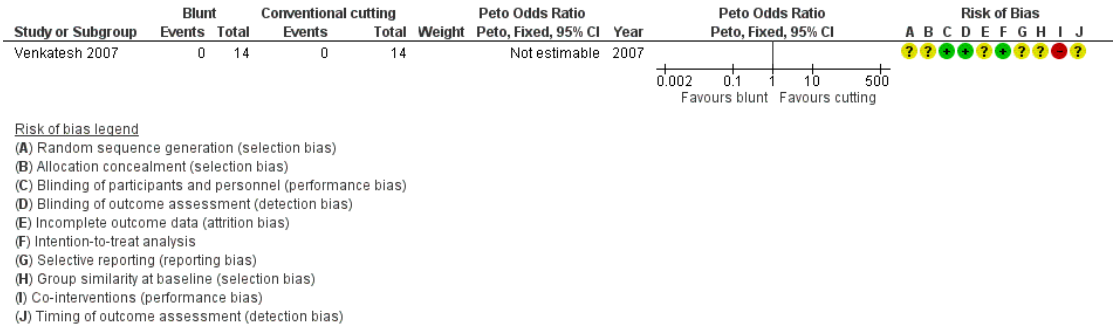
## 3. Radially expanding trocar versus conical blunt-tipped trocar

#### Primary outcomes: major trocar-related complications

### 3.1 Visceral injury

See Figure 10. One study (28 participants) provided data on visceral injury, and reported none within either the radial expanding trocar or conical blunt-tipped trocar groups (Venkatesh 2007).

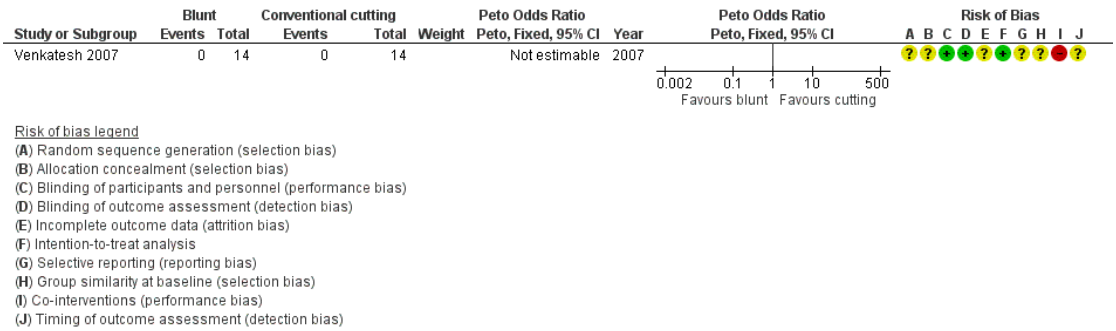
**Figure 10. Forest plot of comparison: 3 Radially expanding trocar versus conical blunt-tipped trocar for secondary port entry, outcome: 3.1 Visceral injury.**




### 3.2 Vascular injury

See Figure 11. One study (28 participants) provided data on vascular injury, and reported none within either the radial expanding trocar or conical blunt-tipped trocar groups (Venkatesh 2007).

**Figure 11. Forest plot of comparison: 3 Radially expanding trocar versus conical blunt-tipped trocar for secondary port entry, outcome: 3.2 Vascular injury.**



### Secondary outcomes

#### 3.3 Minor trocar-related complications

One study provided data on minor trocar-related complications. It reported no herniations and two ports with trocar site bleeding: one out of the 43 radially trocar sites and one out of the 38 conical blunt-tipped trocar sites. These study data presented unit-of-analysis issues and data were insufficient to present in meta-analysis (Venkatesh 2007).

#### 3.4 Postoperative pain

One study reported mean VAS scores at three hours, 24 hours and one week postoperative (Venkatesh 2007), and found no evidence of a difference between radially expanding and conical blunt-tipped trocars. We could not calculate adequate measures because of insufficient statistical data and issues on unit of analysis.

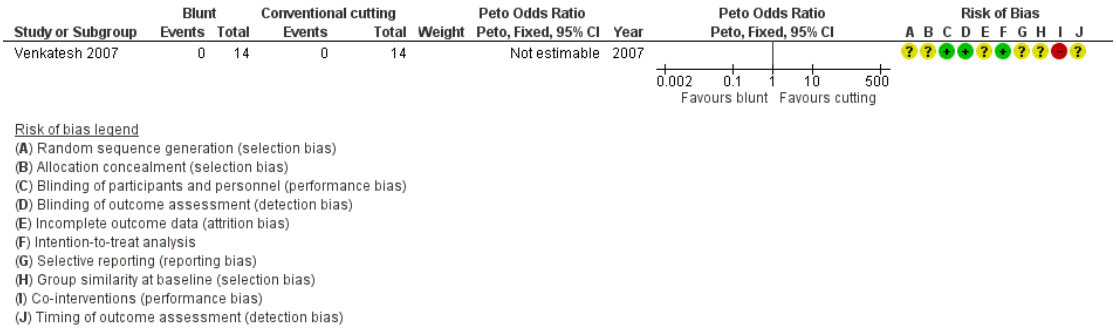
## 4. Single-bladed trocar versus pyramidal-bladed trocar

### Primary outcomes: major trocar-related complications

#### 4.1 Visceral injury

See Figure 12. One study (28 participants) provided data on visceral injury, and reported none within either the single-bladed trocar or pyramidal-bladed trocar groups (Venkatesh 2007).

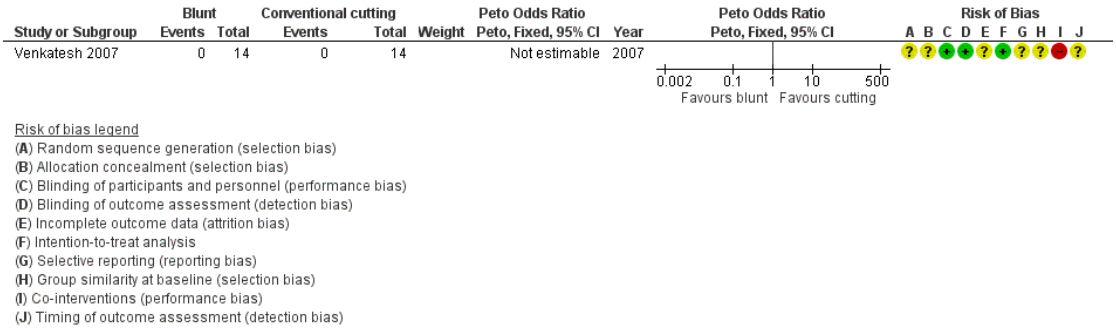
**Figure 12. Forest plot of comparison: 4 Single-bladed trocar versus pyramidal-bladed trocar, outcome: 4.1 Visceral injury.**




#### 4.2 Vascular injury

See Figure 13. One study (28 participants) provided data on vascular injury, and reported no vascular injuries within either the single-bladed trocar or pyramidal-bladed trocar groups (Venkatesh 2007).

**Figure 13. Forest plot of comparison: 4 Single-bladed trocar versus pyramidal-bladed trocar, outcome: 4.2 Vascular injury.**




### Secondary outcomes: minor trocar-related complications

One study provided data on minor trocar-related complications and postoperative pain (Venkatesh 2007). There were no herniations and five ports with trocar site bleeding (one of the 41 single-bladed trocar sites and four of the 43 pyramidal-bladed trocar sites). This study reported mean VAS scores at three hours, 24 hours and 1 week postoperative. They found no evidence of a difference between single-bladed and pyramidal-bladed trocars. We could not calculate adequate measures because of insufficient statistical data and issues on unit-of-analysis.

### Sensitivity analyses

We could not perform planned sensitivity analyses due to the small number of included studies.

## ADDITIONAL SUMMARY OF FINDINGS [Explanation]

**Conical blunt-tipped trocar compared to cutting trocar for laparoscopy**

**Patient or population:** people undergoing laparoscopy
**Settings:** surgical
**Intervention:** conical blunt-tipped trocar
**Comparison:** cutting trocar

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Assumed risk | Corresponding risk | | | | |
| | Cutting trocar | Conical blunt-tipped trocar | | | | |
| **Visceral injury** | No events reported | No events reported | Not estimable[1] | 42 (1 study) | ⊕◯◯◯ **very low**[2,3] | - |
| **Vascular injury** | No events reported | No events reported | Not estimable[1] | 42 (1 study) | ⊕◯◯◯ **very low**[2,3] | - |
| **Trocar site bleeding** | 133 per 1000 | 20 per 1000 (2 to 246) | OR 0.13 (0.01 to 2.12) | 30 (1 study) | ⊕◯◯◯ **very low**[3,4] | - |
| **Postoperative pain**[5] | See comment[5] | See comment[5] | Not estimable[5] | 42 (1 study) | ⊕◯◯◯ **very low**[2,6,7] | - |

*The basis for the **assumed risk** is the *mean control group risk* across studies. 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] No events reported.
[2] Downgraded one level due to high risk of selection bias: unclear randomisation and allocation.
[3] Downgraded two levels due to imprecision: the number of events was fewer than 300 (the threshold rule-of-thumb value).
[4] Downgraded one level due to high risk of performance bias: personnel not blinded, unclear type and frequency of port manipulation.
[5] Study provided insufficient statistical data, making it inappropriate to calculate adequate measures.
[6] Downgraded one level due to risk of bias: attrition bias due lack of clarity on completeness of the outcome data and 'unit of analysis' issues and performance bias due to lack of clarity on degree and frequency of port manipulation.
[7] Downgraded one level due to imprecision.

