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Ahmad G, Baker J, Finnerty J, Phillips K, Watson A

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Laparoscopic entry techniques (Review)

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[Intervention Review]

Laparoscopic entry techniques

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ABSTRACT

Background

Laparoscopy is a common procedure in many surgical specialties. Complications arising from laparoscopy are often related to initial entry into the abdomen. Life-threatening complications include injury to viscera (e.g. bowel, bladder) or to vasculature (e.g. major abdominal and anterior abdominal wall vessels). No clear consensus has been reached as to the optimal method of laparoscopic entry into the peritoneal cavity.

Objectives

To evaluate the benefits and risks of different laparoscopic entry techniques in gynaecological and non-gynaecological surgery.

Search methods

We searched the Cochrane Gynaecology and Fertility (CGF) Group trials register, CENTRAL, MEDLINE, Embase, PsycINFO, and trials registers in January 2018. We also checked the references of articles retrieved.

Selection criteria

We included randomised controlled trials (RCTs) that compared one laparoscopic entry technique versus another. Primary outcomes were major complications including mortality, vascular injury of major vessels and abdominal wall vessels, visceral injury of bladder or bowel, gas embolism, solid organ injury, and failed entry (inability to access the peritoneal cavity). Secondary outcomes were extraperitoneal insufflation, trocar site bleeding, trocar site infection, incisional hernia, omentum injury, and uterine bleeding.

Data collection and analysis

Two review authors independently selected studies, assessed risk of bias, and extracted data. We expressed findings as Peto odds ratios (Peto ORs) with 95% confidence intervals (CIs). We assessed statistical heterogeneity using the I^2 statistic. We assessed the overall quality of evidence for the main comparisons using GRADE methods.

Main results

The review included 57 RCTs including four multi-arm trials, with a total of 9865 participants, and evaluated 25 different laparoscopic entry techniques. Most studies selected low-risk patients, and many studies excluded patients with high body mass index (BMI) and previous abdominal surgery. Researchers did not find evidence of differences in major vascular or visceral complications, as would be anticipated given that event rates were very low and sample sizes were far too small to identify plausible differences in rare but serious adverse events.

Open-entry versus closed-entry

Ten RCTs investigating Veress needle entry reported vascular injury as an outcome. There was a total of 1086 participants and 10 events of vascular injury were reported. Four RCTs looking at open entry technique reported vascular injury as an outcome. There was a total of 376 participants and 0 events of vascular injury were reported. This was not a direct comparison. In the direct comparison of Veress needle and Open-entry technique, there was insufficient evidence to determine whether there was a difference in rates of vascular injury (Peto OR 0.14, 95% CI 0.00 to 6.82; 4 RCTs; $n = 915$; $I^2 = N/A$, very low-quality evidence). Evidence was insufficient to show whether there were differences between groups for visceral injury (Peto OR 0.61, 95% CI 0.06 to 6.08; 4 RCTs; $n = 915$; $I^2 = 0\%$; very low-quality evidence), or failed entry (Peto OR 0.45, 95% CI 0.14 to 1.42; 3 RCTs; $n = 865$; $I^2 = 63\%$; very low-quality evidence). Two studies reported mortality with no events in either group. No studies reported gas embolism or solid organ injury.

Direct trocar versus Veress needle entry

Trial results show a reduction in failed entry into the abdomen with the use of a direct trocar in comparison with Veress needle entry (OR 0.24, 95% CI 0.17 to 0.34; 8 RCTs; $N = 3185$; $I^2 = 45\%$; moderate-quality evidence). Evidence was insufficient to show whether there were differences between groups in rates of vascular injury (Peto OR 0.59, 95% CI 0.18 to 1.96; 6 RCTs; $n = 1603$; $I^2 = 75\%$; very low-quality evidence), visceral injury (Peto OR 2.02, 95% CI 0.21 to 19.42; 5 RCTs; $n = 1519$; $I^2 = 25\%$; very low-quality evidence), or solid organ injury (Peto OR 0.58, 95% CI 0.06 to 5.65; 3 RCTs; $n = 1079$; $I^2 = 61\%$; very low-quality evidence). Four studies reported mortality with no events in either group. Two studies reported gas embolism, with no events in either group.

Direct vision entry versus Veress needle entry

Evidence was insufficient to show whether there were differences between groups in rates of vascular injury (Peto OR 0.39, 95% CI 0.05 to 2.85; 1 RCT; $n = 186$; very low-quality evidence) or visceral injury (Peto OR 0.15, 95% CI 0.01 to 2.34; 2 RCTs; $n = 380$; $I^2 = N/A$; very low-quality evidence). Trials did not report our other primary outcomes.

Direct vision entry versus open entry

Evidence was insufficient to show whether there were differences between groups in rates of visceral injury (Peto OR 0.13, 95% CI 0.00 to 6.50; 2 RCTs; $n = 392$; $I^2 = N/A$; very low-quality evidence), solid organ injury (Peto OR 6.16, 95% CI 0.12 to 316.67; 1 RCT; $n = 60$; very low-quality evidence), or failed entry (Peto OR 0.40, 95% CI 0.04 to 4.09; 1 RCT; $n = 60$; very low-quality evidence). Two studies reported vascular injury with no events in either arm. Trials did not report our other primary outcomes.

Radially expanding (STEP) trocars versus non-expanding trocars

Evidence was insufficient to show whether there were differences between groups in rates of vascular injury (Peto OR 0.24, 95% CI 0.05 to 1.21; 2 RCTs; $n = 331$; $I^2 = 0\%$; very low-quality evidence), visceral injury (Peto OR 0.13, 95% CI 0.00 to 6.37; 2 RCTs; $n = 331$; very low-quality evidence), or solid organ injury (Peto OR 1.05, 95% CI 0.07 to 16.91; 1 RCT; $n = 244$; very low-quality evidence). Trials did not report our other primary outcomes.

Other studies compared a wide variety of other laparoscopic entry techniques, but all evidence was of very low quality and evidence was insufficient to support the use of one technique over another.

Authors' conclusions

Overall, evidence was insufficient to support the use of one laparoscopic entry technique over another. Researchers noted an advantage of direct trocar entry over Veress needle entry for failed entry. Most evidence was of very low quality; the main limitations were imprecision (due to small sample sizes and very low event rates) and risk of bias associated with poor reporting of study methods.

PLAIN LANGUAGE SUMMARY

Laparoscopic entry techniques

Review question

Cochrane review authors evaluated the benefits and risks of different laparoscopic entry techniques in gynaecological and non-gynaecological surgery.

Background

Laparoscopy is a procedure that uses a laparoscope - a thin tube with a light and a camera on the end, similar to a telescope - that is inserted under general anaesthesia through a small cut or incision (0.5 cm to 1 cm) into, or near, the navel. The camera can project images onto external screens, which allow surgeons to directly visualise the pelvic and abdominal organs. This permits performance of keyhole surgery, which uses much smaller surgical tools without the need for large incisions. When laparoscopy is performed, gas is gently pumped into the abdomen to increase the workspace for the camera and tools. The method by which incisions are made to introduce the laparoscope may influence the likelihood of complications.

Laparoscopic entry techniques (Review)

Although laparoscopy is usually safe, a small minority of patients experience life-threatening complications, including injury to surrounding blood vessels or the bowel. These complications often occur at the first step of the procedure, when the abdominal wall is pierced with specialised instruments to insert the gas. Different doctors use different specialised instruments and techniques.

Study characteristics

Systematic review authors included 57 randomised controlled trials with a total of 9865 individuals undergoing laparoscopy. The RCTs compared 25 different laparoscopic entry techniques. Patients included in the review were men, women, and children who required laparoscopic surgery for a range of gynaecological and non-gynaecological conditions. Most of these studies included low-risk patients, and many studies excluded patients with high body mass index (BMI) and previous abdominal surgery. Fifty-three of 57 studies did not mention sources of funding. Two studies received funding from industry through a grant or through free use of medical equipment during trials. Two studies received government funding. The evidence is current to January 2018.

Key results

Evidence is insufficient to show whether there were differences between groups in the rate of failed entry, vascular injury, or visceral injury, or in other major complications with the use of an open-entry technique in comparison to a closed-entry technique.

Comparison of closed techniques revealed a reduction in the risk of failed entry with use of a direct trocar entry technique in comparison to a Veress needle entry technique (8 RCTs; 3185 participants; moderate-quality evidence). Here the evidence suggests that for every 1000 patients operated on, 65 patients in the Veress needle group will experience failed entry compared to between 11 and 22 patients in the direct trocar group (i.e. between 43 and 54 fewer incidents of failed entry occurred per 1000 patients operated on with a direct trocar vs a Veress needle). Evidence was insufficient to show whether there were differences between groups in vascular injury, visceral injury, solid organ injury, or other major complications.

Evidence was insufficient to show whether there were differences between direct vision entry and Veress needle entry in rates of vascular injury or visceral injury. Equally, evidence was insufficient to show whether there were differences between direct vision entry and open entry in rates of visceral injury, solid organ injury, or failed entry.

Evidence was insufficient to show whether there were differences in rates of vascular injury, visceral injury, or solid organ injury between use of radially expanding trocars and use of non-expanding trocars.

Other studies compared a wide variety of other laparoscopic entry techniques, but all evidence was of very low quality and evidence was insufficient to support the use of one technique over another.

Overall, evidence is insufficient to support the use of one laparoscopic entry technique over another. Researchers noted an advantage of direct trocar entry over Veress needle entry for failed entry. No study in any comparison reported any deaths.

More research is required to examine the safety of entry techniques and to discover whether the risk of major complications differs between techniques.

Quality of the evidence

Most evidence is of very low quality; the main limitations were imprecision (due to small sample sizes and very low event rates) and risk of bias associated with poor reporting of study methods.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Open-entry vs closed-entry technique for patients undergoing laparoscopy

Open-entry vs closed-entry technique for patients undergoing laparoscopy

Patient or population: patients undergoing laparoscopy

Setting: surgical

Intervention: open-entry techniques

Comparison: closed-entry techniques

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with closed-entry techniques	Risk with open-entry techniques				
Mortality	No events reported in any study			715 (2 RCTs)		
Vascular injury (major vessels and abdominal wall vessels)	2 per 1000	3 per 1000 (0 to 13)	Peto OR 0.14 (0.00 to 6.82)	915 (4 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b}	
Visceral injury (bladder or bowel)	4 per 1000	2 per 1000 (0 to 23)	Peto OR 0.61 (0.06 to 6.08)	915 (4 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b}	
Gas embolism	No studies reported this outcome					
Solid organ injury	No studies reported this outcome					
Failed entry	17 per 1000	8 per 1000 (2 to 25)	Peto OR 0.45 (0.14 to 1.42)	865 (3 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,c,d}	I ² = 68%

***The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). The control group rate is based on the mean rate in the comparison group.

CI: confidence interval; OR: odds ratio; RCT: randomised controlled trial.

GRADE Working Group grades of evidence.

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded one level for serious risk of bias: studies lacked information on randomisation, allocation concealment, and blinding.

^bDowngraded two levels for very serious imprecision: very few events occurred across the studies. Results crossed the line of no effect and were imprecise with wide CIs.

^cDowngraded one level for serious imprecision. Results were imprecise with wide confidence intervals

^dDowngraded one level for significant unexplained heterogeneity ($I^2 = 68\%$).

Summary of findings 2. Direct trocar entry vs Veress needle entry for patients undergoing laparoscopy

Direct trocar entry vs Veress needle entry for patients undergoing laparoscopy

Patient or population: patients undergoing laparoscopic surgery

Setting: surgical

Intervention: direct trocar entry

Comparison: Veress needle entry

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with Veress needle entry	Risk with direct trocar entry				
Mortality	No events reported in any study			1438 (4 RCTs)		
Vascular injury (major vessels and abdominal wall vessels)	8 per 1000	5 per 1000 (2 to 17)	Peto OR 0.59 (0.18 to 1.96)	1603 (6 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b,c}	$I^2 = 73\%$
Visceral injury (bladder or bowel)	1 per 1000	3 per 1000 (0 to 25)	Peto OR 2.02 (0.21 to 19.42)	1519 (5 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b}	
Gas embolism	No events reported in any study			810 (2 RCTs)		
Solid organ injury	4 per 1000	2 per 1000 (0 to 20)	Peto OR 0.58 (0.06 to 5.65)	1079 (3 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b,c}	$I^2 = 61\%$
Failed entry	65 per 1000	16 per 1000 (11 to 22)	Peto OR 0.24 (0.17 to 0.34)	3185 (8 RCTs)	⊕⊕⊕⊕ MODERATE ^a	

***The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). The control group rate is based on the mean rate in the comparison group.

CI: confidence interval; OR: odds ratio; RCT: randomised controlled trial.

GRADE Working Group grades of evidence.

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded one level for serious risk of bias. Studies lacked information on randomisation, allocation concealment, and blinding. One study was open-label, therefore at high risk of performance bias; however this is unlikely to affect this outcome.

^bDowngraded two levels for very serious imprecision: very few events occurred across the studies. Results crossed the line of no effect and were imprecise with wide CIs.

^cSignificant heterogeneity may be explained by different study populations; therefore quality of evidence was not downgraded on this basis.