**Radially expanding trocar compared to conical blunt-tipped trocar for laparoscopy**

**Patient or population:** people undergoing laparoscopy
**Settings:** surgical
**Intervention:** radially expanding trocar
**Comparison:** conical blunt-tipped trocar

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Assumed risk | Corresponding risk | | | | |
| | Conical blunt-tipped trocar | Radially expanding trocar | | | | |
| **Visceral injury** | No events reported | No events reported | Not estimable[1] | 28 (1 study) | ⊕◯◯◯ **very low**[2,3] | - |
| **Vascular injury** | No events reported | No events reported | Not estimable[1] | 28 (1 study) | ⊕◯◯◯ **very low**[2,3] | - |
| **Trocar site herniation** | No events reported | No events reported | Not estimable[1] | 28 (1 study) | ⊕◯◯◯ **very low**[3,4] | - |

*The basis for the **assumed risk** is the *mean control group risk* across studies. 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] No events reported.
[2] Downgraded one level due to high risk of selection bias: unclear randomisation and allocation.
[3] Downgraded two levels due to imprecision: Only 28 participants.

[4] Downgraded one level due to risk of bias: attrition bias due to unclear loss to follow-up and performance bias.

**Single-bladed trocar compared to pyramidal-bladed trocar for laparoscopy**

**Patient or population:** people undergoing laparoscopy
**Settings:** surgical
**Intervention:** single-bladed trocar
**Comparison:** pyramidal-bladed trocar

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Assumed risk | Corresponding risk | | | | |
| | Pyramidal-bladed trocar | Single-bladed trocar | | | | |
| **Visceral injury** | No events reported | No events reported | Not estimable[1] | 28 (1 study) | ⊕◯◯◯ **very low**[2,3] | - |
| **Vascular injury** | No events reported | No events reported | Not estimable[1] | 28 (1 study) | ⊕◯◯◯ **very low**[2,3] | - |
| **Trocar site herniation** | No events reported | No events reported | Not estimable[1] | 28 (1 study) | ⊕◯◯◯ **very low**[3,4] | - |

*The basis for the **assumed risk** is the *mean control group risk* across studies. 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] No events reported.
[2] Downgraded one level due to high risk of selection bias: unclear randomisation and allocation.
[3] Downgraded two levels due to imprecision: only 28 participants.

[4] Downgraded one level due to risk of bias: attrition bias due to unclear loss to follow-up and performance bias.

# DISCUSSION

## Summary of main results

This systematic review evaluated the rates of trocar-related complications and postoperative pain for different trocar types used in people undergoing laparoscopy. We divided the outcomes into primary outcomes (including major trocar-related complications), and secondary outcomes (including minor trocar-related complications and postoperative pain). For major trocar-related complications, the studies reported events of vascular and visceral injury. The reported minor trocar-related complications were trocar site herniation, trocar site bleeding and trocar site infection. The trocar designs assessed in this review were radially expanding, cutting, conical blunt-tipped, single-bladed and pyramidal-bladed trocars. The result of seven RCTs (654 participants) showed no advantage of the use of a specific trocar design to minimise major trocar-related complications. Concerning minor trocar-related complications, very low quality evidence demonstrated a lower risk of trocar site bleeding with the use of radially expanding trocars in comparison to cutting trocars (five studies, 553 participants). There was no advantage of a specific trocar design in terms of reducing the incidence of trocar site herniation, haematoma and infection with very low quality evidence (five studies, 477 participants). Very low quality evidence suggested less postoperative pain after the use of radially expanding trocars compared to cutting trocars (two studies, 187 participants). However, these findings could not be imputed in a meta-analysis because of incompleteness and heterogeneity of the statistical data. Very low quality evidence indicated no difference in postoperative pain between participants who had received conical blunt-tipped trocars, radially expanding trocars, single-bladed trocars or pyramidal-bladed trocars.

## Overall completeness and applicability of evidence

Vascular and visceral injuries are the most serious trocar-related complications and therefore our main interest. These major complications often require additional surgical intervention, conversion to laparotomy and are associated with postoperative morbidity and mortality (Jansen 1997). This review included seven studies (654 participants), representing insufficient power to demonstrate a beneficial effect of one trocar type over another effectively. Minor trocar-related complications, such as trocar site herniation, trocar site bleeding or postoperative wound haematoma and trocar site infection, are generally more common and can be studied with smaller study populations. This could also be applied to the outcome of postoperative pain, depending on the clinically relevant difference in pain score that should be identified. However, with the exception of trocar site bleeding, the studies were not sufficient to address (all of) the defined outcomes in this review. Apparently, the included studies focused on short-term outcomes as their primary outcome parameter. The study data particularly concerned complications that occurred intraoperatively or within the first 24 hours after surgery. Longer-term complications such as haematoma, wound infection and trocar site herniation, were studied with very limited precision.

The trocar types included in this review for comparisons were limited to the radially expanding trocar, the cutting trocar, the conical blunt-tipped trocar, the single-bladed trocar and the pyramidal-bladed trocar. A myriad of device designs exists (Fuller 2003), but this review only evaluated a small number of these types. RCTs have not studied other types of trocars. Remarkably, we found no comparison between reusable and disposable trocars. The sharpness of disposable cutting trocars is usually better compared to that of reusable cutting trocars, which may lose their sharpness through repetitive insertion. Therefore, reusable trocars may require a relatively high puncture force for penetration through the abdominal wall, with a higher chance of resulting in an abrupt and uncontrolled introduction of the trocar that may result in a deeper penetration and potentially serious visceral and vascular injury (Tansatit 2006). None of the studies analysed the disposability of the trocars as a confounding factor for trocar-related complications. It is notable that six of the seven included RCTs studied radially expanding trocars, which does not seem in proportion to current practice. In view of the higher cost of radially expanding devices, it can be questioned whether this scientific attention can be regarded as clinically relevant. Another shortcoming was that many studies did not report the diameter of the trocars used. In the studies that did report diameters, there was much variety. To assess whether the trocar diameter affects the outcome of trocar-related complications, future studies should analyse individual participant data. A larger trocar diameter creates a larger defect in the abdominal wall and probably results in an increased risk of trocar site herniation and bleeding. In 1993, one retrospective study demonstrated an increased risk of trocar site herniation when trocars with a diameter of 12 mm were used compared to 10 mm (Kadar 1993). More recent studies on cholecystectomy did not show clear clinical advantages of mini laparoscopy (Gurusamy 2013; Sajid 2009).

We studied trials on traditional laparoscopy. We did not include newer techniques such as robot-assisted laparoscopy, LESS and NOTES. The results of this review should not be extrapolated to these other techniques.

Various types of participants were included in the studies for this review, all undergoing laparoscopy. The vast majority of the participants underwent laparoscopy for surgical indications, fewer for gynaecological conditions and fewer for renal conditions. Many different exclusion criteria were applied in the included studies and there was a wide age range. This large heterogeneity of included studies means there were too few data to perform a sensitivity analysis. From a clinical perspective, we do not expect a difference in trocar-related complications in people undergoing laparoscopy for

different conditions. This should be examined when more studies become available and adequate sensitivity analyses can be conducted.

## Quality of the evidence

The quality of the evidence was generally very low as shown in the 'Summary of findings' tables, the main limitation being very serious imprecision. This systematic review did not allow a robust conclusion regarding the rates of trocar-related complications and postoperative pain for different trocar types used in people undergoing laparoscopy. The main methodological limitation was the small number of included participants, due to the small number of RCTs included in this review. The incidences of trocar-related complications are low; particularly the incidence of major trocar-related complications is very low. To detect a risk difference for bowel injury from 0.3% to 0.2%, over 800,000 participants would be needed for inclusion in a trial (Garry 1999). Obviously, RCTs are not the design of choice to detect risk differences for major trocar-related complications. In our opinion, interventions to prevent events that occur only infrequently may be best assessed by good-quality observational studies such as cohort and case-control studies.

With respect to minor complications with a higher incidence (trocar site herniation, trocar site bleeding and haematoma) and postoperative pain, other study limitations came into view: heterogeneity of intervention and comparator within and between studies. Within the included studies, there was a considerable risk of performance bias: differences or ambiguities between study groups for closure of the fascial defect at trocar sites. This could have resulted in the inconsistencies in outcome trocar site bleeding, haematoma and postoperative pain. A third type of risk of performance bias resulted from limited reporting on the use of analgesics to prevent postoperative pain. In three of the studies, the type and amount of used analgesics was not reported, while pain was one of the evaluated outcomes. Another notable limitation was the high risk of attrition bias in most studies: short-term outcome data were incomplete, and this is even more pronounced for longer-term outcomes including trocar site infection and herniation.

One issue particularly arose in the analysis of the outcome postoperative pain, which was heterogeneity in the measures of postoperative pain. This was caused by different timings of measurements, use of different assessment tools and different presentations of data. No single study provided sufficient pain data, making it inappropriate to pool the data. Contacting the authors for missing data did not result in sufficient data for pooling.

## Potential biases in the review process

There was a number of limitations to this review. The primary limitation was the lack of studies with a low risk of bias. The second limitation was the possibility of publication bias, which we attempted to minimise through an extensive database search. We also searched the main electronic sources for ongoing trials and contacted the US FDA for regulatory trial data without relevant result. Surprisingly, with the exception of one study, all studies did not have a published protocol and, to our knowledge, had not registered their study in one of the many trial registries. This indicates that many trials conducted in the 21st century still do not conform to international procedure as outlined by the International Committee of Medical Journal Editors (ICJME). The third weakness is the outcomes information in the included studies. Most outcome measures were not properly defined. The reliability of meta-analyses is depending on the reliability with which these complications were measured by the authors. Furthermore, we could not obtain all relevant data. We were unable to obtain some data on the outcome of postoperative pain and missing data to calculate or estimate the standard deviations were not available even though we contacted the study authors. Since this concerned the majority of the pain data, imputation was not possible.

Strengths of this review include the methodological rigor applied according to our published protocol: the search was guided and adapted by the Cochrane Menstrual Disorders and Subfertility Group. Two review authors independently conducted the study selection, risk of bias assessment and data collection. We resolved any disagreements by discussion with a third review author. We attempted to deal with missing information and data by contacting the primary authors of Bhoyrul 2000, Bisgaard 2007, Feste 2000, and Mettler 2000, and we received partial responses.

## Agreements and disagreements with other studies or reviews

We identified two systematic reviews that have included this topic (Ahmad 2015; Antoniou 2013). In an update of their Cochrane review on laparoscopic entry performed during the development of this review, Ahmad et al. also included the outcomes of secondary ports, and, as a result, there is agreement between their review and ours. Their results are consistent with this review in finding an advantage of radially expanding trocars compared to standard trocars in terms of trocar site bleeding (Peto OR 0.31, 95% CI 0.15 to 0.62). They found no other evidence suggesting more or less safety of radially expanding, cutting or blunt trocars (Ahmad 2015).

Antoniou 2013 evaluated the risk of abdominal wall bleeding, visceral injuries and overall complications with the use of bladed and blunt-tipped laparoscopic trocars. Radially expanding trocars were included in the 'blunt-tipped' group. Meta-analysis resulted in a lower risk of abdominal wall bleeding for the blunt-tipped trocar group (OR 0.42, 95% CI 0.21 to 0.88). We believe that the expanding function of the radially expanding trocar may have a different effect on trocar-related complications and, therefore, did not pool data from blunt-tipped trocars with radially expanding

trocars. However, their results for trocar site bleeding are consistent with the results in this review since most of their included studies used radially expanding trocars.

## AUTHORS' CONCLUSIONS

### Implications for practice

We found no evidence of a difference in the incidence of major trocar-related complications, such as visceral or vascular injury, when comparing different trocar types with one another. However, caution is urged when interpreting these results because the incidence of serious complications following the use of a trocar is extremely low. There was very low quality evidence for minor trocar-related complications suggesting that the use of radially expanding trocars compared to cutting trocars leads to reduced incidence of trocar site bleeding. These secondary outcomes are viewed to be of less clinical importance.

### Implications for research

Large, well-conducted observational studies are necessary in order to answer the questions addressed in this review because serious complications, such as visceral or vascular injury, are extremely rare. However, for other outcomes, such as trocar site herniation, bleeding or infection, large observational studies may be needed as well. In order to answer these questions, it is advisable to establish an international network for recording these types of complications following laparoscopic surgery.

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* *Indicates the major publication for the study*

## CHARACTERISTICS OF STUDIES

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

**Bhoyrul 2000**

| | | |
|---|---|---|
| Methods | Multicentre, 16 surgeons, randomised, double-blinded study<br>Study duration: undefined | |
| Participants | 250 adults were enrolled, age not reported, sex not reported, BMI or weight not reported<br>119 participants included in the radially expanding (STEP) trocar group and 125 in the conventional cutting trocar group<br>Type of procedure/setting: elective laparoscopic: cholecystectomy (86 participants), hernia (59), fundoplication (57), colectomy (13), other (29). At tertiary care centres and community hospitals in San Francisco, US<br>Exclusion criteria: acute inflammatory conditions and conversion to laparotomy not related to a trocar-related complication | |
| Interventions | Intervention group: primary (and secondary) entry with radially expanding trocars (Step, Innerdyne, Inc., Sunnyvale, USA), diameter not reported<br>Control group: primary (and secondary) entry with conventional disposable cutting trocars (US Surgical Corp. Norwalk, Connecticut USA and Ethicon Endo-Surgery, Cincinnati, USA or Origin Inc., Sunnyvale USA), diameter not reported<br>Technique/type of surgeons: insertion of the first port after establishing a pneumoperitoneum with the use of a standard Veress needle and inserting the device using the blind technique. 16 different general surgeons<br>Closure of fascial defects: defects created by conventional cutting trocars $\geq$ 10 mm were closed unless they were too small to be found. Any defect large enough to accommodate the tip of the surgeon's little finger was closed. Defects created by the radially expanding trocars were not closed unless they met this criterion<br>Analgesics: not recorded | |
| Outcomes | Visceral injury, intraoperative<br>Vascular injury, intraoperative<br>Trocar site bleeding, intraoperative<br>Trocar site herniation, 6-18 months' follow-up<br>Wound haematoma, 4 and 24 hours postoperative<br>Continued wound bleeding, 4 and 24 hours postoperative<br>Incisional pain, 4, 8, 12 and 24 hours postoperative | |
| Length of follow up | 6-18 months, not further specified | |
| Funding source | Not reported | |
| Notes | | |
| ***Risk of bias*** | | |
| **Bias** | **Authors' judgement** | **Support for judgement** |

**Bhoyrul 2000** (*Continued*)

| | | |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Randomisation table |
| Allocation concealment (selection bias) | Low risk | Assignment of participants to either the radially expanding trocar group or the conventional cutting trocar group was carried out at the time of surgery by drawing consecutive sealed envelopes |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Low risk | Participants were blinded to the choice of trocar used in the operations |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | Postoperative observers were blinded to the choice of trocar used in the operations |
| Incomplete outcome data (attrition bias)<br>All outcomes | High risk | In the outcome table for intraoperative complications in the STEP group approximately 6% and in the conventional group approximately 3% of data were missing<br>For the outcome, pain, completeness of data was unclear. For the outcome, wound complications (haematoma and continued bleeding) at follow-up, 4-hour data of approximately 22% of participants were missing and 24-hour data approximately 33% |
| Intention-to-treat analysis | Low risk | 6 excluded participants were randomised into the radially expanding trocar group. These participants are excluded for reasons other than trocar-related complications. The data were analysed as randomised |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information. No protocol was published. Endpoints in results section are according to those in methods section |
| Group similarity at baseline (selection bias) | Low risk | The groups were similar with regard to age, sex and type of procedure. Adequate randomisation and allocation concealment, no exclusion of participants leading to imbalance |
| Co-interventions (performance bias) | High risk | Fascial defects created by conventional trocars $\geq$ 10 mm were closed unless they were too small to be found. Any defect large enough to accommodate the tip of the surgeon's little finger was closed. Defects cre- |

**Bhoyrul 2000** (*Continued*)

| | | |
|---|---|---|
| | | ated by the Step trocars were not closed unless they met this criterion. In the Step group 3% of participants had fascial defects that needed to be closed, compared to 93% in the conventional group<br>Port manipulation was unclear (material extraction or morcellation)<br>The different type of procedures and 16 participating surgeons<br>Different analgesia protocols were used, specification not reported |
| Timing of outcome assessment (detection bias) | Low risk | The outcome assessment for intraoperative complications, postoperative haematoma, persistent bleeding and pain was identical for both intervention groups until 24 hours postoperative. The timing, method of assessment and completeness for trocar site herniation is unclear and varies between 6 and 18 months |

**Bisgaard 2007**

| | |
|---|---|
| Methods | Single centre, randomised, double-blind study. Number of surgeons unclear<br>Study duration: from April 2003 to May 2004 |
| Participants | 77 adults; median age: study group 47 years, control group 48 years; median BMI: study group 24, control group 25; male : female ratio: study group 35 : 3, control group 28 : 11<br>38 participants were included in the radially expanding trocar group and 39 participants were included in the conventional cutting trocar group<br>Type of procedure/setting: elective laparoscopic cholecystectomy in a semi-ambulatory unit in an university hospital Gentofte Hospital, Denmark<br>Exclusion criteria: ASA 4, aged < 18 and > 75 years, pregnancy, chronic pain diseases other than gallstone, use of opioids or tranquillisers (for > 1 week before surgery), foreign language, mental disorder, history of alcoholism or drug abuse and conversion to laparotomy |
| Interventions | Study group: primary and secondary entry with radially expanding trocars (VersaStep system, Tyco Healthcare, Copenhagen, Denmark)<br>Control group: primary and secondary entry with conventional cutting trocars (Endopath II, Ethicon Endosurgery, Inc, Cincinnati, USA). Disposable<br>Technique/type of surgeons: laparoscopic cholecystectomy was performed using 2 x 10-mm and 2 x 5-mm trocars. Gallbladder was retracted via the umbilical 10-mm trocar port incision. The closed entry technique was used. Operations were conducted or supervised by experienced laparoscopic surgeons, equally distributed between the 2 surgical groups<br>Closure of fascial defects: fascia at the umbilical port incision was closed using a resorbable suture |

| | |
|---|---|
| | Analgesics: all participants received a similar general anaesthesia, incisional local aesthetics were given and postoperative standard analgesics were given |
| Outcomes | Trocar site bleeding, intraoperative<br>Trocar site herniation, up to 3 year<br>Postoperative wound haematoma, postoperative day 2<br>Incisional pain during mobilisation (overall, not at individual ports) 6, 24 and 48 hours postoperatively (primary); VAS and VRS |
| Length of follow up | 30 days' and 3 years' follow-up via the electronic national hospital data register and manual check of hospital files. Median follow-up was 39 months (range 33-46 months) |
| Funding source | Not reported |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Based on block-randomised computer-generated list. After introduction of anaesthesia, the surgeon randomised the participants to laparoscopic cholecystectomy using radially expanding trocar or conventional cutting trocars |
| Allocation concealment (selection bias) | Low risk | Sealed envelope method. The randomisation code was kept separate from the investigators in a lockup, and the randomisation sequence was concealed until data analysis was completed |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Low risk | The participants were blinded to the type of trocar used. At the end of the operation, the incisions were covered with non-transparent standard dressing and the participants were instructed to keep the dressings on for the first 2 postoperative days |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | The surgical staff, including the nurses, was blinded to the type of trocar used. The operating surgeon and the anaesthesiologist in charge did not participate in the postoperative assessment and did not attend to the participants |

| | | |
|---|---|---|
| Incomplete outcome data (attrition bias) All outcomes | Low risk | 3 exclusions from trial. "One of the three excluded patients underwent conversion to an open procedure (radial group) and the remaining two patients (one from each group) had no study data available due to loss of their study diary." The number of 3 out of 77 participants loss for short-term follow-up would not lead to a substantial bias. It remains unclear what the numbers were for follow-up at 30 days for complications, and for the 3 years of evaluation |
| Intention-to-treat analysis | Low risk | All randomised participants are analysed in the group they were allocated to |
| Selective reporting (reporting bias) | Unclear risk | Not referred to. No protocol was published. Endpoints in results section were according to those in methods section |
| Group similarity at baseline (selection bias) | Low risk | Groups did not significantly differ for age, BMI, ASA classification and the regimen of general anaesthesia. The sex ratio was significantly different: more women in the study group. Preoperative pain scores were equal for both groups |
| Co-interventions (performance bias) | High risk | In the radially expanding trocar group, significantly more participants (23/38) needed an additional incision to retract the gallbladder compared to the cutting group (11/39). All participants received standardised anaesthetic and analgesic treatment. There were no significant differences in total opioid requirements |
| Timing of outcome assessment (detection bias) | Low risk | The outcome assessment was identical for both groups until 48 hours postoperative. The timing of assessment for trocar site herniation was unclear and varied between 33 and 46 months. Participants were not clinically examined for trocar herniation during the follow-up |