Summary of findings 3. Direct vision entry vs Veress needle entry for patients undergoing laparoscopy

Direct vision entry vs Veress needle entry for patients undergoing laparoscopy

Patient or population: patients undergoing laparoscopy

Setting: surgical

Intervention: direct vision entry

Comparison: Veress needle entry

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with Veress needle entry	Risk with direct vision entry				
Mortality	No studies reported this outcome					
Vascular injury (major vessels and abdominal wall vessels)	31 per 1000	12 per 1000 (2 to 88)	Peto OR 0.39 (0.05 to 2.85)	186 (1 RCT)	⊕⊕⊕⊕ VERY LOW^{a,b}	
Visceral injury (bladder or bowel)	10 per 1000	2 per 1000 (0 to 24)	Peto OR 0.15 (0.01 to 2.34)	380 (2 RCTs)	⊕⊕⊕⊕ VERY LOW^{a,b}	
Gas embolism	No studies reported this outcome					

Solid organ injury	No studies reported this outcome
Failed entry	No studies reported this outcome

***The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). The control group rate is based on the mean rate in the comparison group.

CI: confidence interval; OR: odds ratio; RCT: randomised controlled trial.

GRADE Working Group grades of evidence.

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded one level for serious risk of bias: studies lacked information on randomisation, allocation concealment, and blinding.

^bDowngraded two levels for very serious imprecision: very few events occurred across studies. Results were based on one or two RCTs with few participants. Results crossed the line of no effect and were imprecise with wide CIs.

Summary of findings 4. Direct vision entry vs open-entry technique for patients undergoing laparoscopy

Direct vision entry vs open-entry technique for patients undergoing laparoscopy

Patient or population: patients undergoing laparoscopy

Setting: surgical

Intervention: direct vision entry trocars

Comparison: open-entry technique

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with open-entry technique	Risk with direct vision entry trocars				
Mortality	No studies reported this outcome					
Vascular injury (major vessels and abdominal wall vessels)	No events reported in any study			392 (2 RCTs)		
Visceral injury (bladder or bowel)	5 per 1000	1 per 1000 (0 to 33)	Peto OR 0.13 (0.00 to 6.50)	392 (2 RCTs)	⊕⊕⊕⊕ VERY LOW^{a,b}	

Gas embolism	No studies reported this outcome				
Solid organ injury	0 per 1000	0 per 1000 (0 to 0)	Peto OR 6.16 (0.12 to 316.67)	60 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b}
Failed entry	74 per 1000	30 per 1000 (3 to 303)	Peto OR 0.40 (0.04 to 4.09)	60 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b}

***The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). The control group rate is based on the mean rate in the comparison group.

CI: confidence interval; OR: odds ratio; RCT: randomised controlled trial.

GRADE Working Group grades of evidence.

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded one level for serious risk of bias: studies lacked information on randomisation, allocation concealment, and blinding.

^bDowngraded two levels for very serious imprecision: very few events occurred across studies. Results were based on one or two RCTs with few participants. Results crossed the line of no effect and were imprecise with wide CIs.

Summary of findings 5. Radially expanding (STEP) trocars for primary port entry vs standard (non-expanding) trocars for patients undergoing laparoscopy

Radially expanding (STEP) trocars for primary port entry vs standard (non-expanding) trocars for patients undergoing laparoscopy

Patient or population: patients undergoing laparoscopy

Setting: surgical

Intervention: radially expanding (STEP) trocars

Comparison: non-expanding trocars

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with non-expanding trocars	Risk with radially expanding (STEP) trocars				
Mortality	No studies reported this outcome					

Vascular injury (major vessels and abdominal wall vessels)	30 per 1000	7 per 1000 (2 to 36)	Peto OR 0.24 (0.05 to 1.21)	331 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b}
Visceral injury (bladder or bowel)	6 per 1000	1 per 1000 (0 to 37)	Peto OR 0.13 (0.00 to 6.37)	331 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b}
Gas embolism	No studies reported this outcome				
Solid organ injury	8 per 1000	8 per 1000 (1 to 120)	Peto OR 1.05 (0.07 to 16.91)	244 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b}
Failed entry	No studies reported this outcome				

***The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). The control group rate is based on the mean rate in the comparison group.

CI: confidence interval; OR: odds ratio; RCT: randomised controlled trial; STEP: radially expanding trocar.

GRADE Working Group grades of evidence.

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded one level for serious risk of risk of bias: studies lacked adequate information on randomisation and allocation concealment.

^bDowngraded two levels for very serious imprecision: very few events occurred across studies. Results were based on one or two RCTs with few participants. Results crossed the line of no effect and were imprecise with wide CIs.

BACKGROUND

Description of the condition

Laparoscopy is a surgical procedure commonly used in gynaecology whereby a laparoscope is used to gain intra-abdominal access via less extensive incisions. Evidence suggests that laparoscopy provides significant benefits compared to laparotomy in terms of surgical outcomes for patients and costs for healthcare providers (Bijen 2009). Unlike in conventional open surgery, the surgeon is usually unable to visualise the initial entry into the peritoneal cavity. Most laparoscopic complications occur during the initial entry (Alkatout 2017). These may happen at several stages including Veress needle insertion, creation of a pneumoperitoneum, and primary trocar insertion. Opinion is divided as to the safest entry technique, and clinical practice is varied. Although gynaecologists commonly use a closed method of entry, other surgical specialties routinely use open methods of entry.

General risks are associated with laparoscopic entry regardless of the technique used and the particular method of entry applied. Estimates from one study of 25,764 laparoscopic gynaecological cases suggest that complications related to entry had an incidence of 0.3% (Jansen 1997; Jansen 2004). Potentially life-threatening complications include perforation of the bowel - a major abdominal vessel - and of an anterior abdominal wall vessel. One study analysing trocar-related injuries reported to the FDA between 1993 and 1996 that 81% of deaths resulting from trocar injury were the result of vascular injury and 19% resulted from bowel injury (Bhojru 2001). Bowel injuries following laparoscopic procedures often are not diagnosed intraoperatively, and this increases their associated mortality. Mortality rates following injury to the bowel during laparoscopic procedures ranged from 2.5% to 5% (Magrina 2002).

Fortunately, these serious complications are rarely described in the recorded literature. Researchers have estimated the incidence of bowel wall perforation at 0.0% to 0.5% of cases, and the incidence of major vessel injury at 0.01% to 1.0% of cases (Magrina 2002). Although these low rates are reassuring, the data still imply that more than 250 individuals in the United Kingdom will suffer a serious complication each year (Middlesbrough Consensus 1999). Minor complications such as postoperative infection, subcutaneous emphysema, extraperitoneal insufflation, and trocar site hernia, are also associated with laparoscopic entry (Magrina 2002; Swank 2012).

Description of the intervention

Researchers have described many differing laparoscopic entry methods. In response to feedback received from a previously published version of this review, we have tried to include descriptions of the exact laparoscopic entry device used in each study.

Closed techniques

The first closed technique involves insertion of a Veress needle (a needle equipped with a spring-loaded obturator) into the peritoneal cavity, followed by gas insufflation (act of blowing) and insertion of a trocar (a sharp, pointed instrument with a cannula that can be used to enter the body cavity). Finally, the laparoscope is passed through the trocar once the obturator is

removed. Numerous studies have shown that the Veress needle entry technique is highly favoured by gynaecologists worldwide (Lalchandani 2005; Vilos 2007). A second closed technique involves insertion of a trocar directly into the peritoneal cavity (direct trocar entry), followed by laparoscopic inspection and then gas insufflation. Potential benefits of direct trocar entry include shorter operating times, immediate recognition of bowel or vascular injuries, and immediate recognition of failed entry (Krishnakumar 2009; Molloy 2002).

The radially expanding access system, STEP™ (InnerDyne Inc., Sunnyvale, California, USA), is a closed technique that was developed to minimise tissue trauma. This system uses a pneumoperitoneum needle with a polymeric sleeve. Following routine insufflation, the needle is removed, leaving the outer sleeve in situ. Direct dilatation of the sleeve results in a 12-mm port. Suggested benefits are that only one sharp instrument enters the abdominal cavity, less tissue trauma occurs, and, in theory, fewer bowel and vascular injuries occur (Bhojru 2000).

Open techniques

An open technique, as first described by Hasson, involves cutting down the peritoneum, inserting a blunt trocar under direct visualisation, providing gas insufflation, and inserting the laparoscope (Hasson 1971). Potential benefits of this technique include prevention of vascular injury, gas embolism, and pre-peritoneal insufflation, and a low incidence of bowel injury (Vilos 2007). It should be noted that the type of trocar used for primary port entry can influence complication rates (Fuller 2005).

Single-incision laparoscopic surgery (SILS) (Covidien Plc, Dublin, Ireland) was designed with the aim of reducing the invasiveness of entry into the peritoneal cavity compared to that seen with traditional laparoscopic entry techniques (Tsimoyiannis 2009). Laparo-endoscopic single site (LESS) surgery (Olympus Medical Systems Corp., Tokyo, Japan) is another common term that is often used interchangeably with SILS; however neither has been universally adopted (Fader 2010). The SILS/LESS approach is an open technique that involves a single infraumbilical 12-mm incision with the umbilicus pulled out, exposing the fascia. Pneumoperitoneum is induced when an atraumatic trocar is introduced into the abdomen. Second and third trocars are introduced to the left and right of the first trocar, leaving a small bridge of fascia between them to avoid leakage of carbon dioxide. Suggested benefits include a reduction in postoperative pain and an improved cosmetic result (Tsimoyiannis 2009).

The X-cone is a reusable access device that allows manipulation of multiple instruments through a single abdominal incision. Two interlocking metal elements are connected to form a cone, on top of which sits a silicon cap containing ports through which trocars can be inserted. The seal between the silicon cap and the trocars prevents leakage of carbon dioxide (Liliana 2011).

Researchers have also described several techniques for secondary port insertion. This involves insertion of additional trocars once the laparoscope has been introduced through the initial, primary insertion site. As secondary ports are inserted under direct vision, the surgeon can directly observe the insertion of secondary trocars by using the laparoscope intraperitoneally, and complication rates should be lower. This review will analyse both primary and secondary port entry techniques.

How the intervention might work

Observational studies have indicated that the incidence of vascular injury was reduced when open-entry techniques were used instead of closed-entry techniques (Molloy 2002). It has been hypothesised that, as the closed technique involves blind insertion of trocars, an open technique may be a safer option for primary port insertion.

Among the closed-entry techniques, investigators have hypothesised that use of direct vision with an optical trocar to visualise passage of the trocar through the abdominal wall layers should reduce complication rates, as trocars are not inserted blindly (Mettler 1997).

Theoretical benefits of direct trocar entry over Veress needle entry include immediate recognition of bowel or vascular injuries and immediate recognition of failed entry, as the initial trocar can be used to introduce a laparoscope (Krishnakumar 2009; Molloy 2002).

It has been hypothesised that use of radially expanding blunt trocars may reduce the rate of entry-related injuries, as these trocars have a blunt tip; however, users are required to apply greater force to enter the abdomen, which may result in an increase in entry-related injuries caused by overthrusting of the trocar (Tarnay 1999; Vilos 2007).

Why it is important to do this review

Researchers have reached no clear consensus as to the optimal method of entry into the peritoneal cavity (Merlin 2003; Molloy 2002). The Royal College of Obstetricians and Gynaecologists produced a national Green-top guideline in 2008 entitled "Preventing entry-related gynaecological laparoscopic injuries" (RCOG 2008). This document emphasised the need for an infraumbilical incision and a sharp Veress needle and for use of pressure, not volume, of insufflated gas to determine when the trocar should be placed within the peritoneal cavity.

In 2007, a survey of gynaecologists in the United Kingdom who had an interest in minimal access surgery revealed wide variation in practice (Ahmad 2007). One-third of these clinicians were unwilling to change their practice unless supported by good quality evidence. This evidence is lacking in part due to low complication event rates for trocar entry; therefore most RCTs are underpowered to detect differences between different laparoscopic entry techniques. Through systematic review and meta-analysis of available data, it may be possible to produce good quality evidence to inform clinical practice.

OBJECTIVES

To evaluate the benefits and risks of different laparoscopic entry techniques in gynaecological and non-gynaecological surgery.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) that compared one laparoscopic port entry technique versus another for primary or secondary port entry.

Types of participants

Trials included men, women, and children (no age range specified) who were undergoing diagnostic, operative, or mixed laparoscopy, performed by gynaecologists or general surgeons.

Types of interventions

We analysed the following laparoscopic entry techniques.