**Feste 2000**

| | |
|---|---|
| Methods | Multicentre, 7 surgeons, randomised, double-blind study<br>Study duration: April 1996 to January 1997 |
| Participants | 87 women, aged 18-54 years, BMI or weight not reported<br>45 participants were randomised in the radially expanding (REA) trocar group and 42 participants were randomised in the conventional cutting trocar group<br>Type of procedures/setting: various (22 participants) operative and diagnostic laparoscopic procedures in 2 hospitals (Germany and the US)<br>Exclusion criteria were not reported |
| Interventions | Intervention group: primary and secondary entry with radially expanding trocars (Step, InnerDyne, Inc., Sunnyvale, USA), diameter not specified<br>Control group: primary and secondary entry with either disposable or non-disposable conventional cutting trocars, diameter not specified<br>Technique/type of surgeons: primary and secondary ports were created with REA or conventional cutting trocars. Probably the closed technique was used. 7 different surgeons well trained, and 1 year' experience with REA<br>Closure of fascial defects: defects created by conventional cutting trocars $\geq$ 10 mm were closed. Defects created by the radially expanding trocars were intended not to be closed: it was up to the surgeon<br>Analgesics: type and amount of postoperative analgesics were not recorded |
| Outcomes | Visceral injury, intraoperative<br>Vascular injury, intraoperative<br>Trocar site bleeding, intraoperative, 4 and 24 hours postoperative<br>Incisional pain, 4, 8, 12 and 24 hours postoperative |
| Length of follow up | 24 hours |
| Funding source | Not reported |
| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Not referred to means of randomisation |
| Allocation concealment (selection bias) | Unclear risk | Not referred to allocation concealment |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Low risk | Participants were blinded as to which type of instrument was used |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | A blinded observer assessed the operative wounds at 4 and 24 hours postoperatively |

**Feste 2000** (*Continued*)

| | | |
|---|---|---|
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | The number of participants who were included in the study was unclear. The number of evaluated participants was recorded. But unclear if all observations are complete |
| Intention-to-treat analysis | Low risk | Participants' outcomes were analysed as randomised |
| Selective reporting (reporting bias) | Unclear risk | Not referred to. Unknown if all the results from all pre-specified outcomes were adequately reported. Insufficient information |
| Group similarity at baseline (selection bias) | High risk | Unclear method of randomisation and allocation concealment. There was a significant difference in the BMI and in the mean weights for the 2 groups, with participants in the radially expanding trocar group having lower weights. Pain scores were not measured before surgery |
| Co-interventions (performance bias) | High risk | All conventional trocar sites $\geq$ 10 mm or larger were closed (100% sutured), full or partial thickness as required. In contrast, all but 2 of the $\geq$ 10 mm Step device sites were left unsutured (4, 17% sutured)<br>Type and frequency of port manipulation (material extraction or morcellation) was unclear. "One of the two Step defects requiring closure resulted from the enlargement of the defect to allow passage of a bag containing a dermoid cyst." This was not clearly reported for both groups<br>Type and amount of postoperative analgesics given were not recorded |
| Timing of outcome assessment (detection bias) | Low risk | Outcome assessment identical for both intervention groups |

**Hamade 2007**

| | |
|---|---|
| Methods | Single centre, randomised, non-blinded study. Number of surgeons unclear<br>Study duration: undefined |
| Participants | 30 adults, median age: cutting group 45 years, blunt group 42 years; median BMI: cutting group 27 kg/$m^2$, blunt group 29 kg/$m^2$, male : female ratio: cutting group 2 : 3, blunt group 1 : 2<br>15 participants were randomised in the cutting trocar group and 15 participants were randomised in the blunt-tipped trocar group |

| | |
|---|---|
| | Type of procedure/setting: laparoscopic procedures including cholecystectomy (14 participants), Nissen fundoplication (5), staging laparoscopy (4), gastrojejunostomy (3), others (4). Setting not clearly described<br>Exclusion criteria: not reported |
| Interventions | Intervention group: secondary port entry using 5 and 10 mm reusable conical blunt-tipped metal trocars (Mantis Surgical Ltd, Newbury, UK)<br>Control group: secondary port entry using 5 and 10 mm reusable cutting metal trocars with 3 sharp fixed blades (Mantis Surgical Ltd, Newbury, UK)<br>Technique/type of surgeons: primary port insertion was accomplished using direct a blunt-tipped trocar at a site other than the umbilicus and without insufflation. Experience of surgeon(s) unclear. A device, to apply traction force to displace the port, was attached to the port<br>Closure of fascial defects: not reported<br>Analgesics: general anaesthesia, postoperative analgesia not recorded |
| Outcomes | Trocar site bleeding, intraoperative |
| Length of follow up | No follow-up, only intraoperative measures |
| Funding source | Not reported |
| Notes | Primary outcomes of this study were port fixity, friction forces and port dislodgement |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Computer-generated randomisation list, produced by independent statistician. Entry of a participant into the randomisation process was initiated after consent had been obtained and the participant had been given a general anaesthetic and brought into the theatre for surgery |
| Allocation concealment (selection bias) | Low risk | An independent person produced envelopes containing the number of the study participant and a card labelled 'blunt' or 'sharp'. The envelopes were sealed and placed in the operating theatre |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Low risk | Not applicable. The surgeon was not blinded to the type of trocar. This will probably not have had influence on trocar site bleeding |

**Hamade 2007** (*Continued*)

| | | |
|---|---|---|
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Not referred to. Unclear if the surgeon's assessment for port site bleeding could have been influenced by being unblinded |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | None. No per-operative drop-out |
| Intention-to-treat analysis | Low risk | All randomised participants were analysed in the group they were allocated to by randomisation |
| Selective reporting (reporting bias) | Unclear risk | Protocol was published online on 29 September 2006, after the projected finish of the study. Protocol described inclusion of 2 x 25 participants, while 2 x 15 participants were randomised. No explanation was given in the article |
| Group similarity at baseline (selection bias) | Low risk | The 2 groups were comparable for age, gender, BMI and operating time |
| Co-interventions (performance bias) | Unclear risk | In the blunt trocar group, more trocars were applied: 63 ports in the blunt group and 51 in the cutting group. In all participants, generous skin incisions were made to ensure a loose fit of the skin around the port so that the anchorage of the port to the abdominal wall could be solely attributed to the fascial and muscular layers of the anterior abdominal wall. The anaesthetist ensured full muscle relaxation during the procedure<br>Type and frequency of port manipulation (material extraction or morcellation) is unclear |
| Timing of outcome assessment (detection bias) | Low risk | Trocar site bleeding was assessed intraoperative, no postoperative follow-up |

**Lam 2000**

| | |
|---|---|
| Methods | Single centre, randomised, single-blind study. Number of surgeons unclear<br>Study duration: July 1997 to September 1998 |
| Participants | 54 adults, mean age: study group 55.1 years, control group 57.8 years; male : female ratio 35 : 19; BMI or weight not reported<br>23 participants in the REA group and 31 participants in the conventional cutting trocar group had their data entry completed and returned for analysis |

| | |
|---|---|
| | Type of procedure/setting: laparoscopic cholecystectomy at the Department of Surgery, United Christian Hospital, Hong Kong<br>Exclusion criteria: acute cholecystitis, known gallbladder malignancy |
| Interventions | Intervention group: secondary epigastric port entry with a 10 mm epigastric transverse skin incision followed by introduction of a 10 mm radially expanding trocar (Step, Innerdyne, Inc., Sunnyvale, USA)<br>Control group: secondary epigastric port entry with a 10 mm epigastric transverse skin incision followed by introduction of a 10 mm conventional metal cutting trocar<br>Technique: Hasson technique entry, the operation was performed with a standardised technique with 4 trocars. Gallbladder recovered through the epigastric port. Experience of surgeons unclear<br>Closure of fascial defects: not recorded<br>Analgesia: oral dologesic (paracetamol/phenyltoloxamine) on demand up to 4 times, intake not recorded |
| Outcomes | Conversion rate, unspecified whether trocar related or not, intraoperative<br>Trocar site bleeding, timing and method of assessment unspecified<br>Trocar site infection, timing and method of assessment unclear<br>Incisional pain, 24, 48 and 72 hours postoperative |
| Length of follow up | Up to 72 hours for the outcome, pain. Undefined for other outcomes |
| Funding source | All STEP™ trocars used in this study were supplied free of charge by Kojima Healthcare Asia Ltd |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Computer-generated randomisation table |
| Allocation concealment (selection bias) | Unclear risk | An erroneous duplication of a randomisation envelope led to the inclusion of 1 more case in the control group. Not reported how assignment was generated |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Low risk | The participants were blinded to the type of epigastric trocar used for their surgery |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | Physicians not performing the surgery served as independent observers to measure pain experience by the participants. Participants were blinded |

**Lam 2000** (*Continued*)

| | | |
|---|---|---|
| Incomplete outcome data (attrition bias) All outcomes | High risk | In the study group, 23/30 (77%) participants had their data entry completed and returned for analysis. All 31 participants of the control group had their results available for analysis. Unclear how missing values were dealt with and the conversion rates (10% conversion rate in the control group and 9% in the study group) |
| Intention-to-treat analysis | Low risk | Intention-to-treat analysis was applied |
| Selective reporting (reporting bias) | Unclear risk | Unclear if all the results from all pre-specified outcomes were adequately reported. Insufficient information. No protocol was published. Endpoints in results section were according to those in methods section |
| Group similarity at baseline (selection bias) | Low risk | Variables used to check for balanced randomisation included the participant's age, sex, diagnosis, operation time, conversion rate and subumbilical wound pain. Subumbilical wound pain was measured in addition to epigastric wound pain as a test for case randomisation |
| Co-interventions (performance bias) | Unclear risk | Operation was performed with a standardised technique. The gallbladder recovered through the epigastric port. Fascial closure management was unclear |
| Timing of outcome assessment (detection bias) | Low risk | Outcome assessment for pain was identical for both intervention groups |

**Mettler 2000**

| | |
|---|---|
| Methods | Multicentre (2 centres), randomised, double-blind study. 3 surgeons<br>Study duration: July 2005 to March 2006 |
| Participants | 100 women; age, BMI and weight not reported<br>49 participants were randomised into treatment with radially expanding trocars, 51 participants were randomised into treatment with conventional cutting trocars<br>Type of procedure/setting: elective laparoscopic benign gynaecological surgical procedures in 2 centres: University Hospital of Kiel, Germany and Mercy Hospital for Women, Victoria, Australia<br>Exclusion criteria: acute inflammatory conditions |

**Mettler 2000** (*Continued*)

| | |
|---|---|
| Interventions | Intervention group: primary and secondary entry with radially expanding trocars (Step, Innerdyne, Inc., Sunnyvale USA), diameter not specified<br>Control group: primary and secondary entry with reusable conventional cutting trocars, diameter not specified<br>Closed entry technique<br>Technique/type of surgeons: conventional conic trocars were introduced in a Z-wise fashion not further specified. Experience of the surgeons unclear<br>Closure of fascial defects: participants for whom regular trocars were used had 10 mm trocar sites closed, as opposed to the Step defects, which were 50% smaller and therefore did not require closure<br>Analgesics: neither group was any more likely than the other to use analgesics at any time postoperatively |
| Outcomes | Visceral injury, intraoperative<br>Vascular injury, intraoperative<br>Trocar site bleeding, intraoperative<br>Trocar site herniation, up to 12 months<br>Pain at 4, 8, 12, 24, 48 and 72 hours postoperative |
| Length of follow up | 12 months, completeness not specified |
| Funding source | Not reported |
| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Randomisation table |
| Allocation concealment (selection bias) | Unclear risk | Not referred to allocation concealment |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Low risk | All participants were blinded as to which type of access instrument was used |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | A trained observer was blinded as to which type of access instrument was used |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | No loss to follow-up until 72 hours postoperative of exclusions stated. For long-term outcome (trocar site herniation, the completeness of follow-up was unclear |
| Intention-to-treat analysis | Low risk | Data are analysed as randomised. |

**Mettler 2000** (*Continued*)

| | | |
|---|---|---|
| Selective reporting (reporting bias) | Unclear risk | Remains unknown if all the results from all pre-specified outcomes were adequately reported. Insufficient information. No protocol was published. Endpoints in results section were according to those in methods section |
| Group similarity at baseline (selection bias) | Unclear risk | Not referred to |
| Co-interventions (performance bias) | High risk | All participants for whom regular trocars were used had > 10 mm trocar sites closed, as opposed to the Step sites, which were 50% smaller and did therefore not require closure. Type and frequency of port manipulation (material extraction or morcellation) is unclear. Analgesics use was unclear |
| Timing of outcome assessment (detection bias) | Low risk | Outcome assessment identical for both intervention groups. The timing, method of assessment and completeness for trocar site herniation is unclear |

**Venkatesh 2007**

| | |
|---|---|
| Methods | Single centre, randomised, 4 arm, double-blind study. Number of surgeons unclear<br>Study duration: undefined |
| Participants | 56 adults, 30 men and 26 women, mean age: 58 years, mean BMI: 31.3<br>14 participants randomised in each arm (total 56 participants) to receive 1 of the 4 types of 12-mm study trocars a pyramidal-bladed, single-bladed, axially dilating and radially dilating trocar. 165 trocar sites for evaluation in the study including 43 pyramidal-bladed, 41 single-bladed, 38 axially dilating and 43 radially dilating trocar sites<br>Setting: US<br>Type of surgery: laparoscopic transperitoneal renal procedures, flank approach. The procedures included radical or total nephrectomy (36 participants), nephron-sparing surgery (9), pyeloplasty (8) and renal cyst decortication (3)<br>Exclusion criteria: not reported |
| Interventions | Pyramidal-bladed group: disposable pyramidal-bladed trocars (Ethicon Inc., Cincinnati, OH)<br>Single-bladed group: disposable single-bladed trocars (Ethicon Inc., Cincinnati, OH)<br>Axially dilating group: disposable axially dilating trocars (Ethicon Inc., Cincinnati, OH)<br>Radially dilating group: disposable radially dilating trocars (US Surgicals Inc., CA)<br>Technique/type of surgeons: all trocars were inserted after pneumoperitoneum was established with a Veress needle. A standardised lateral 5 mm, non-cutting, metal trocar was placed in each participant. Trocars were placed in a standard 'diamond' configuration: 3 x 12-mm study trocars and 1 lateral 5-mm trocar that served as a reference point for |

| | |
|---|---|
| | normalising participant's pain scores. Experience of surgeons unclear<br>The morcellation site, specimen extraction and hand-assist device site location when used were documented<br>Closure of fascial defects: performed for single-bladed and pyramidal-bladed trocar sites by using a Carter-Thomason closure device. Radially dilating and axially dilating trocar sites were not routinely closed unless frequent dislodgment of the trocar occurred<br>Analgesics: not reported |
| Outcomes | Visceral injury, intraoperative<br>Vascular injury, intraoperative<br>Trocar site herniation, 1 week; 3, 6, 12 and 18 months; during clinic visit or telephone interview<br>Trocar site bleeding, intraoperative, 3 and 24 hours postoperative<br>Wound infection, postoperative but unclear which time intervals<br>Postoperative wound haematoma, 3 and 24 hour postoperative<br>Pain at 3 hours, 24 hours, 1 week and 3 months postoperatively |
| Length of follow up | Follow-up for trocar site hernias was 18 months (range 14-36) |
| Funding source | The manufacturing companies supplied all the trocars used in this study. There was no financial assistance provided by any company |
| Notes | Normalisation of pain scores was performed by calculating the mean pain score for lumbar trocar site and normalising it to the 5 mm lateral port pain score for each individual participant |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Not referred to |
| Allocation concealment (selection bias) | Unclear risk | Not referred to |
| Blinding of participants and personnel (performance bias)<br>All outcomes | Low risk | Participants were blinded |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | A physician who did not perform or assist the operation assessed the trocar sites for pain, bleeding and ecchymoses at 3 and 24 hours postoperative |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | No exclusions or loss to follow-up stated |

**Venkatesh 2007** (*Continued*)

| | | |
|---|---|---|
| Intention-to-treat analysis | Low risk | Ports were analysed as randomised. There are issues on 'unit-of-analysis': the number of observations in the analysis (= number of ports) did not match the number of 'units' that were randomised (number of participants) |
| Selective reporting (reporting bias) | Unclear risk | Not referred to. No protocol was published. Endpoints in results section were according to those pre-specified in methods section |
| Group similarity at baseline (selection bias) | Unclear risk | "Mean body mass index was 31.3 (range 20 to 62) and was similar among all 4 trocar study groups." Other baseline characteristics were not compared |
| Co-interventions (performance bias) | High risk | The location of the primary entry port was not standard. Closure of the fascial layer was not performed with the expanding trocars on 82% of occasions. The fascial layer of the expanding trocar sites was closed on 6 occasions, and all the cutting trocar sites were closed. It was unclear how they dealt with the morcellation, hand-assistance and specimen extraction sites. Analgesics use was not reported |
| Timing of outcome assessment (detection bias) | Unclear risk | Follow-up evaluations were performed at 1 week and 3 months for pain and trocar site hernia. Physical examination specifically evaluating for the presence of trocar site hernia was carried out during the clinic visit by the attending physician or by a telephone interview at 6, 12 and 18 months. The range in follow-up was 14-36 months. Therefore, detection bias in the long term was possible. Low risk for short-term endpoints |

ASA: American Society of Anaesthesiologists; BMI: body mass index; REA: radially expanding access; VAS: visual analogue scale; VRS: visual rating scale.

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

| Study | Reason for exclusion |
|---|---|
| Herati 2011 | Non-randomised study |
| Huang 2012 | Non-randomised study |
| Stephanian 2007 | Randomisation of different sites of the body/abdomen to *different* trocars. 'Split-mouth' design |
| Tansatit 2006 | Study tried both trocar type and trocar entry method at same time |
| Tchartchian 2010 | Study evaluated intervention time and the duration of interruption of the intervention for correction of trocars. Trocar-related complications or postoperative pain were not studied |
| Yim 2001 | Randomisation of different sites of the body/abdomen to *different* trocars. 'Split-mouth' design |

## DATA AND ANALYSES

### Comparison 1. Radially expanding trocar versus cutting trocar for primary and secondary port entry

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Visceral injury | 4 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |
| 2 Vascular injury | 4 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |
| 3 Trocar site herniation | 4 | 463 | Peto Odds Ratio (Peto, Fixed, 95% CI) | 0.0 [0.0, 0.0] |
| 4 Trocar site bleeding | 5 | 553 | Peto Odds Ratio (Peto, Fixed, 95% CI) | 0.28 [0.14, 0.54] |
| 5 Trocar site haematoma | 2 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |

### Comparison 2. Conical blunt-tipped trocar versus cutting trocar for secondary port entry

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Visceral injury | 1 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |
| 2 Vascular injury | 1 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |
| 3 Trocar site herniation | 1 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |
| 4 Trocar site bleeding, intraoperative | 1 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |

### Comparison 3. Radially expanding trocar versus conical blunt-tipped trocar for secondary port entry

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Visceral injury | 1 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |
| 2 Vascular injury | 1 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |

### Comparison 4. Single-bladed trocar versus pyramidal-bladed trocar

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Visceral injury | 1 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |
| 2 Vascular injury | 1 | | Peto Odds Ratio (Peto, Fixed, 95% CI) | Subtotals only |