1. Open-entry technique versus closed-entry technique (primary port entry).
 - a. Open-entry versus direct trocar entry.
 - b. Open-entry versus Veress needle entry.
2. Direct trocar entry versus Veress needle entry (primary port entry).
3. Direct vision entry versus Veress needle entry (primary port entry).
4. Direct vision entry versus open-entry technique (primary port entry).
5. Disposable instruments versus reusable instruments (primary port entry).
6. Radially expanding (STEP) trocars versus standard (non-expanding) trocars (primary port entry).
7. Trendelenburg position for entry versus supine position for entry (primary port entry).
8. Volume of gas used as an indicator for entry versus intra-abdominal pressure as an indicator for entry (primary port entry).
9. Comparisons of sites of entry.
 - a. Transfundal versus infraumbilical insertion of the Veress needle.
 - b. Left upper quadrant versus caudally displaced umbilical insertion of the Veress needle.
10. SILS versus Veress needle entry.
11. SILS versus Hasson entry technique.
12. Comparisons of other laparoscopic entry techniques for primary or secondary port insertion.
 - a. Lifting versus not lifting the abdominal wall before Veress needle insertion (primary port entry).
 - b. Carbon dioxide gas insufflation versus use of a gasless abdominal wall retractor (primary port entry).
 - c. Closed technique versus a parallel technique of Veress needle insertion (primary port entry).
 - d. Cutting trocar versus blunt trocar (primary port entry).
 - e. 5-mm versus 3-mm trocar for secondary port entry.
 - f. Radially expanding access device versus conventional (non-expanding) cutting tip trocar for secondary port entry.
 - g. X-cone versus Veress needle insertion (primary port entry).
 - h. X-cone versus SILS laparoscopy.
 - i. Comparisons of intra-abdominal pressures for secondary port entry
 - ii. Intra-abdominal pressure (IAP) 25 mmHg versus IAP 15 mmHg for secondary port entry.
 - iii. IAP 25 mmHg versus IAP 25 mmHg with external compression for secondary port entry.
 - iii. IAP 15 mmHg versus IAP 25 mmHg with external compression for secondary port entry.

Types of outcome measures

Primary outcomes

Major complications

1. Mortality
2. Vascular injury (major vessels and abdominal wall vessels)
3. Visceral injury (bladder or bowel)
4. Gas embolism
5. Solid organ injury
6. Failed entry (inability to access the peritoneal cavity)

Secondary outcomes

7. Extraperitoneal insufflation
8. Trocar site bleeding
9. Trocar site infection
10. Incisional hernia
11. Omentum injury
12. Uterine bleeding

Search methods for identification of studies

We sought all published and unpublished RCTs studying laparoscopic entry techniques. We used the following search strategies, without language restriction and in consultation with the Information Specialist of the Cochrane Gynaecology and Fertility Group.

Electronic searches

We searched the following databases with no language restrictions.

1. The specialised register of controlled trials of the Cochrane Gynaecology and Fertility (CGF) Group (PROCITE platform), searched 25 January 2018 ([Appendix 1](#)).
2. The Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Central Register of Studies Online (CRSO web platform), searched 25 January 2018 ([Appendix 2](#)).
3. With Ovid software, MEDLINE (from 1946 to 25 January 2018), Embase (from 1980 to 25 January 2018), and PsycINFO (from 1806 to 25 January 2018) ([Appendix 3](#); [Appendix 4](#); [Appendix 5](#)).

We combined the MEDLINE search with the Cochrane highly sensitive search strategy for identifying randomised trials, which

appears in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Lefebvre 2011](#)). We combined the Embase search with use of trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) (www.sign.ac.uk/methodology/filters.html#random).

Other electronic sources of trials (searched through to January 2018) included:

1. trial registers for ongoing and registered trials: ClinicalTrials.gov, a service of the US National Institutes of Health (www.clinicaltrials.gov); and the World Health Organization International Trials Registry Platform search portal (www.clinicaltrials.gov);
2. PubMed (www.ncbi.nlm.nih.gov/pubmed/): we took the random control filter for PubMed from the *Cochrane Handbook for Systematic Reviews of Interventions* ([Lefebvre 2011](#)); and
3. for grey literature, OpenSIGLE database (www.opensigle.inist.fr/) and Google.

Searching other resources

We searched conference proceedings and handsearched the reference lists of articles retrieved by the search. In liaison with the Information Specialist, we handsearched any relevant journals and conference abstracts that are not covered in the CGF specialised register.

Data collection and analysis

Selection of studies

Two review authors (JF and JB) independently examined the retrieved search results for relevant titles and abstracts. These two authors then independently selected trials to be included in accordance with the above mentioned criteria. We encountered no disagreements about study inclusion. We extracted data and analysed trials for the following quality criteria: methodological details and descriptive data for participants and outcomes. We presented this information under [Results of the search](#) and in the [Characteristics of included studies](#) tables. When necessary, review authors corresponded with study investigators to clarify study eligibility (e.g. with respect to participant eligibility criteria and allocation method). We have summarised the selection of studies process in the PRISMA ([Moher 2009](#)) flow chart ([Figure 1](#)).

Figure 1. Study flow diagram.

Data extraction and management

Two review authors (JF and JB) independently extracted data from eligible studies. We discussed any discrepancies, and GA independently verified final extractions. We imported extracted data into RevMan 5. Two review authors (JF and JB) independently verified imported data and matched extracted data.

Assessment of risk of bias in included studies

We assessed each included trial for the following criteria using the Cochrane 'Risk of bias' tool: sequence generation; allocation concealment; blinding of participants, providers, and outcome assessors; completeness of outcome data; selective outcome reporting; and other potential sources of bias (Higgins 2011a). We presented study conclusions in the 'Risk of bias' table and

incorporated interpretation of review findings by performing sensitivity analyses. Two review authors (JF and JB) independently performed all assessments of trial quality. GA resolved any discrepancies that arose.

Measures of treatment effect

We used numbers of events in the control and intervention groups of each study to calculate odds ratios (ORs) with 95% confidence intervals (CIs). We used the Peto OR, as we expected events to be rare. We performed statistical analysis in accordance with guidelines presented in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011), while excluding from meta-analysis studies that reported no events in both arms.

Method of analysis for multi-arm trials

In addition to two studies from the previous review ([Angioli 1 2013](#); [Bemelman 2000](#)), we included two new multi-arm trials ([He 1 2015](#); [Köstü 1 2016](#)). As in the previous edition of this review, to utilise these studies in meta-analysis, we assigned each study three study identification numbers (IDs). This approach is recommended in the *Cochrane Handbook for Systematic Reviews of Interventions*, Section 16.5.4 ([Higgins 2011b](#)).

Unit of analysis issues

The primary analysis was per participant, randomised.

Dealing with missing data

We analysed the data on an intention-to-treat (ITT) basis, as far as possible, and we made attempts to obtain missing data from the original investigators. For all outcomes, we analysed only available data.

Assessment of heterogeneity

We considered whether clinical and methodological characteristics of included studies were sufficiently similar for meta-analysis to provide a meaningful summary. We assessed statistical heterogeneity by determining the I^2 statistic. An I^2 value greater than 50% indicated substantial heterogeneity ([Higgins 2011a](#)). When heterogeneity was present, we investigated this by examining clinical and methodological differences between studies. When data were available, we performed sensitivity analysis.

Assessment of reporting biases

In view of the difficulty involved in detecting and correcting for publication bias and other reporting biases, we aimed to minimise their potential impact by ensuring a comprehensive search for eligible studies and staying alert for duplication of data.

If we included 10 or more studies in an analysis, we planned to use a funnel plot to explore the possibility of small-study effects (the tendency for estimates of the intervention effect to be more beneficial in smaller studies).

Data synthesis

We reported the pooled odds ratios with a 95% confidence interval using a fixed-effect Peto model and Review Manager 5 software ([RevMan 2014](#)). We used the Peto OR, as we expected events to be rare.

An increase in the odds of a particular outcome was displayed graphically in 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 performed subgroup analyses for the following interventions.

1. Open-entry technique versus closed-entry technique.
 - a. Open-entry technique versus Veress needle entry technique.
 - b. Open-entry technique versus direct trocar entry.

When we identified substantial heterogeneity, we examined clinical and methodological differences between studies, and we took any statistical heterogeneity into account when interpreting the results.

Sensitivity analysis

We conducted sensitivity analyses for the primary outcomes to determine whether conclusions were robust to arbitrary decisions made regarding eligibility of studies and analysis. We performed sensitivity analysis by restricting eligibility to studies at low risk of bias (defined as studies not at high risk of bias in any domain, and at low risk of selection bias). When we performed sensitivity analysis for outcomes which included studies that selected for paediatric or obese participants, we restricted eligibility to studies that either selected for non-obese adult patients or did not specify a body mass index (BMI) threshold.

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

Two review authors (JF and JB) working independently prepared 'Summary of findings' tables ([Summary of findings for the main comparison](#); [Summary of findings 2](#); [Summary of findings 3](#); [Summary of findings 4](#); [Summary of findings 5](#)) using GRADEproGDT and Cochrane methods ([GRADEproGDT 2015](#); [Higgins 2011a](#)). We resolved disagreements by discussion. We used these tables to evaluate the overall quality of the body of evidence for the main review comparison (open vs closed entry) and for the main review outcomes (mortality, vascular injury, visceral injury, gas embolism, solid organ injury, failed entry) using GRADE criteria (study limitations (i.e. risk of bias), consistency of effect, imprecision, indirectness, and publication bias). We prepared additional 'Summary of findings' tables for the main review outcomes for other important comparisons (direct trocar vs Veress needle, direct vision vs Veress needle, direct vision vs open entry, and radially expanding STEP trocars vs non-expanding trocars). We justified, documented, and incorporated judgements about evidence quality (high, moderate, low, or very low) into reporting of results for each outcome.

RESULTS

Description of studies

Results of the search

The search yielded 2566 articles. After reviewing article abstracts, we determined that 32 studies were potentially eligible for inclusion in this update, and we retrieved their full texts. Of these studies, we excluded 21, with reasons given below, and included 11 new studies in the updated review. We included 46 studies from previous versions of this review. Therefore, a total of 57 randomised controlled trials (RCTs) including six multi-arm studies and covering 25 different laparoscopic entry techniques were eligible for inclusion in this review. We have provided further descriptive details about the included studies in the [Characteristics of included studies](#) tables. We identified published reports (full papers or abstracts) for all included trials.

Included studies

Participants

In total, we included in this systematic review 57 RCTs with 9865 individuals undergoing laparoscopy. For this update, we included 11 new studies with 2037 participants. The number of participants in each trial ranged from 17 in [Schulze 1999](#) to 1000 in [Zakerah 2010](#).

Interventions

The interventions studied are listed below, together with the identified studies.

1. Open-entry technique versus closed-entry technique (primary port entry)

Seven RCTs investigated an open-entry technique versus a closed-entry technique (direct trocar or Veress needle) (Akbar 2008; Angioli 1 2013; Bemelman 2000; Channa 2009; Cogliandolo 1998; Peitgen 1997; Zaman 2015).

1.1. Open-entry versus direct trocar entry

Two RCTs investigated an open technique versus direct trocar entry (Angioli 1 2013; Bemelman 2000).

1.2. Open-entry versus Veress needle entry

Seven RCTs investigated an open technique versus Veress needle entry (Akbar 2008; Angioli 2 2013; Bemelman 2000; Channa 2009; Cogliandolo 1998; Peitgen 1997; Zaman 2015).

2. Direct trocar entry versus Veress needle entry (primary port entry)

Twelve RCTs investigated direct trocar entry versus Veress needle entry (Agresta 2004; Angioli 3 2013; Bemelman 2000; Borgatta 1990; Byron 1993; Ertugrul 2015; Gunenc 2005; Imran 2014; Karaca 2014; Prieto-Díaz-Chávez 2006; Tansatit 2006; Zakerah 2010).

3. Direct vision entry versus Veress needle entry (primary port entry)

Two RCTs investigated direct vision entry versus Veress needle entry (Tinelli 2009; Tinelli 2010).

4. Direct vision entry versus open entry (primary port entry)

Three RCTs investigated direct vision entry versus an open technique (Minervini 2008; Tinelli 2011; Tinelli 2013).

5. Disposable instruments versus reusable instruments (primary port entry)

We did not identify any RCTs for this comparison.

6. Radially expanding (STEP) trocars versus standard (non-expanding) trocars (primary port entry)

Four RCTs compared radially expanding (STEP) trocars versus standard trocars (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Mettler 2000).

7. Trendelenburg position for entry versus supine position for entry (primary port entry)

We did not identify any RCTs for this comparison.

8. Volume of gas used as an indicator for entry versus intra-abdominal pressure as an indicator for entry (primary port entry)

We did not identify any RCTs for this comparison.

9. Comparisons of sites of entry

Two RCTs compared sites of entry.

9.1. Transfundal versus infraumbilical insertion of the Veress needle.

A single RCT compared the transfundal versus the infraumbilical site for Veress needle insertion (Santala 1999).

9.2. Left upper quadrant versus caudally displaced umbilical insertion of the Veress needle.

A single RCT compared caudally displaced umbilical versus left upper quadrant sites for Veress needle insertion (Vilos 2015).

10. SILS versus Veress needle entry

Six RCTs compared SILS laparoscopic entry versus Veress needle insertion (Deveci 2013; Guo 2015; He 1 2015; Partelli 2016; Porta 2017; Youssef 2015).

11. SILS versus Hasson entry technique

Ten RCTs compared SILS laparoscopic surgery versus modified Hasson technique laparoscopy (Carter 2013; Chang 2015; Fonollosa 2012; Lai 2011; Luna 2013; Perez 2013; Phillips 2012; Tsimoyiannis 2009; Vilallonga 2012; Villalobos 2014).