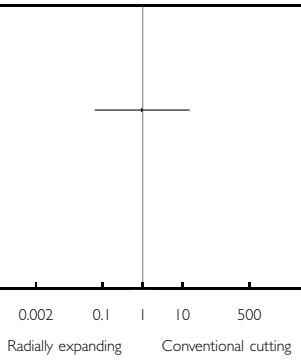
**Analysis 1.1. Comparison 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry, Outcome 1 Visceral injury.**

Review: Trocar types in laparoscopy

Comparison: 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry

Outcome: 1 Visceral injury

| Study or subgroup | Radially expanding n/N | Cutting n/N | Peto Odds Ratio Peto,Fixed,95% CI | Weight | Peto Odds Ratio Peto,Fixed,95% CI |
|---|---|---|---|---|---|
| Feste 2000 | 0/45 | 0/42 | | | Not estimable |
| Mettler 2000 | 0/49 | 0/51 | | | Not estimable |
| Bhoyrul 2000 | 1/125 | 1/119 | | | 0.95 [ 0.06, 15.32 ] |
| Venkatesh 2007 | 0/14 | 0/28 | | | Not estimable |
| Test for subgroup differences: Not applicable | | | | | |



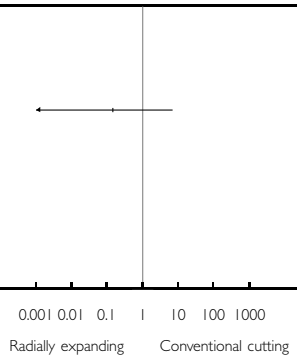
**Analysis 1.2. Comparison 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry, Outcome 2 Vascular injury.**

Review: Trocar types in laparoscopy

Comparison: 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry

Outcome: 2 Vascular injury

| Study or subgroup | Radially expanding n/N | Cutting n/N | Peto Odds Ratio Peto,Fixed,95% CI | Weight | Peto Odds Ratio Peto,Fixed,95% CI |
|---|---|---|---|---|---|
| Mettler 2000 | 0/49 | 0/51 | | | Not estimable |
| Feste 2000 | 0/45 | 0/42 | | | Not estimable |
| Bhoyrul 2000 | 0/119 | 1/125 | | | 0.14 [ 0.00, 7.16 ] |
| Venkatesh 2007 | 0/14 | 0/28 | | | Not estimable |
| Test for subgroup differences: Not applicable | | | | | |



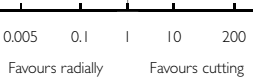
**Analysis 1.3. Comparison 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry, Outcome 3 Trocar site herniation.**

Review: Trocar types in laparoscopy

Comparison: 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry

Outcome: 3 Trocar site herniation

| Study or subgroup | Radially expanding n/N | Conventional cutting n/N | Peto Odds Ratio Peto,Fixed,95% CI | Weight | Peto Odds Ratio Peto,Fixed,95% CI |
|---|---|---|---|---|---|
| Venkatesh 2007 (1) | 0/14 | 0/28 | | | Not estimable |
| Bisgaard 2007 | 0/38 | 0/39 | | | Not estimable |
| Bhoyrul 2000 | 0/119 | 0/125 | | | Not estimable |
| Mettler 2000 | 0/49 | 0/51 | | | Not estimable |
| **Total (95% CI)** | **220** | **243** | | | **Not estimable** |
| Total events: 0 (Radially expanding), 0 (Conventional cutting) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: not applicable | | | | | |
| Test for subgroup differences: Not applicable | | | | | |




(1) Conventional cutting total included 2 arms of this study: the pyramidal bladed and single bladed trocars

## Analysis 1.4. Comparison 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry, Outcome 4 Trocar site bleeding.

Review: Trocar types in laparoscopy

Comparison: 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry

Outcome: 4 Trocar site bleeding

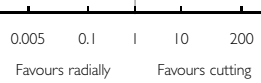
| Study or subgroup | Radially expanding n/N | Conventional cutting n/N | Peto Odds Ratio Peto,Fixed,95% CI | Weight | Peto Odds Ratio Peto,Fixed,95% CI |
|---|---|---|---|---|---|
| Mettler 2000 | 0/49 | 2/51 | | 5.7 % | 0.14 [ 0.01, 2.24 ] |
| Bhoyrul 2000 | 0/112 | 13/123 | | 35.3 % | 0.13 [ 0.04, 0.41 ] |
| Lam 2000 | 0/23 | 0/31 | | | Not estimable |
| Feste 2000 | 0/45 | 4/42 | | 11.1 % | 0.12 [ 0.02, 0.86 ] |
| Bisgaard 2007 | 10/38 | 14/39 | | 48.0 % | 0.64 [ 0.25, 1.68 ] |
| **Total (95% CI)** | **267** | **286** | | **100.0 %** | **0.28 [ 0.14, 0.54 ]** |

Total events: 10 (Radially expanding), 33 (Conventional cutting)

Heterogeneity: $Chi^2 = 5.57$, df = 3 (P = 0.13); $I^2 = 46\%$

Test for overall effect: Z = 3.76 (P = 0.00017)

Test for subgroup differences: Not applicable

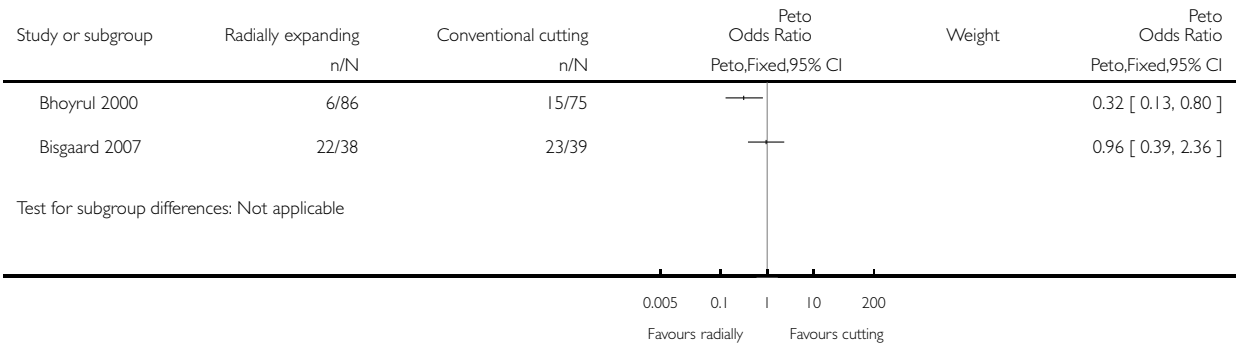


**Analysis 1.5. Comparison 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry, Outcome 5 Trocar site haematoma.**

Review: Trocar types in laparoscopy

Comparison: 1 Radially expanding trocar versus cutting trocar for primary and secondary port entry

Outcome: 5 Trocar site haematoma

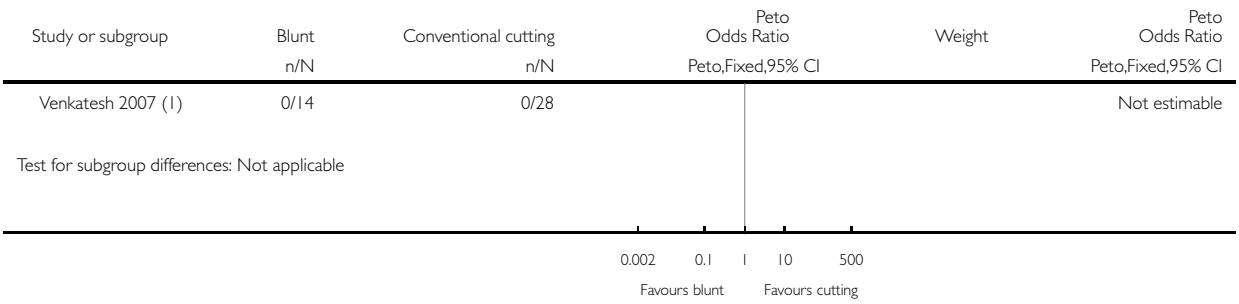



**Analysis 2.1. Comparison 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry, Outcome 1 Visceral injury.**

Review: Trocar types in laparoscopy

Comparison: 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry

Outcome: 1 Visceral injury



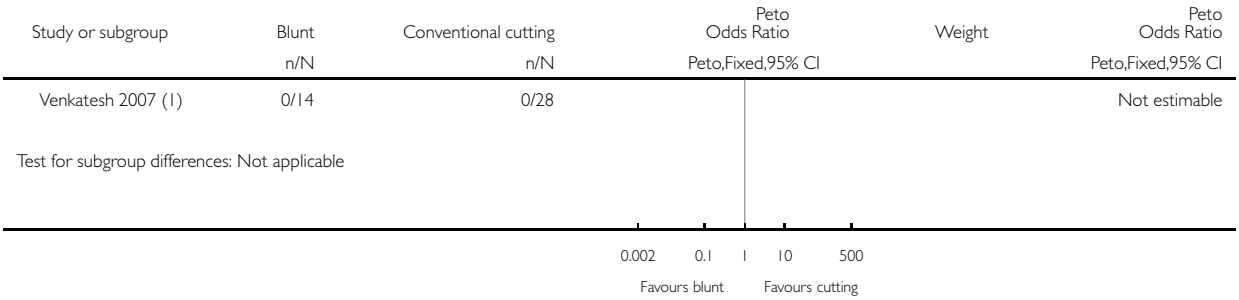

(1) Conventional cutting total included 2 arms of this study: the pyramidal bladed and single bladed trocars