12. Comparisons of other laparoscopic entry techniques for primary or secondary port insertion

12.1. Lifting versus not lifting the abdominal wall before Veress needle insertion (primary port entry)

A single RCT compared lifting and not lifting the abdominal wall before Veress needle insertion (Briel 2000).

12.2. Carbon dioxide gas insufflation versus use of a gasless abdominal wall retractor (primary port entry)

Four RCTs compared carbon dioxide gas insufflation with use of a gasless abdominal wall retractor (Cravello 1999; Johnson 1997; Kitano 1993; Schulze 1999).

12.3. Closed technique versus a parallel technique of Veress needle insertion (primary port entry)

A single RCT compared a closed technique with a parallel technique of Veress needle insertion (Ostrzenski 1999).

12.4. Cutting trocar versus blunt trocar (primary port entry)

Three RCTs compared cutting trocars with blunt trocars (Hamade 2007; Huang 2012; Venkatesh 2007).

12.5. 5-mm versus 3-mm trocar for secondary port entry

A single RCT compared the use of 5-mm trocars versus 3-mm trocars for secondary port entry (Ghezzi 2005).

12.6. Radially expanding access device versus conventional (non-expanding) cutting tip trocar for secondary port entry

Two RCTs compared the use of radially expanding trocars versus standard trocars for secondary port entry (Lam 2000; Yim 2001).

12.7. X-cone versus Veress needle insertion (primary port entry)

A single RCT compared X-cone laparoscopic entry versus Veress needle insertion (He 1 2015).

12.8. X-cone versus SILS laparoscopy

A single RCT compared X-cone laparoscopic entry with conventional SILS laparoscopy (He 1 2015).

12.9. IAP 25 mmHg versus IAP 15 mmHg for secondary port entry

A single RCT compared secondary port entry at intra-abdominal pressure (IAP) 25 mmHg achieved solely via insufflation and at IAP 15 mmHg achieved solely via insufflation (Köstü 1 2016).

12.10. IAP 25 mmHg versus IAP 25 mmHg with external compression for secondary port entry

A single RCT compared secondary port entry at IAP 25 mmHg achieved solely via insufflation and at IAP 25 mmHg achieved via insufflation and manual external abdominal compression (Köstü 1 2016).

12.11. IAP 15 mmHg versus IAP 25 mmHg with external compression for secondary port entry

A single RCT compared secondary port entry at IAP 15 mmHg achieved solely via insufflation and at IAP 25 mmHg achieved via insufflation and manual external abdominal compression (Köstü 1 2016).

Intervention standardisation

Several RCTs stated clearly that all operators had received standardised operative training in both interventions especially for the study (Agresta 2004; Bemelman 2000; Cogliandolo 1998; Kitano 1993; Mettler 2000; Ostrzenski 1999; Santala 1999; Tansatit 2006). Several RCTs also stated clearly that all operators deployed a standardised operative technique (Agresta 2004; Akbar 2008; Angioli 1 2013; Bemelman 2000; Bhoyrul 2000; Bisgaard 2007; Carter 2013; Channa 2009; Cogliandolo 1998; Cravello 1999; Deveci 2013; Ertugrul 2015; Fonollosa 2012; Ghezzi 2005; Gunenc 2005; Hamade 2007; He 1 2015; Huang 2012; Imran 2014; Johnson 1997; Kitano 1993; Lai 2011; Luna 2013; Mettler 2000; Ostrzenski 1999; Perez 2013; Prieto-Díaz-Chávez 2006; Santala 1999; Schulze 1999; Tansatit 2006; Tinelli 2010; Tinelli 2011; Tinelli 2013; Tsimoyiannis 2009; Vilallonga 2012; Yim 2001; Zakerah 2010).

Outcomes

Studies reported the following primary outcome measures.

1. Mortality (Agresta 2004; Angioli 1 2013; Channa 2009; Fonollosa 2012; Huang 2012; Imran 2014; Karaca 2014; Porta 2017).
2. Vascular injury (major vessels and abdominal wall vessels) (Agresta 2004; Angioli 1 2013; Bhoyrul 2000; Channa 2009; Cogliandolo 1998; Cravello 1999; Ertugrul 2015; Feste 2000; Imran 2014; Karaca 2014; Kitano 1993; Lai 2011; Mettler 2000; Ostrzenski 1999; Peitgen 1997; Prieto-Díaz-Chávez 2006; Tinelli 2009; Tinelli 2011; Tinelli 2013; Venkatesh 2007; Vilos 2015). Only three studies stated a clear definition for vascular injury (Mettler 2000: major vascular injury and abdominal wall vascular injury; Ostrzenski 1999: laceration of large blood vessels; Tinelli 2009 and Ertugrul 2015: nature of vascular injuries for all events described in text).
3. Visceral injury (bladder or bowel) (Agresta 2004; Angioli 1 2013; Bhoyrul 2000; Briel 2000; Channa 2009; Cogliandolo 1998; Ertugrul 2015; Feste 2000; He 1 2015; Imran 2014; Karaca 2014; Mettler 2000; Ostrzenski 1999; Peitgen 1997; Tinelli 2009; Tinelli 2010; Tinelli 2011; Tinelli 2013; Venkatesh 2007).
4. Gas embolism (Agresta 2004; Borgatta 1990).
5. Solid organ injury (Agresta 2004; Bhoyrul 2000; Ertugrul 2015; Karaca 2014; Kitano 1993; Minervini 2008).
6. Failed entry (inability to access the peritoneal cavity) (Agresta 2004; Akbar 2008; Angioli 1 2013; Borgatta 1990; Briel 2000; Byron 1993; Ertugrul 2015; Fonollosa 2012; Gunenc 2005; Lai 2011; Mettler 2000; Minervini 2008; Perez 2013; Phillips 2012; Prieto-Díaz-Chávez 2006; Santala 1999; Vilallonga 2012; Zakerah 2010; Zaman 2015).

Studies reported the following secondary outcome measures.

1. Extraperitoneal insufflation (Agresta 2004; Akbar 2008; Angioli 1 2013; Borgatta 1990; Briel 2000; Byron 1993; Channa 2009; Cogliandolo 1998; Gunenc 2005; Imran 2014; Karaca 2014; Kitano 1993; Köstü 1 2016; Ostrzenski 1999; Peitgen 1997; Prieto-Díaz-Chávez 2006; Vilos 2015; Zakerah 2010).
2. Trocar site bleeding (Angioli 1 2013; Bhoyrul 2000; Bisgaard 2007; Channa 2009; Cogliandolo 1998; Cravello 1999; Ghezzi 2005; Hamade 2007; He 1 2015; Köstü 1 2016; Lam 2000; Mettler 2000; Minervini 2008; Porta 2017; Tinelli 2010; Venkatesh 2007; Yim 2001).
3. Trocar site infection (Akbar 2008; Angioli 1 2013; Borgatta 1990; Carter 2013; Chang 2015; Channa 2009; Cogliandolo 1998; Cravello 1999; Deveci 2013; Guo 2015; He 1 2015; Imran 2014; Kitano 1993; Lai 2011; Lam 2000; Luna 2013; Partelli 2016; Peitgen 1997; Porta 2017; Prieto-Díaz-Chávez 2006; Venkatesh 2007; Villalobos 2014; Yim 2001; Youssef 2015; Zaman 2015).
4. Incisional hernia (Bhoyrul 2000; Chang 2015; Channa 2009; Deveci 2013; Guo 2015; Porta 2017; Yim 2001; Youssef 2015; Zaman 2015).
5. Omental injury (Akbar 2008; Angioli 1 2013; Borgatta 1990; Ertugrul 2015; Köstü 1 2016; Zakerah 2010).
6. Uterine bleeding (Santala 1999).

Several RCTs compared laparoscopic entry techniques but did not report any of our outcome measures: in Johnson 1997 and Tansatit 2006, outcome measures included operative technique and patient pain; Schulze 1999 reported haemodynamic and pulmonary function and postoperative pain; Bemelman 2000 and Köstü 2016a reported total time and number of attempts to establish pneumoperitoneum; Tsimoyiannis 2009 reported the ease of the operative technique; Prabakar 2015 reported length of the trocar beneath the peritoneum after entry.

Addressing feedback from previous versions of this review

In 2014 we received feedback on trocar site bleeding for STEP secondary trocars versus standard secondary trocars, description of trocars, and inclusion of relevant other meta-analyses. We have addressed these points in the [Feedback](#) section at the end of the 2015 review.

In September 2018 we received feedback on the 2015 version of this review, concerning safety data reported in analyses. We have addressed these points in the [Feedback](#) section at the end of this review.

Excluded studies

After initial screening of abstracts and retrieval of full papers, we excluded 21 studies for the following reasons.

1. Nine studies were not RCTs (Cardin 2011; Dunne 2011; Fagotti 2010; Garg 2012; Lu 2012; Sangrasi 2011; Shayani-Nasab 2013; Taye 2016; Zhao 2015).
2. Seven studies compared SILS versus a multi-port technique, but study authors did not specify which entry technique was utilised for the multi-port surgery (Alekbazade 2015; Artis 2014; Chakravarty 2014; Dabbagh 2015; Rizwi 2014; Singh 2014; Watanabe 2016).
3. Five studies did not compare entry techniques: one study compared effects of different methods of creating the peritoneal

operating field (lifting abdomen, pneumoperitoneum) on stress response ([Han 2012](#)), two studies compared different techniques for maintenance of the pneumoperitoneum ([Joshi 2009](#); [Sandhu 2009](#)), one study compared operative technique rather than entry technique ([Kim 2009](#)), and one study compared the effects of different pneumoperitoneum pressures on live kidney donor comfort ([Warle 2013](#)).

Studies awaiting classification

Two studies available only as conference abstracts compared different laparoscopic entry techniques but did not report any of our outcomes ([Köstü 2016a](#); [Prabakar 2015](#)). We were not able to contact the study authors to find out whether additional data are available, as no correspondence details were given in the abstracts.

Ongoing studies

We identified three ongoing studies upon searching trials registers. [NCT00731107](#) aims to compare Veress needle entry

versus XCEL bladeless trocar insertion in 200 women undergoing laparoscopic gynaecological surgery. [NCT02804529](#) seeks to compare periumbilical versus Palmer's point versus Meng's point for insertion of the Veress needle in 90 patients aged 18 to 80 undergoing gastrointestinal surgery. Patients undergoing previous abdominal surgery will be excluded. [NCT03306238](#) is undertaking a comparison of the Hasson (open) technique versus the Veress needle (closed) technique in 300 participants undergoing laparoscopic renal surgery. Researchers will exclude patients with BMI > 40 kg/m² and patients who have previously undergone laparotomy.

Risk of bias in included studies

We have provided further details about risk of bias of included studies in the 'Risk of bias' tables that accompany the [Characteristics of included studies](#) tables and in [Figure 2](#) and [Figure 3](#).

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

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Agresta 2004	?	+	?	+	+	+
Akbar 2008	?	+	?	?	+	+
Angioli 1 2013	+	+	?	+	+	+
Angioli 2 2013	+	+	?	+	+	+
Angioli 3 2013	+	+	?	+	+	+
Bemelman 2000	?	+	?	?	+	+
Bhoyrul 2000	+	?	+	+	+	+
Bisgaard 2007	+	+	+	?	?	+
Borgatta 1990	?	?	?	+	+	+
Briel 2000	?	?	?	+	+	+
Byron 1993	+	?	+	+	+	+
Carter 2013	+	+	?	+	+	+
Chang 2015	?	?	+	+	+	+
Channa 2009	+	?	?	+	+	+
Cogliandolo 1998	+	?	?	+	+	+
Cravello 1999	+	?	?	+	+	+
Deveci 2013	+	?	?	+	+	+
Ertugrul 2015	?	?	-	+	+	+
Feste 2000	?	?	+	?	+	+
Fonollosa 2012	+	?	?	+	+	+
Ghezzi 2005	+	?	+	+	+	+
Gunenc 2005	?	?	?	+	+	+

Figure 2. (Continued)

Gunenc 2005	?	?	?	+	+	+
Guo 2015	?	+	+	+	+	+
Hamade 2007	+	+	?	+	+	+
He 1 2015	?	?	?	?	+	+
He 2 2015	?	?	?	?	+	+
He 3 2015	?	?	?	?	+	+
Huang 2012	+	?	?	+	+	+
Imran 2014	+	?	?	+	+	+
Johnson 1997	+	?	+	?	-	+
Karaca 2014	?	?	?	+	+	+
Kitano 1993	+	?	?	+	+	+
Köstü 1 2016	+	-	?	+	+	+
Köstü 2 2016	+	-	?	+	+	+
Köstü 3 2016	+	-	?	+	+	+
Lai 2011	+	+	+	+	+	+
Lam 2000	+	?	+	+	?	+
Luna 2013	?	?	?	+	+	?
Mettler 2000	+	?	?	+	+	+
Minervini 2008	?	?	?	+	+	+
Ostrzenski 1999	?	?	+	+	+	+
Partelli 2016	+	+	+	+	+	+
Peitgen 1997	?	?	?	+	+	+
Perez 2013	+	?	+	+	+	+
Phillips 2012	?	?	+	+	+	+
Porta 2017	?	?	?	+	-	?
Prieto-Díaz-Chávez 2006	+	?	?	+	+	+
Santala 1999	+	+	?	+	+	+
Schulze 1999	?	?	?	?	+	+
Tansatit 2006	?	?	?	+	+	+
Tinelli 2009	?	?	?	+	+	+
Tinelli 2010	?	?	?	+	+	+

Figure 2. (Continued)

Tinelli 2010	?	?	?	+	+	+
Tinelli 2011	+	?	?	+	+	+
Tinelli 2013	+	+	?	+	+	?
Tsimoyiannis 2009	?	?	+	+	+	+
Venkatesh 2007	?	?	?	?	?	+
Vilallonga 2012	?	?	?	+	+	+
Villalobos 2014	?	+	?	+	+	?
Vilos 2015	?	?	+	+	-	+
Yim 2001	+	+	+	+	+	+
Youssef 2015	?	?	?	+	-	+
Zakerah 2010	+	+	?	+	?	+
Zaman 2015	?	?	?	+	-	+

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

Trial design

All included trials stated that they are RCTs.