### Analysis 2.2. Comparison 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry, Outcome 2 Vascular injury.

Review: Trocar types in laparoscopy

Comparison: 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry

Outcome: 2 Vascular injury



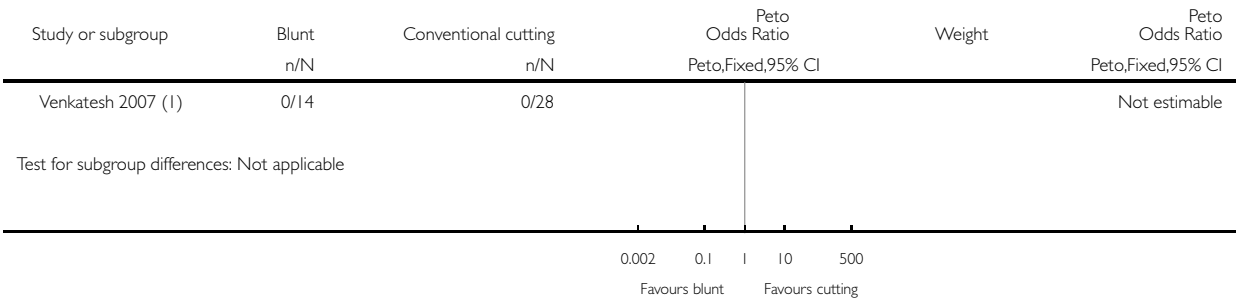

(1) Conventional cutting total included 2 arms of this study: the pyramidal bladed and single bladed trocars

### Analysis 2.3. Comparison 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry, Outcome 3 Trocar site herniation.

Review: Trocar types in laparoscopy

Comparison: 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry

Outcome: 3 Trocar site herniation



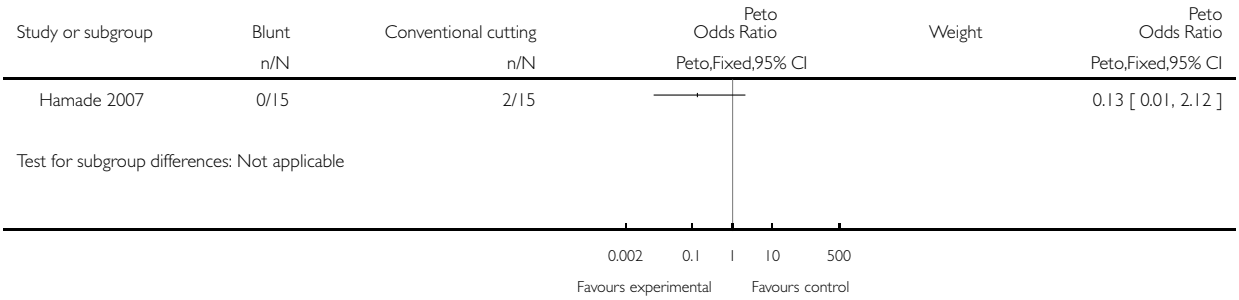

(1) Conventional cutting total included 2 arms of this study: the pyramidal bladed and single bladed trocars

### Analysis 2.4. Comparison 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry, Outcome 4 Trocar site bleeding, intraoperative.

Review: Trocar types in laparoscopy

Comparison: 2 Conical blunt-tipped trocar versus cutting trocar for secondary port entry

Outcome: 4 Trocar site bleeding, intraoperative

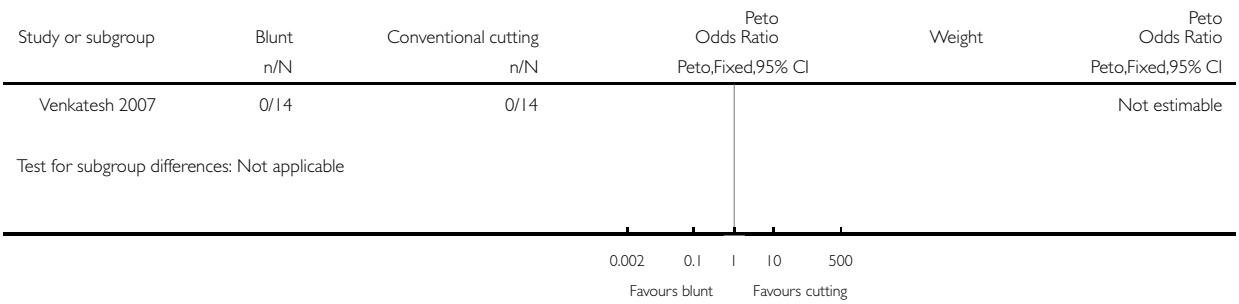



### Analysis 3.1. Comparison 3 Radially expanding trocar versus conical blunt-tipped trocar for secondary port entry, Outcome 1 Visceral injury.

Review: Trocar types in laparoscopy

Comparison: 3 Radially expanding trocar versus conical blunt-tipped trocar for secondary port entry

Outcome: 1 Visceral injury

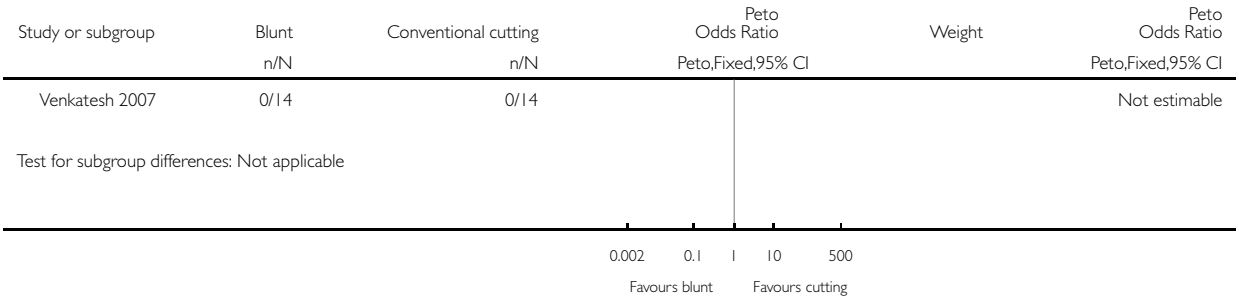


### Analysis 3.2. Comparison 3 Radially expanding trocar versus conical blunt-tipped trocar for secondary port entry, Outcome 2 Vascular injury.

Review: Trocar types in laparoscopy

Comparison: 3 Radially expanding trocar versus conical blunt-tipped trocar for secondary port entry

Outcome: 2 Vascular injury

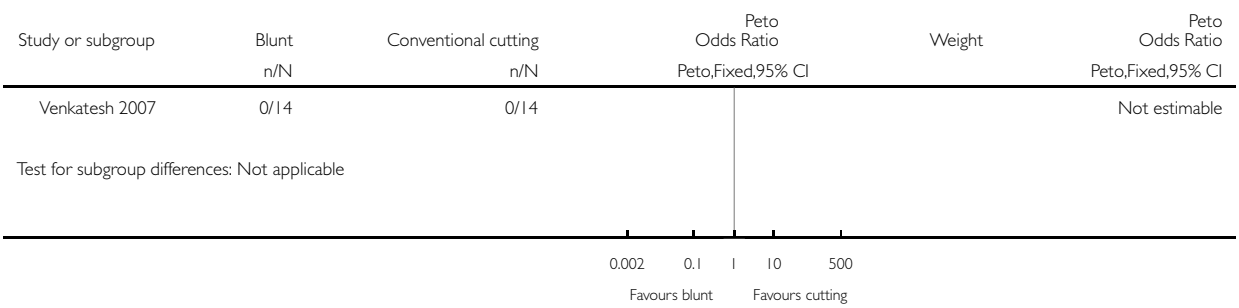



### Analysis 4.1. Comparison 4 Single-bladed trocar versus pyramidal-bladed trocar, Outcome 1 Visceral injury.

Review: Trocar types in laparoscopy

Comparison: 4 Single-bladed trocar versus pyramidal-bladed trocar

Outcome: 1 Visceral injury

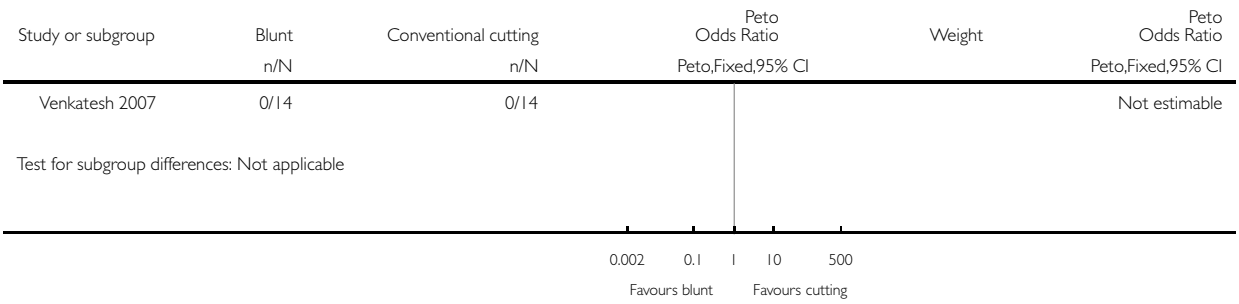


**Analysis 4.2. Comparison 4 Single-bladed trocar versus pyramidal-bladed trocar, Outcome 2 Vascular injury.**

Review: Trocar types in laparoscopy

Comparison: 4 Single-bladed trocar versus pyramidal-bladed trocar

Outcome: 2 Vascular injury




# APPENDICES

## Appendix 1. Menstrual Disorders and Subfertility Group (MDSG) search strategy

Keywords CONTAINS "laparoscopic"or"laparoscope size"or"laparoscopy"or"laparoscopically assisted hysterectomy"or "laparoscopically assisted vaginal hysterectomy"or"laparoscopy-assisted vaginal hysterectomy"or"mini-laparoscopy" or Title CONTAINS"laparoscopic"or"laparoscope size"or"laparoscopy"or"laparoscopically assisted hysterectomy"or "laparoscopically assisted vaginal hysterectomy"or"laparoscopy-assisted vaginal hysterectomy"or"mini-laparoscopy"
AND
Keywords CONTAINS "trocar" or "trocar - dilating-tip" or "trocar - non-shielded-bladed" or "trocar ports" or "pneumoperitoneum" or Title CONTAINS"trocar" or "trocar - dilating-tip" or "trocar - non-shielded-bladed" or "trocar ports" or "pneumoperitoneum"