Allocation

Random sequence generation

Twenty-eight studies were at low risk of bias: Bhoirul 2000; Byron 1993; Channa 2009; Cravello 1999; Fonollosa 2012; Huang 2012; Imran 2014; Johnson 1997; Kitano 1993; Lam 2000; Mettler 2000; Prieto-Díaz-Chávez 2006; Santala 1999; Tinelli 2011; and Tinelli 2013 clearly stated that they achieved randomisation by using

random number tables; Angioli 1 2013; Bisgaard 2007; Carter 2013; Cogliandolo 1998; Deveci 2013; Ghezzi 2005; Hamade 2007; Köstü 1 2016; Lai 2011; Partelli 2016; Perez 2013; Yim 2001; and Zakerah 2010 clearly stated that they achieved randomisation by using computerised random number selection.

In 29 studies, the method of randomisation was unclear (Agresta 2004; Akbar 2008; Bemelman 2000; Borgatta 1990; Briel 2000; Chang 2015; Ertugrul 2015; Feste 2000; He 1 2015; Gunenc 2005; Guo 2015; Karaca 2014; Luna 2013; Minervini 2008; Ostrzenski 1999; Peitgen 1997; Phillips 2012; Porta 2017; Schulze 1999; Tansatit 2006; Tinelli

2009; Tinelli 2010; Tsimoyiannis 2009; Venkatesh 2007; Vilallonga 2012; Villalobos 2014; Vilos 2015; Youssef 2015; Zaman 2015).

Allocation concealment

Twenty studies referenced allocation concealment: Agresta 2004; Akbar 2008; Angioli 1 2013; Bemelman 2000; Bisgaard 2007; Carter 2013; Chang 2015; Ertugrul 2015; Guo 2015; Hamade 2007; Köstü 1 2016; Lai 2011; Partelli 2016; Santala 1999; Tinelli 2013; Tsimoyiannis 2009; Villalobos 2014; Youssef 2015; Yim 2001; Zakerah 2010. Partelli 2016 described consent of patients before allocation and revelation of allocation to operating surgeons only on the day of the operation. In all other cases, investigators attempted to attain allocation concealment by using sealed envelopes. In reference to the new studies included in this update that referenced the sealed envelope technique, in all cases it was not stated whether the envelopes were sealed shut or were serially numbered, or whether patients consented before or after allocation. Consequently, risk of allocation concealment remained unclear for these studies (Chang 2015; Ertugrul 2015; Youssef 2015). Köstü 1 2016 stated clearly that allocation concealment was not performed (high risk). For all other studies, the use of allocation concealment was unclear.

Blinding

Seven RCTs were single-blinded (i.e. patients were blinded): Byron 1993; Ghezzi 2005; Johnson 1997; Lam 2000; Ostrzenski 1999; Phillips 2012; Vilos 2015. He 1 2015 is described as a single-blinded study, but study authors did not state whether patients or outcome assessors were blinded. Lai 2011 and Tsimoyiannis 2009 were single-blinded with only outcome assessors blinded. Eight RCTs were double-blinded (patients and outcome assessors) (Bhoyrul 2000; Bisgaard 2007; Chang 2015; Feste 2000; Guo 2015; Partelli 2016; Perez 2013; Yim 2001). Zaman 2015 is described in the abstract as a "prospective randomized double blind study", but blinding is not mentioned in the main body of the paper. Ertugrul 2015 was unblinded. The method of blinding was unclear for the remaining trials.

Incomplete outcome data

Eight trials referred to and used intention-to-treat analysis (Agresta 2004; Bhoyrul 2000; Carter 2013; Chang 2015; Ertugrul 2015; Feste 2000; Guo 2015; Partelli 2016); we assessed these as being at low risk of attrition bias. The other trials made no reference to an intention-to-treat analysis, and there is no indication that it had been used.

Six RCTs reported post-randomisation exclusion of participants along with the reasons for doing so (Angioli 1 2013; Bhoyrul 2000; Chang 2015; Cravello 1999; Peitgen 1997; Tsimoyiannis 2009).

Two RCTs reported participants as lost to follow-up because of intraoperative complications (Feste 2000; Schulze 1999). Bisgaard 2007 reported one participant as lost to follow-up due to loss of a study diary. Akbar 2008 stated exclusions but gave no reasons. Carter 2013 reported that eight participants were lost to long-term follow-up, as they did not attend outpatient clinics. Chang 2015

reported that seven participants were lost to follow-up, as the team was unable to contact them. Youssef 2015 reported 13 participants lost to follow-up: seven elected to follow up with their local doctors, four had travelled abroad, and phone numbers were incorrect for two. Guo 2015 reported 36 losses to follow-up due to relocation or changes in contact information.

All other study authors stated no exclusions, loss to follow-up, or dropouts; or did not mention exclusions within the study.

Selective reporting

We deemed Johnson 1997 to be at high risk of reporting bias, as study authors did not include all outcome values in the published results. Bisgaard 2007 presented subgroups of data in relation to levels of bruising and nausea and vomiting. Lam 2000 and Zaman 2015 did not report a breakdown of the major complications that they reported in the study. Porta 2017, Vilos 2015, and Youssef 2015 did not consistently quote absolute significance values, for example, P value given as "NS" or "<0.05". Venkatesh 2007 reported complications as the rate per trocar insertion instead of the rate per number of participants. Zakerah 2010 used differing statistical analyses between outcomes.

Other potential sources of bias

We did not identify further potential sources of within-study bias.

Effects of interventions

See: [Summary of findings for the main comparison](#) Open-entry vs closed-entry technique for patients undergoing laparoscopy; [Summary of findings 2](#) Direct trocar entry vs Veress needle entry for patients undergoing laparoscopy; [Summary of findings 3](#) Direct vision entry vs Veress needle entry for patients undergoing laparoscopy; [Summary of findings 4](#) Direct vision entry vs open-entry technique for patients undergoing laparoscopy; [Summary of findings 5](#) Radially expanding (STEP) trocars for primary port entry vs standard (non-expanding) trocars for patients undergoing laparoscopy

1. Open-entry technique versus closed-entry technique (primary port entry)

Seven RCTs with a total of 1225 participants compared an open-entry technique versus a closed-entry technique (direct trocar or Veress needle) (Akbar 2008; Angioli 1 2013; Bemelman 2000; Channa 2009; Cogliandolo 1998; Peitgen 1997; Zaman 2015). Bemelman 2000 did not report our outcomes. See [Summary of findings for the main comparison](#).

Primary outcomes

1.1. Mortality

Two RCTs compared an open-entry technique versus direct trocar or Veress needle entry (Angioli 1 2013, Channa 2009). Researchers reported no events in any group.

1.2. Vascular injury (major vessels and abdominal wall vessels)

See [Analysis 1.2](#) and [Figure 4](#).

Figure 4. Forest plot of comparison: 1 Open-entry technique vs closed-entry technique (primary port entry), outcome: 1.2 Vascular injury (major vessels and abdominal wall vessels).

One RCT compared an open-entry technique with direct trocar entry, with no events in either group (Angioli 1 2013). Four RCTs compared an open-entry technique versus Veress needle entry (Angioli 2 2013; Channa 2009; Cogliandolo 1998; Peitgen 1997); three of these studies reported no events in either group (Angioli 2 2013; Channa 2009; Peitgen 1997).

Evidence was insufficient to show whether there was a difference in vascular injury rates between open-entry and closed-entry techniques (Peto odds ratio (OR) 0.14, 95% confidence interval (CI) 0.00 to 6.82; 4 RCTs; n = 915; I² = N/A; very low-quality evidence).

1.3. Visceral injury (bladder or bowel)

See Analysis 1.3 and Figure 5.

Figure 5. Forest plot of comparison: 1 Open-entry technique vs closed-entry technique (primary port entry), outcome: 1.3 Visceral injury (bladder or bowel).

One RCT compared an open-entry technique with direct trocar entry (Angioli 1 2013), with no events in either group. Four RCTs compared an open-entry technique versus Veress needle entry (Angioli 2 2013; Channa 2009; Cogliandolo 1998; Peitgen 1997); two of these studies reported no events in either group (Channa 2009; Peitgen 1997). Evidence was insufficient to show whether there was a difference in visceral injury rates between open-entry and closed-entry techniques (Peto OR 0.61, 95% CI 0.06 to 6.08; 4 RCTs; $n = 915$; $I^2 = 0\%$; very low-quality evidence).

1.4. Gas embolism

No studies reported this outcome.

1.5. Solid organ injury

No studies reported this outcome.

1.6. Failed entry (inability to access the peritoneal cavity)

See Analysis 1.4.

One RCT compared an open-entry technique versus direct trocar entry (Angioli 1 2013). Evidence was insufficient to show whether there was a difference in rates of failed entry between open entry and direct trocar entry (Peto OR 0.21, 95% CI 0.00 to 12.20; 1 RCT; $n = 294$; very low-quality evidence).

Three RCTs compared an open-entry technique versus Veress needle entry (Akbar 2008; Angioli 2 2013; Zaman 2015). Evidence was insufficient to show whether there was a difference in rates of failed entry between open entry and Veress needle entry (Peto OR

0.48, 95% CI 0.14 to 1.60; 3 RCTs; $n = 571$; $I^2 = 75\%$; very low-quality evidence).

Evidence was insufficient to show whether there was a difference in rates of failed entry between open-entry and closed-entry techniques overall (Peto OR 0.45, 95% CI 0.14 to 1.42; $n = 865$; 4 RCTs; $I^2 = 63\%$; very low-quality evidence). We found no cause for the substantial heterogeneity. Data were insufficient for performance of any sensitivity analysis.

Secondary outcomes

1.7. Extraperitoneal insufflation

See Analysis 1.5.

One RCT compared an open-entry technique versus direct trocar entry, with no events in either group (Angioli 1 2013).

Five RCTs compared open-entry and Veress needle entry techniques (Akbar 2008; Angioli 2 2013; Channa 2009; Cogliandolo 1998; Peitgen 1997); two of these studies reported no events in either arm (Channa 2009; Peitgen 1997). Evidence suggested a reduction in the rate of extraperitoneal insufflation in the open-entry group compared with the Veress needle entry group (Peto OR 0.26, 95% CI 0.07 to 0.94; 5 RCTs; $n = 691$; $I^2 = 0\%$; low-quality evidence).

After removal of studies at high risk of bias in any domain and/or high or unclear risk of selection bias (Akbar 2008; Channa 2009; Cogliandolo 1998; Peitgen 1997) in a sensitivity analysis, this finding

did not change substantially (Peto OR 0.12, 95% CI 0.02 to 0.59; 1 RCT; n = 408).

Evidence suggested a reduction in extraperitoneal insufflation in the open-entry group compared with the closed-entry group overall (Peto OR 0.26, 95% CI 0.07 to 0.94; 5 RCTs; n = 985; $I^2 = 0\%$; low-quality evidence). However, after removal of studies at high risk of bias in any domain and/or high or unclear risk of selection bias (Akbar 2008; Channa 2009; Cogliandolo 1998; Peitgen 1997) in a sensitivity analysis, evidence was insufficient to show whether there was a difference in rates of extraperitoneal insufflation between open-entry and closed-entry (Peto OR 0.12, 95% CI 0.07 to 0.94; 1 RCT; n = 301).

1.8. Trocar site bleeding

See Analysis 1.6.

One RCT compared an open-entry technique versus direct trocar entry (Angioli 1 2013). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between open entry and direct trocar entry (Peto OR 0.21, 95% CI 0.01 to 3.70; 1 RCT; n = 294; very low-quality evidence). Three RCTs compared an open-entry technique versus Veress needle entry (Angioli 2 2013; Channa 2009; Cogliandolo 1998). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between open entry and Veress needle entry (Peto OR 0.94, 95% CI 0.15 to 5.67; 3 RCTs; n = 571; $I^2 = 0\%$; very low-quality evidence).

Three RCTs compared open-entry and closed-entry techniques (Angioli 1 2013; Channa 2009; Cogliandolo 1998). Evidence was insufficient to show whether there was a difference between open-entry and closed-entry techniques in the rate of trocar site bleeding (Peto OR 0.61, 95% CI 0.13 to 2.83; 4 RCTs; n = 865; $I^2 = 0\%$; low-quality evidence).

1.9. Trocar site infection

See Analysis 1.7.

One RCT compared an open-entry technique versus direct trocar entry (Angioli 1 2013). Evidence suggested a reduction in the rate of trocar site infection with use of direct trocar entry compared with open entry (Peto OR 15.90, 95% CI 1.50 to 168.43; 1 RCT; n = 294; very low-quality evidence).

Six RCTs compared an open-entry technique versus Veress needle entry (Akbar 2008; Angioli 2 2013; Channa 2009; Cogliandolo 1998; Peitgen 1997; Zaman 2015). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between open entry and Veress needle entry (Peto OR 1.12, 95% CI 0.48 to 2.61; 6 RCTs; n = 891; $I^2 = 17\%$; very low-quality evidence).

Six RCTs compared open-entry and closed-entry techniques (Akbar 2008; Angioli 1 2013; Channa 2009; Cogliandolo 1998; Peitgen 1997; Zaman 2015); one RCT reported no events in either arm (Peitgen 1997).

Evidence was insufficient to show whether there was a difference in rates of trocar site infection between open-entry and closed-entry techniques (Peto OR 1.51, 95% CI 0.69 to 3.35; 7 RCTs; n = 1185; $I^2 = 45\%$; very low-quality evidence).

1.10. Incisional hernia

See Analysis 1.8.

No RCTs compared open-entry with direct trocar entry. Two RCTs compared open-entry and Veress needle entry (Channa 2009; Zaman 2015); one RCT reported no events in either arm (Channa 2009).

Evidence was insufficient to show whether there was a difference in rates of incisional hernia between open-entry and closed-entry techniques (Peto OR 7.39, 95% CI 0.15 to 372.38; 2 RCTs; n = 320; $I^2 = 0\%$; very low-quality evidence).

1.11. Omental injury

See Analysis 1.9.

One RCT compared an open-entry technique versus direct trocar entry (Angioli 1 2013). Evidence was insufficient to show whether there was a difference in rates of omental injury between open entry and direct trocar entry (Peto OR 0.21, 95% CI 0.02 to 2.17; 1 RCT; n = 294; very low-quality evidence).

Two RCTs compared an open-entry technique versus Veress needle entry (Akbar 2008; Angioli 2 2013). Results show a reduction in omental injury with use of open-entry compared with Veress needle entry (Peto OR 0.19, 95% CI 0.04 to 0.90; 2 RCTs; n = 371; $I^2 = 0\%$; low-quality evidence).

Two RCTs compared open-entry and closed-entry techniques (Akbar 2008; Angioli 1 2013). Results show a reduction in omental injury in the open-entry group compared with the closed-entry group (Peto OR 0.20, 95% CI 0.05 to 0.71; 2 RCTs; n = 665; $I^2 = 0\%$; low-quality evidence).

After removal of studies at high risk of bias in any domain and/or high or unclear risk of selection bias (Akbar 2008) in a sensitivity analysis, this finding did not change substantially (Peto OR 0.20, 95% CI 0.04 to 1.10; 1 RCT; n = 301).

1.12. Uterine bleeding

No studies reported this outcome.

2. Direct trocar entry versus Veress needle entry (primary port entry)

Twelve RCTs compared direct trocar entry versus Veress needle entry (Agresta 2004; Angioli 3 2013; Bemelman 2000; Borgatta 1990; Byron 1993; Ertugrul 2015; Gunenc 2005; Imran 2014; Karaca 2014; Prieto-Díaz-Chávez 2006; Tansatit 2006; Zakerah 2010), with a total of 4704 participants. Tansatit 2006 reported no complications in either group. Bemelman 2000 did not report our outcomes. See Summary of findings 2.

Primary outcomes

2.1. Mortality

Four RCTs reported this outcome (Agresta 2004; Angioli 3 2013; Imran 2014; Karaca 2014). No studies reported any events.

2.2. Vascular injury (major vessels and abdominal wall vessels)

See Analysis 2.1 and Figure 6.

Figure 6. Forest plot of comparison: 2 Direct trocar entry vs Veress needle entry (primary port entry), outcome: 2.1 Vascular injury (major vessels and abdominal wall vessels).

Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding (performance bias and detection bias)
- (D) Incomplete outcome data (attrition bias)
- (E) Selective reporting (reporting bias)
- (F) Other bias

Six RCTs reported this outcome (Agresta 2004; Angioli 3 2013; Ertugrul 2015; Imran 2014; Karaca 2014; Prieto-Díaz-Chávez 2006); three of these trials reported no events in either arm (Agresta 2004; Angioli 3 2013; Imran 2014). Evidence was insufficient to show whether there was a difference in rates of vascular injury between direct trocar entry and Veress needle entry (Peto OR 0.59, 95% CI 0.18 to 1.96; 6 RCTs; n = 1603; I² = 73%; very low-quality evidence).

Both Karaca 2014 and Prieto-Díaz-Chávez 2006 reported three events of vascular injury, each in the Veress needle arm of the study. In the Karaca 2014 study, bleeding was due to mesenteric laceration, which required intracorporeal suturing in two cases and resolved spontaneously in the other case. In the Prieto-Díaz-Chávez 2006 study, the three cases of vascular injury were due to epigastric vessel haemorrhage and study authors did not provide information on how the bleeding was controlled. The epigastric vessel lesion was produced upon Veress needle insertion into the midline.

In the Ertugrul 2015 study, four of the five bleeding events occurred from abdominal wall vessels. Researchers reported three events in the direct trocar arm and one event in the Veress needle arm of the study. They provided no further details regarding how this

bleeding was controlled. Results show one case of damage to the jejunal branch of the superior mesenteric vein from direct trocar entry, resulting in uncontrollable bleeding. This patient required emergency conversion to open surgery repair of the bleeding vein and transfusion of 7 units of red blood cells.

Substantial heterogeneity was evidence after Ertugrul 2015 was added at this update (I² = 73%), which may be explained by the inclusion criteria. All participants in this study were obese with BMI > 40 kg/m² or BMI 35 to 40 kg/m², with comorbidities related to obesity. It is possible that in this cohort of participants, greater force is required to penetrate the subcutaneous fat of the abdomen, which may increase the risk of vascular injury with the direct trocar entry technique. We performed sensitivity analysis by restricting eligibility to studies that selected for non-obese adult patients or did not specify a BMI threshold. This analysis showed a reduction in vascular injury in the direct trocar entry group along with a substantial reduction in heterogeneity (Peto OR 0.13, 95% CI 0.03 to 0.66; 5 RCTs; n = 1522; I² = 0%; very low-quality evidence).

2.3. Visceral injury (bladder or bowel)

See Analysis 2.2 and Figure 7.

Figure 7. Forest plot of comparison: 2 Direct trocar entry vs Veress needle entry (primary port entry), outcome: 2.2 Visceral injury (bladder or bowel).

Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding (performance bias and detection bias)
- (D) Incomplete outcome data (attrition bias)
- (E) Selective reporting (reporting bias)
- (F) Other bias

Five RCTs reported this outcome (Agresta 2004; Angioli 3 2013; Ertugrul 2015; Imran 2014; Karaca 2014); two of these studies reported no events in either arm (Agresta 2004; Imran 2014). Evidence was insufficient to show whether there was a difference in rates of visceral injury between direct trocar entry and Veress needle entry (Peto OR 2.02, 95% CI 0.21 to 19.42; 5 RCTs; n = 1519; I² = 25%; very low-quality evidence).

2.4. Gas embolism

Two RCTs reported this outcome (Agresta 2004; Borgatta 1990) and described no events in either arm.

2.5. Solid organ injury

See Analysis 2.3.

Three RCTs reported this outcome (Agresta 2004; Ertugrul 2015; Karaca 2014); Karaca 2014 reported no events in either arm. Evidence was insufficient to show whether there was a difference in rates of solid organ injury between direct trocar entry and Veress needle entry (Peto OR 0.58, 95% CI 0.06 to 5.65; 3 RCTs; n = 1079; I² = 61%; very low-quality evidence).

As stated above, the substantial heterogeneity may be explained by differences in participant characteristics. Ertugrul 2015 included only obese patients. Data were insufficient to perform sensitivity analysis to further investigate the source of the heterogeneity.

2.6. Failed entry (inability to access the peritoneal cavity)

See Analysis 2.4 and Figure 8.

Figure 8. Forest plot of comparison: 2 Direct trocar entry vs Veress needle entry (primary port entry), outcome: 2.4 Failed entry.

Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding (performance bias and detection bias)
- (D) Incomplete outcome data (attrition bias)
- (E) Selective reporting (reporting bias)
- (F) Other bias

Eight RCTs reported this outcome (Agresta 2004; Angioli 3 2013; Borgatta 1990; Byron 1993; Ertugrul 2015; Gunenc 2005; Prieto-

Díaz-Chávez 2006; Zakerah 2010). Meta-analysis demonstrated a reduction in failed entry into the abdomen with the use of direct

trocac entry in comparison with the Veress needle entry technique (OR 0.24, 95% CI 0.17 to 0.34; 8 RCTs; $n = 3185$; $I^2 = 45\%$; moderate-quality evidence). This means that for every 1000 patients operated on, 64 patients in the Veress needle group will experience failed entry compared to between 11 and 22 patients in the direct trocar group (i.e. between 42 and 53 fewer incidents of failed entry will occur per 1000 patients operated on with a direct trocar compared to a Veress needle).

After removal of studies at high risk of bias in any domain and/or high or unclear risk of selection bias (Agresta 2004; Borgatta 1990; Byron 1993; Ertugrul 2015; Gunenc 2005; Prieto-Díaz-Chávez 2006) in a sensitivity analysis, the reduction in failed entry was still evident (Peto OR 0.20, 95% CI 0.13 to 0.31; 2 RCTs; $n = 1380$).

Secondary outcomes

2.7. Extraperitoneal insufflation

See Analysis 2.5.

Nine RCTs compared direct trocar and Veress needle entry (Agresta 2004; Angioli 3 2013; Borgatta 1990; Byron 1993; Gunenc 2005; Imran 2014; Karaca 2014; Prieto-Díaz-Chávez 2006; Zakerah 2010); one RCT reported no events in either arm (Prieto-Díaz-Chávez 2006). Evidence shows a reduction in extraperitoneal insufflation with the use of direct trocar entry compared to Veress needle entry (Peto OR 0.19, 95% CI 0.14 to 0.26; 9 RCTs; $n = 3564$; $I^2 = 0\%$; moderate-quality evidence).

After removal of studies at high risk of bias in any domain and/or high or unclear risk of selection bias (Agresta 2004; Borgatta 1990; Byron 1993; Gunenc 2005; Imran 2014; Karaca 2014; Prieto-Díaz-Chávez 2006) in a sensitivity analysis, the reduction in extraperitoneal insufflation with direct trocar was still evident (Peto OR 0.19, 95% CI 0.12 to 0.30; 2 RCTs; $n = 1380$).

2.8. Trocar site bleeding

No studies reported this outcome.

2.9. Trocar site infection

See Analysis 2.6.

Four RCTs compared direct trocar and Veress needle entry (Angioli 3 2013; Borgatta 1990; Imran 2014; Prieto-Díaz-Chávez 2006). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between direct trocar entry and Veress needle entry (Peto OR 0.52, 95% CI 0.16 to 1.62; 4 RCTs; $n = 736$; $I^2 = 62\%$; very low-quality evidence). We did not find any cause for the substantial heterogeneity. Data were insufficient for performance of sensitivity analysis.

2.10. Incisional hernia

No studies reported this outcome.

2.11. Omental injury

See Analysis 2.7.

Four RCTs compared direct trocar versus Veress needle entry (Angioli 3 2013; Borgatta 1990; Ertugrul 2015; Zakerah 2010). Evidence shows a reduction in omental injury with the use of direct trocar entry compared with Veress needle entry (Peto OR 0.34,

95% CI 0.19 to 0.60; 4 RCTs; $n = 1673$; $I^2 = 14\%$; moderate-quality evidence).

After removal of studies at high risk of bias in any domain and/or high or unclear risk of selection bias (Borgatta 1990; Ertugrul 2015) in a sensitivity analysis, the reduction in omental injury was still evident with use of a direct trocar (Peto OR 0.25, 95% CI 0.12 to 0.52; 2 RCTs; $n = 1380$).

2.12. Uterine bleeding

No studies reported this outcome.

3. Direct vision entry versus Veress needle entry (primary port entry)

Two RCTs with a total of 380 participants compared direct vision entry versus Veress needle entry (Tinelli 2009; Tinelli 2010). See Summary of findings 3.

Primary outcomes

3.1. Mortality

No studies reported this outcome.

3.2. Vascular injury (major vessels and abdominal wall vessels)

See Analysis 3.1.

A single RCT compared direct vision entry with Veress needle entry (Tinelli 2009). Evidence was insufficient to show whether there was a difference in rates of vascular injury between direct vision entry and Veress needle entry (Peto OR 0.39, 95% CI 0.05 to 2.85; 1 RCT; $n = 186$; very low-quality evidence).

3.3. Visceral injury (bladder or bowel)

See Analysis 3.2.