## Appendix 2. Ovid Cochrane Central Register of Controlled Trials (CENTRAL)

Database searched 28 February 2011, 1 February 2012, 15 January 2014, 24 July 2014 and 26 May 2015.
1 exp Laparoscopy/ (3605)
2 exp Laparoscopes/ (92)
3 (Laparoscop$ or Laparascop$).tw. (7064)
4 (minimal$ adj invasive).tw. (1544)
5 or/1-4 (8532)
6 (trocar$ or troicar$ or trochar$).tw. (306)
7 cannula$.tw. (1757)
8 (visual adj2 entry system$).tw. (3)
9 pneumoperiton$.tw. (455)
10 exp Pneumoperitoneum, Artificial/ (225)
11 (optiview$ or endotip$).tw. (3)
12 visiport$.tw. (0)

13 access technique$.tw. (22)
14 (Veress or veress-needle$).tw. (35)
15 Hasson.tw. (8)
16 or/6-15 (2535)
17 5 and 16 (729)

## Appendix 3. Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE®

**Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) (1950 to present)**
Database searched 28 February 2011, 1 February 2012, 15 January 2014, 24 July 2014 and 26 May 2015.
1 exp Laparoscopy/ (72404)
2 exp Laparoscopes/ (3453)
3 (Laparoscop$ or Laparascop$).tw. (88645)
4 (minimal$ adj invasive).tw. (40910)
5 or/1-4 (132344)
6 (trocar$ or troicar$ or trochar$).tw. (5224)
7 cannula$.tw. (35322)
8 (visual adj2 entry system$).tw. (6)
9 pneumoperiton$.tw. (5927)
10 exp Pneumoperitoneum, Artificial/ (3860)
11 (optiview$ or endotip$).tw. (38)
12 visiport$.tw. (15)
13 access technique$.tw. (530)
14 (Veress or veress-needle$).tw. (387)
15 Hasson.tw. (153)
16 or/6-15 (47827)
17 randomized controlled trial.pt. (395860)
18 controlled clinical trial.pt. (89548)
19 randomized.ab. (321300)
20 placebo.tw. (167185)
21 clinical trials as topic.sh. (173005)
22 randomly.ab. (231296)
23 trial.ti. (138894)
24 (crossover or cross-over or cross over).tw. (64217)
25 or/17-24 (984055)
26 exp animals/ not humans.sh. (4043807)
27 25 not 26 (906186)
28 5 and 16 and 27 (774)

## Appendix 4. Ovid EMBASE

**Ovid EMBASE (January 2010 to present)**
Database searched 28 February 2011, 1 February 2012, 15 January 2014, 24 July 2014 and 26 May 2015.
1 exp Laparoscopy/ (108007)
2 (Laparoscop$ or Laparascop$).tw. (131384)
3 (minimal$ adj invasive).tw. (59604)
4 exp laparoscope/ (2885)
5 or/1-4 (199188)
6 exp trocar/ (5725)
7 (trocar$ or troicar$ or trochar$).tw. (9064)

8 (Veress or veress-needle$).tw. (657)
9 Hasson.tw. (270)
10 gastrointestinal radiography/ (4308)
11 pneumoperiton$.tw. (7441)
12 cannula$.tw. (42077)
13 (visual adj2 entry system$).tw. (6)
14 (optiview$ or endotip$).tw. (99)
15 visiport$.tw. (43)
16 access technique$.tw. (777)
17 or/6-16 (62302)
18 Clinical Trial/ (844393)
19 Randomized Controlled Trial/ (370996)
20 exp randomization/ (66369)
21 Single Blind Procedure/ (20206)
22 Double Blind Procedure/ (120351)
23 Crossover Procedure/ (42869)
24 Placebo/ (256309)
25 Randomi?ed controlled trial$.tw. (116070)
26 Rct.tw. (16937)
27 random allocation.tw. (1411)
28 randomly allocated.tw. (22280)
29 allocated randomly.tw. (2019)
30 (allocated adj2 random).tw. (726)
31 Single blind$.tw. (15724)
32 Double blind$.tw. (150401)
33 ((treble or triple) adj blind$).tw. (449)
34 placebo$.tw. (213796)
35 prospective study/ (290100)
36 or/18-35 (1459024)
37 case study/ (31673)
38 case report.tw. (281336)
39 abstract report/ or letter/ (923420)
40 or/37-39 (1230185)
41 36 not 40 (1419880)
42 5 and 17 and 41 (1495)

## Appendix 5. Ovid PsycINFO

**Ovid PsycINFO (inception to present)**
Database searched 28 February 2011, 1 February 2012, 15 January 2014, 24 July 2014 and 26 May 2015.
1 (Laparoscop$ or Laparascop$).tw. (282)
2 (minimal$ adj invasive).tw. (284)
3 or/1-2 (542)
4 (trocar$ or troicar$ or trochar$).tw. (7)
5 cannula$.tw. (1976)
6 (visual adj2 entry system$).tw. (0)
7 (optiview$ or endotip$).tw. (0)
8 visiport$.tw. (0)
9 pneumoperiton$.tw. (3)
10 or/4-9 (1986)
11 3 and 10 (6)

## Appendix 6. CINAHL, Cumulative Index of Nursing and Allied Health Literature

CINAHL search for CC1505 15 January 2014, and updated on 26 May 2015.

| # | Query | Results |
|---|---|---|
| S27 | S11 AND S25 | 18 |
| S26 | S11 AND S25 | 97 |
| S25 | S12 OR S13 or S14 or S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 | Display |
| S24 | TX allocat* random* | Display |
| S23 | (MH "Quantitative Studies") | Display |
| S22 | (MH "Placebos") | Display |
| S21 | TX placebo* | Display |
| S20 | TX random* allocat* | Display |
| S19 | (MH "Random Assignment") | Display |
| S18 | TX randomi* control* trial* | Display |
| S17 | TX ( (singl* n1 blind*) or (singl* n1 mask*) ) or TX ( (doubl* n1 blind*) or (doubl* n1 mask*) ) or TX ( (tripl* n1 blind*) or (tripl* n1 mask*) ) or TX ( (trebl* n1 blind*) or (trebl* n1 mask*) ) | Display |
| S16 | TX ( (trebl* n1 blind*) or (trebl* n1 mask*) ) | Display |
| S15 | TX ( (trebl* n1 blind*) or (trebl* n1 mask*) ) | Display |
| S14 | TX clinic* n1 trial* | Display |
| S13 | PT Clinical trial | Display |
| S12 | (MH "Clinical Trials+") | Display |
| S11 | S4 AND S10 | 471 |
| S10 | S5 OR S6 OR S7 OR S8 OR S9 | 892 |
| S9 | TX Pneumoperiton* | 572 |
| S8 | TX endotip* | 2 |

(*Continued*)

| | | |
|---|---|---|
| S7 | TX visual entry system* | 2 |
| S6 | TX trochar* | 14 |
| S5 | TX trocar* | 329 |
| S4 | S1 OR S2 OR S3 | 16,899 |
| S3 | (MM "Minimally Invasive Procedures") OR "tx minimal* invasive" | 2,714 |
| S2 | TX Laparoscop* | 14,593 |
| S1 | (MM "Laparoscopy"# OR "laparoscopy" OR #MH "Surgery, Laparoscopic"# | 11,161 |

## Appendix 7. Cochrane Database of Systematic Reviews, DARE, Wiley - Database of Abstracts of Reviews of Effects (reference lists)

#1 MeSH descriptor Laparoscopy explode all trees
#2 MeSH descriptor Laparoscopes explode all trees
#3 (Laparoscop* or Laparascop*):ti,ab,kw
#4 (minimal* invasive*):ti,ab,kw
#5 (#1 OR #2 OR #3 OR #4)
#6 (trocar* or troicar* or trochar):ti,ab,kw
#7 MeSH descriptor Pneumoperitoneum, Artificial explode all trees
#8 (pneumoperiton*):ti,ab,kw
#9 (access technique*):ti,ab,kw
#10 (cannula*):ti,ab,kw
#11 ("visual entry system" or "visual entry systems"):ti,ab,kw
#12 (optiview* or endotip*):ti,ab,kw
#13 (visiport*):ti,ab,kw
#14 (Veress or veress-needle*):ti,ab,kw
#15 (Hasson*):ti,ab,kw
#16 (#6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15)
#17 (#5 AND #16)

## CONTRIBUTIONS OF AUTHORS

CC contributed to the conception of the review, co-ordinated the review, wrote to authors of papers for additional information and worked on the data management.

CC and HS together designed and drafted the review, collected data for the review, organised retrieval of papers, screened the retrieved papers, appraised the quality of the papers, extracted the data of the papers, obtained and screened data on unpublished studies, entered data into Review Manager 5, analysed and interpreted the data and wrote the review.

SMR contributed to the conception and designing of the review, helped in providing a methodological perspective, helped with the interpretation of data and critically revised the draft review.

MW and CC together designed search strategies.

MW undertook the searches (in consultation with the Trials Search Co-ordinator of the Cochrane Gynaecology and Fertility Group, Marian Showell).

FWJ contributed to the conception and design of the review, helped interpreting the data, provided a clinical and consumer perspective and critically reviewed the draft review.

BWM contributed to the conception of the review and critically reviewed the draft review.

All authors approved the final version of the review.

## DECLARATIONS OF INTEREST

The authors do not have any potential conflicts of interest.

## SOURCES OF SUPPORT


### Internal sources

- None, Other.

### External sources

- None, Other.


## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We used a fixed-effect model for meta-analysis of dichotomous data.

We have added three subgroups: primary entry technique, secondary entry technique and differing trocar diameter.

We removed the planned sensitivity analysis where eligibility would be restricted to studies on bariatric surgery.

## INDEX TERMS

### Medical Subject Headings (MeSH)

*Patient Safety; Abdominal Injuries [etiology]; Equipment Design [adverse effects]; Hernia, Abdominal [etiology]; Laparoscopy [adverse effects; *instrumentation]; Pain, Postoperative [prevention & control]; Randomized Controlled Trials as Topic; Surgical Instruments [*adverse effects]; Vascular System Injuries [*etiology]; Viscera [*injuries]

## MeSH check words

Humans