Two RCTs compared direct vision entry with Veress needle entry (Tinelli 2009; Tinelli 2010); one of these studies reported no events in either arm (Tinelli 2009). Evidence was insufficient to show whether there was a difference in rates of visceral injury between direct vision entry and Veress needle entry (Peto OR 0.15, 95% CI 0.01 to 2.34; 2 RCTs; $n = 380$; $I^2 = N/A$; very low-quality evidence).

3.4. Gas embolism

No studies reported this outcome.

3.5. Solid organ injury

Researchers did not report this outcome.

3.6. Failed entry (inability to access the peritoneal cavity)

No studies reported this outcome.

Secondary outcomes

3.7. Trocar site bleeding

See Analysis 3.3.

A single RCT (Tinelli 2010) compared direct vision entry versus Veress needle entry. Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between direct vision entry and Veress needle entry (Peto OR 0.55, 95% CI 0.11 to 2.78; 1 RCT; $n = 194$; $I^2 = N/A$; very low-quality evidence).

Researchers reported no other secondary outcomes.

4. Direct vision entry versus open-entry technique (primary port entry)

Three RCTs with a total of 452 participants investigated direct vision entry versus an open technique (Minervini 2008; Tinelli 2011; Tinelli 2013). See [Summary of findings 4](#).

Primary outcomes

4.1. Mortality

No studies reported this outcome.

4.2. Vascular injury (major vessels and abdominal wall vessels)

Two RCTs reported this outcome (Tinelli 2011; Tinelli 2013) and described no events in either group.

4.3. Visceral injury (bladder or bowel)

See [Analysis 4.1](#).

Two RCTs reported this outcome (Tinelli 2011; Tinelli 2013); Tinelli 2013 reported no events in either arm. In one event in the open-entry group in Tinelli 2011, a bowel loop strictly adherent to the abdominal wall was cut. This was recognised immediately and required intracorporeal suturing. Evidence was insufficient to show whether there was a difference in rates of visceral injury between direct vision entry and open entry (Peto OR 0.13, 95% CI 0.00 to 6.50; 2 RCTs; n = 392; $I^2 = N/A$; very low-quality evidence).

4.4. Gas embolism

No studies reported this outcome.

4.5. Solid organ injury

See [Analysis 4.2](#).

One RCT reported this outcome (Minervini 2008). Evidence was insufficient to show whether there was a difference in rates of solid organ injury between direct vision entry and open entry (Peto OR 6.16, 95% CI 0.12 to 316.67; 1 RCT; n = 60; very low-quality evidence).

4.6. Failed entry (inability to access the peritoneal cavity)

See [Analysis 4.3](#).

One RCT reported this outcome (Minervini 2008). Evidence was insufficient to show whether there was a difference in rates of failed entry between direct vision entry and open entry (Peto OR 0.40, 95% CI 0.04 to 4.09; 1 RCT; n = 60; very low-quality evidence).

Secondary outcomes

4.7. Trocar site bleeding

See [Analysis 4.4](#).

One RCT reported this outcome (Minervini 2008). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between direct vision entry and open entry (Peto OR 6.16, 95% CI 0.12 to 316.67; 1 RCT; n = 60).

Investigators reported no other secondary outcomes.

5. Disposable instruments versus reusable instruments (primary port entry)

We identified no RCTs for this comparison.

6. Radially expanding (STEP) trocars versus standard (non-expanding) trocars (primary port entry)

Four RCTs with a total of 508 participants investigated the use of radially expanding (STEP) trocars versus standard trocars for laparoscopic entry (Bhoyrul 2000; Bisgaard 2007; Feste 2000; Mettler 2000). See [Summary of findings 5](#).

Primary outcomes

6.1. Mortality

No studies reported this outcome.

6.2. Vascular injury (major vessels and abdominal wall vessels)

See [Analysis 5.1](#).

Two RCTs investigated this outcome (Bhoyrul 2000; Feste 2000). Evidence was insufficient to show whether there was a difference in rates of vascular injury between radially expanding (STEP) trocars and standard trocars (Peto OR 0.24, 95% CI 0.05 to 1.21; 2 RCTs; n = 331; $I^2 = 0\%$; very low-quality evidence).

6.3. Visceral injury (bladder or bowel)

See [Analysis 5.2](#).

Two RCTs investigated this outcome (Bhoyrul 2000; Feste 2000); one of these studies reported no events in both groups (Bhoyrul 2000). Evidence was insufficient to show whether there was a difference in rates of visceral injury between radially expanding (STEP) trocars and standard trocars (Peto OR 0.13, 95% CI 0.00 to 6.37; 2 RCTs; n = 331; $I^2 = N/A$; very low-quality evidence).

6.4. Gas embolism

No studies reported this outcome.

6.5. Solid organ injury

See [Analysis 5.3](#).

One RCT investigated this outcome (Bhoyrul 2000). Evidence was insufficient to show whether there was a difference in rates of solid organ injury between radially expanding (STEP) trocars and standard trocars (Peto OR 1.05, 95% CI 0.07 to 16.91; 1 RCT; n = 244; very low-quality evidence).

6.6. Failed entry (inability to access the peritoneal cavity)

No studies reported this outcome.

Secondary outcomes

6.7. Trocar site bleeding

See [Analysis 5.4](#).

Three RCTs reported this outcome (Bhoyrul 2000; Bisgaard 2007; Mettler 2000). Meta-analysis demonstrated that radially expanding (STEP) trocars were associated with a reduction in trocar site bleeding when compared with standard trocars (Peto OR 0.31, 95% CI 0.15 to 0.62; 3 RCTs; n = 421; $I^2 = 60\%$; low-quality evidence). We

were unable to establish the cause of the substantial heterogeneity in this analysis.

This result was sensitive to choice of statistical model and is no longer evident when a Mantel-Haenszel OR and/or a random-effects model is used in preference to a Peto OR, meaning that the result may be unreliable.

Researchers reported no other secondary outcomes.

7. Trendelenburg position for entry versus supine position for entry (primary port entry)

We found no RCTs for this comparison.

8. Volume of gas used as an indicator for entry versus intra-abdominal pressure as an indicator for entry (primary port entry)

We found no RCTs for this comparison.

9. Comparisons of sites of entry

9.1. Transfundal versus infraumbilical insertion of the Veress needle (primary port entry)

Primary outcomes

One RCT with 100 participants investigated transfundal versus infraumbilical insertion of the Veress needle (Santala 1999).

9.1.1. Mortality

The study did not report this outcome.

9.1.2. Vascular injury (major vessels and abdominal wall vessels)

The study did not report this outcome.

9.1.3. Visceral injury (bladder or bowel)

The study did not report this outcome.

9.1.4. Gas embolism

The study did not report this outcome.

9.1.5. Solid organ injury

The study did not report this outcome.

9.1.6. Failed entry (inability to access the peritoneal cavity)

See Analysis 6.1.

One RCT reported this outcome (Santala 1999). Evidence was insufficient to show whether there was a difference in rates of failed entry between transfundal and infraumbilical insertion of the Veress needle (Peto OR 0.14, 95% CI 0.00 to 6.82; 1 RCT; n = 100; very low-quality evidence).

Secondary outcomes

9.1.7. Uterine bleeding

See Analysis 6.1.

One RCT reported this outcome (Santala 1999). Evidence was insufficient to show whether there was a difference in rates of uterine bleeding between transfundal and infraumbilical insertion of the Veress needle (Peto OR 7.70, 95% CI 0.78 to 75.76; 1 RCT; n = 100; very low-quality evidence).

Investigators reported no other secondary outcomes.

9.2. Left upper quadrant versus caudally displaced umbilical insertion of the Veress needle (primary port entry)

One RCT with 280 participants investigated left upper quadrant versus caudally displaced umbilical insertion of the Veress needle (Vilos 2015).

Primary outcomes

9.2.1. Mortality

The study did not report this outcome.

9.2.2. Vascular injury (major vessels and abdominal wall vessels)

See Analysis 6.2.

One RCT reported this outcome (Vilos 2015). Evidence was insufficient to show whether there was a difference in rates of vascular injury between left upper quadrant and caudally displaced umbilical insertion of the Veress needle (Peto OR 1.04, 95% CI 0.06 to 16.78; 1 RCT; n = 280; very low-quality evidence).

9.2.3. Visceral injury (bladder or bowel)

The study did not report this outcome.

9.2.4. Gas embolism

The study did not report this outcome.

9.2.5. Solid organ injury

The study did not report this outcome.

9.2.6. Failed entry (inability to access the peritoneal cavity)

The study did not report this outcome.

Secondary outcomes

9.2.7. Extraperitoneal insufflation

See Analysis 6.2.

One RCT reported this outcome (Vilos 2015). Evidence was insufficient to show whether there was a difference in rates of extraperitoneal insufflation between left upper quadrant and caudally displaced umbilical insertion of the Veress needle (Peto OR 0.83, 95% CI 0.22 to 3.13; 1 RCT; n = 280; very low-quality evidence).

Researchers reported no other secondary outcomes.

10. SILS versus Veress needle entry

Six RCTs with a total of 1121 participants investigated single-incision laparoscopic surgery versus Veress needle entry (Deveci 2013; Guo 2015; He 1 2015; Partelli 2016; Porta 2017; Youssef 2015).

Primary outcomes

10.1. Mortality

One RCT reported this outcome and described no events in either arm (Porta 2017).

10.2. Vascular injury (major vessels and abdominal wall vessels)

No studies reported this outcome.

10.3. Visceral injury (bladder or bowel)

One RCT reported this outcome and described no events in either arm (He 1 2015).

10.4. Gas embolism

No studies reported this outcome.

10.5. Solid organ injury

No studies reported this outcome.

10.6. Failed entry (inability to access the peritoneal cavity)

No studies reported this outcome.

Secondary outcomes

10.7. Trocar site bleeding

See Analysis 7.3.

Two RCTs reported this outcome (He 1 2015; Porta 2017). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between SILS and Veress needle entry (Peto OR 1.97, 95% CI 0.39 to 9.89; 2 RCTs; $n = 330$; $I^2 = 54\%$; very low-quality evidence). We found no reason for the substantial heterogeneity.

10.8. Trocar site infection

See Analysis 7.4.

Six RCTs reported this outcome (Deveci 2013; Guo 2015; He 1 2015; Partelli 2016; Porta 2017; Youssef 2015; one of these studies reported no events in either arm (Partelli 2016). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between SILS and Veress needle entry (Peto OR 1.10, 95% CI 0.45 to 2.70; 6 RCTs; $n = 1121$; $I^2 = 0\%$; low-quality evidence).

10.9. Incisional hernia

Four RCTs reported this outcome; all of these studies reported no events in either arm (Deveci 2013; Guo 2015; Porta 2017; Youssef 2015).

Investigators reported no other secondary outcomes.

11. SILS versus modified Hasson entry technique (primary port entry)

Ten RCTs with a total of 864 participants investigated single-incision laparoscopic surgery versus modified Hasson entry technique (Carter 2013; Chang 2015; Fonollosa 2012; Lai 2011; Luna 2013; Perez 2013; Phillips 2012; Tsimoyiannis 2009; Vilallonga 2012; Villalobos 2014).

Primary outcomes

11.1. Mortality

One RCT reported this outcome and described no events in either arm (Fonollosa 2012).

11.2. Vascular injury (major vessels and abdominal wall vessels)

One RCT reported this outcome and described no events in either arm (Lai 2011).

11.3. Visceral injury (bladder or bowel)

No studies reported this outcome.

11.4. Gas embolism

No studies reported this outcome.

11.5. Solid organ injury

No studies reported this outcome.

11.6. Failed entry (inability to access the peritoneal cavity)

See Analysis 8.3.

Five RCTs reported this outcome (Fonollosa 2012; Lai 2011; Perez 2013; Phillips 2012; Vilallonga 2012); two of these studies described no events in either arm (Lai 2011; Perez 2013). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between SILS and modified Hasson entry technique (Peto OR 6.56, 95% CI 0.67 to 63.96; 5 RCTs; $n = 488$; $I^2 = 0\%$; very low-quality evidence).

Secondary outcomes

11.7. Trocar site infection

See Analysis 8.4.

Five RCTs reported this outcome (Carter 2013; Chang 2015; Lai 2011; Luna 2013; Villalobos 2014); one of these studies reported no events in either arm (Carter 2013). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between SILS and modified Hasson entry technique (Peto OR 0.67, 95% CI 0.19 to 2.35; 5 RCTs; $n = 387$; $I^2 = 0\%$; very low-quality evidence).

11.8. Incisional hernia

See Analysis 8.5.

One RCT reported incisional hernia (Chang 2015). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between SILS and modified Hasson entry technique (Peto OR 7.25, 95% CI 0.14 to 365.22; 1 RCT; $n = 101$; very low-quality evidence).

Investigators reported no other secondary outcomes.

12. Comparisons of other laparoscopic entry techniques for primary or secondary port insertion

12.1. Lifting versus not lifting the abdominal wall before Veress needle insertion (primary port entry)

One RCT with 150 participants reported this comparison (Briel 2000).

Primary outcomes

12.1.1. Mortality

The study did not report this outcome.

12.1.2. Vascular injury (major vessels and abdominal wall vessels)

The study did not report this outcome.

12.1.3. Visceral injury (bladder or bowel)

Briel 2000 reported this outcome and described no events in either study arm.

12.1.4. Gas embolism

The study did not report this outcome.

12.1.5. Solid organ injury

The study did not report this outcome.

12.1.6. Failed entry (inability to access the peritoneal cavity)

See [Analysis 9.1](#).

[Briel 2000](#) reported this outcome. Not lifting the abdominal wall before Veress needle insertion was associated with a lower rate of failed entry than was lifting the abdominal wall (Peto OR 4.44, 95% CI 2.16 to 9.13; 1 RCT; $n = 150$; $I^2 = N/A$; very low-quality evidence).

Secondary outcomes

12.1.7. Extraperitoneal insufflation

See [Analysis 9.1](#).

[Briel 2000](#) reported this outcome. Evidence was insufficient to show whether there was a difference in rates of extraperitoneal insufflation between lifting and not lifting the abdominal wall (Peto OR 4.43, 95% CI 0.98 to 20.10; 1 RCT; $n = 150$; $I^2 = N/A$; very low-quality evidence).

Researchers reported no other secondary outcomes.

12.2. Carbon dioxide gas insufflation versus use of a gasless abdominal wall retractor (primary port entry)

Four RCTs with a total of 221 participants compared use of carbon dioxide gas insufflation versus use of a gasless abdominal wall retractor ([Cravello 1999](#); [Johnson 1997](#); [Kitano 1993](#); [Schulze 1999](#)).

Primary outcomes

12.2.1. Mortality

No studies reported this outcome.

12.2.2. Vascular injury (major vessels and abdominal wall vessels)

See [Analysis 9.2](#).

Two RCTs reported this outcome ([Cravello 1999](#); [Kitano 1993](#)). Evidence was insufficient to show whether there was a difference in rates of vascular injury between carbon dioxide gas insufflation and use of a gasless abdominal wall retractor (Peto OR 7.23, 95% CI 0.45 to 115.64; 2 RCTs; $n = 186$; $I^2 = 0\%$; very low-quality evidence).

12.2.3. Visceral injury (bladder or bowel)

No studies reported this outcome.

12.2.4. Gas embolism

No studies reported this outcome.

12.2.5. Solid organ injury

No studies reported this outcome.

12.2.6. Failed entry (inability to access the peritoneal cavity)

No studies reported this outcome.

Secondary outcomes

12.2.7. Extraperitoneal insufflation

See [Analysis 9.2](#).

One RCT reported this outcome ([Kitano 1993](#)). Evidence was insufficient to show whether there was a difference in rates of extraperitoneal insufflation between carbon dioxide gas insufflation and use of a gasless abdominal wall retractor (Peto OR 7.58, 95% CI 0.77 to 74.97; 1 RCT; $n = 83$; very low-quality evidence).

12.2.8. Trocar site bleeding

See [Analysis 9.2](#).

One RCT reported this outcome ([Cravello 1999](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between carbon dioxide gas insufflation and use of a gasless abdominal wall retractor (Peto OR 0.13, 95% CI 0.00 to 6.69; 1 RCT; $n = 103$; very low-quality evidence).

12.2.9. Trocar site infection

See [Analysis 9.2](#).

One RCT reported this outcome ([Kitano 1993](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between carbon dioxide gas insufflation and use of a gasless abdominal wall retractor (Peto OR 0.98, 95% CI 0.06 to 15.87; 1 RCT; $n = 83$; very low-quality evidence).

Investigators reported no other secondary outcomes.

12.3. Closed technique versus a parallel technique of Veress needle insertion (primary port entry)

A single RCT with 200 participants compared a closed technique versus a parallel technique of Veress needle insertion ([Ostrzenski 1999](#)).

Primary outcomes

12.3.1. Mortality

The study did not report this outcome.

12.3.2. Vascular injury (major vessels and abdominal wall vessels)

See [Analysis 9.3](#).

Researchers reported this outcome but described no events in either group.

12.3.3. Visceral injury (bladder or bowel)

See [Analysis 9.3](#).

Researchers reported this outcome but described no events in either group.

12.3.4. Gas embolism

The study did not report this outcome.

12.3.5. Solid organ injury

The study did not report this outcome.

12.3.6. Failed entry (inability to access the peritoneal cavity)

The study did not report this outcome.

Secondary outcomes

12.3.7. Extraperitoneal insufflation

See [Analysis 9.3](#).

Researchers reported this outcome but described no events in either group.

Researchers reported no other secondary outcomes.

12.4. Cutting trocar versus blunt trocar (primary port entry)

Three RCTs including 286 participants compared use of a cutting trocar versus a blunt trocar ([Hamade 2007](#); [Huang 2012](#); [Venkatesh 2007](#)).

Primary outcomes

12.4.1. Mortality

One RCT reported this outcome and described no events in either group ([Huang 2012](#)).

12.4.2. Vascular injury (major vessels and abdominal wall vessels)

No studies reported this outcome.

12.4.3. Visceral injury (bladder or bowel)

See [Analysis 9.4](#).

One RCT reported this outcome ([Venkatesh 2007](#)). Evidence was insufficient to show whether there was a difference in rates of visceral injury between cutting and blunt trocar entry (Peto OR 7.67, 95% CI 0.15 to 386.69; 1 RCT; n = 165; very low-quality evidence).

12.4.4. Gas embolism

No studies reported this outcome.

12.4.5. Solid organ injury

No studies reported this outcome.

12.4.6. Failed entry (inability to access the peritoneal cavity)

No studies reported this outcome.

Secondary outcomes

12.4.7. Trocar site bleeding

See [Analysis 9.4](#).

Two RCTs reported this outcome ([Hamade 2007](#); [Venkatesh 2007](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between cutting and blunt trocar entry (Peto OR 0.33, 95% CI 0.09 to 1.23; 2 RCTs; n = 195; $I^2 = 0\%$; very low-quality evidence).

12.4.8. Trocar site infection

See [Analysis 9.4](#).

One RCT reported this outcome ([Venkatesh 2007](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between cutting and blunt trocar entry (Peto OR 7.67, 95% CI 0.15 to 386.69; 1 RCT; n = 165; very low-quality evidence).

Investigators reported no other secondary outcomes.

12.5. 5-mm versus 3-mm trocar for secondary port entry

A single RCT with a total of 102 participants compared 5-mm secondary port entry versus 3-mm secondary port entry ([Ghezzi 2005](#)).

Primary outcomes

Researchers reported no primary outcomes.

Secondary outcomes

12.5.1. Trocar site bleeding

See [Analysis 9.5](#).

One RCT reported this outcome ([Ghezzi 2005](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between a 5-mm trocar and a 3-mm trocar for secondary port entry (Peto OR 0.14, 95% CI 0.01 to 2.24; 1 RCT; n = 102; very low-quality evidence).

Researchers reported no other secondary outcomes.

12.6. Radially expanding access device (STEP) versus conventional (non-expanding) cutting tip trocar for secondary port entry

Two RCTs with a total of 129 participants compared a radially expanding access device with a conventional cutting tip trocar ([Lam 2000](#); [Yim 2001](#)).

Primary outcomes

Study authors reported no primary outcomes.

Secondary outcomes

12.6.1. Trocar site bleeding

See [Analysis 9.6](#).

One RCT reported this outcome ([Yim 2001](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between a radially expanding access device and a conventional cutting tip trocar (Peto OR 0.13, 95% CI 0.01 to 2.14; 1 RCT; n = 68; low-quality evidence).

12.6.2. Trocar site infection

See [Analysis 9.6](#).

One RCT reported this outcome ([Lam 2000](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between a radially expanding access device and a conventional cutting tip trocar (Peto OR 0.14, 95% CI 0.01 to 2.21; 1 RCT; n = 61; very low-quality evidence).

Study authors reported no other secondary outcomes.

12.7. X-cone versus Veress needle insertion (primary port entry)

One tripartite RCT with 200 participants compared X-cone versus Veress needle entry ([He 1 2015](#)).

Primary outcomes

12.7.1. Mortality

The study did not report this outcome.

12.7.2. Vascular injury (major vessels and abdominal wall vessels)

The study did not report this outcome.

12.7.3. Visceral injury (bladder or bowel)

See [Analysis 9.7](#).

One RCT reported visceral injury and described no events in either group ([He 2 2015](#)).

12.7.4. Gas embolism

The study did not report this outcome.

12.7.5. Solid organ injury

The study did not report this outcome.

12.7.6. Failed entry (inability to access the peritoneal cavity)

The study did not report this outcome.

Secondary outcomes

12.7.7. Trocar site bleeding

See [Analysis 9.7](#).

One RCT reported trocar site bleeding ([He 2 2015](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between X-cone and Veress needle entry (Peto OR 2.76, 95% CI 0.38 to 19.89; 1 RCT; n = 200; I^2 = N/A; very low-quality evidence).

12.7.8. Trocar site infection

See [Analysis 9.7](#).

One RCT reported trocar site infection ([He 2 2015](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between X-cone and Veress needle entry (Peto OR 0.36, 95% CI 0.05 to 2.61; 1 RCT; n = 200; I^2 = N/A; very low-quality evidence).

Investigators reported no other secondary outcomes.

12.8. X-cone versus SILS laparoscopy

One RCT compared X-cone with SILS ([He 3 2015](#)).

Primary outcomes

12.8.1. Mortality

The study did not report this outcome.

12.8.2. Vascular injury (major vessels and abdominal wall vessels)

The study did not report this outcome.

12.8.3. Visceral injury (bladder or bowel)

See [Analysis 9.8](#).

One RCT reported visceral injury and described no events in either group ([He 3 2015](#)).

12.8.4. Gas embolism

The study did not report this outcome.

12.8.5. Solid organ injury

The study did not report this outcome.

12.8.6. Failed entry (inability to access the peritoneal cavity)

The study did not report this outcome.

Secondary outcomes

12.8.7. Trocar site bleeding

See [Analysis 9.8](#).

One RCT reported trocar site bleeding ([He 3 2015](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding between X-cone and SILS (Peto OR 0.74, 95% CI 0.17 to 3.35; 1 RCT; n = 200; very low-quality evidence).

12.8.8. Trocar site infection

See [Analysis 9.8](#).

One RCT reported trocar site infection ([He 3 2015](#)). Evidence was insufficient to show whether there was a difference in rates of trocar site infection between X-cone and SILS (Peto OR 1.00, 95% CI 0.06 to 16.10; 1 RCT; n = 200; very low-quality evidence).

Researchers reported no other secondary outcomes.

12.9 Comparisons of intra-abdominal pressures for secondary port entry

A single tripartite RCT with 65 participants compared secondary port entry at intra-abdominal pressure (IAP) 15 mmHg achieved solely via insufflation versus IAP 25 mmHg achieved solely via insufflation versus IAP 25 mmHg achieved via insufflation and manual external abdominal compression ([Köstü 1 2016](#)).

Primary outcomes

Study authors reported no primary outcomes.

Secondary outcomes

12.9.1. Extraperitoneal insufflation

Evidence was insufficient to show whether there was a difference in rates of extraperitoneal insufflation between IAP 25 mmHg and IAP 15 mmHg (Peto OR 2.12, 95% CI 0.21 to 21.52; 1 RCT; n = 43; very low-quality evidence; [Analysis 9.9](#)), IAP 25 mmHg and IAP 25 mmHg with external compression (Peto OR 2.02, 95% CI 0.37 to 11.13; 1 RCT; n = 43; very low-quality evidence; [Analysis 9.10](#)), or IAP 15 mmHg and IAP 25 mmHg with external compression (Peto OR 3.75, 95% CI 0.60 to 23.66; 1 RCT; n = 44; very low-quality evidence; [Analysis 9.11](#)).

12.9.2. Trocar site bleeding

Evidence was insufficient to show whether there was a difference in rates of trocar site bleeding when IAP 25 mmHg was compared with IAP 15 mmHg (Peto OR 7.75, 95% CI 0.15 to 390.96; 1 RCT; n = 43; very low-quality evidence; [Analysis 9.9](#)), when IAP 25 mmHg was compared with IAP 25 mmHg with external compression (Peto OR 0.13, 95% CI 0.00 to 6.51; 1 RCT; n = 43; very low-quality evidence; [Analysis 9.10](#)), or when IAP 15 mmHg was compared with IAP 25 mmHg with external compression (no events in either group; [Analysis 9.11](#)).

12.9.3. Omentum injury

Evidence was insufficient to show whether there was a difference in rates of omentum injury when IAP 25 mmHg was compared with IAP 15 mmHg (no events in either group; [Analysis 9.9](#)), when IAP 25 mmHg was compared with IAP 25 mmHg with external compression (Peto OR 7.41, 95% CI 0.45 to 122.53; 1 RCT; n = 43; very low-quality evidence; [Analysis 9.10](#)), or when IAP 15 mmHg was compared with IAP 25 mmHg with external compression (Peto OR 7.75, 95% CI 0.47 to 128.03; 1 RCT; n = 44; low-quality evidence; [Analysis 9.11](#)).

Study authors reported no other secondary outcomes.

Assessment of reporting biases

Studies included in any single analysis were insufficient to permit construction of a funnel plot.

DISCUSSION

Summary of main results

Meta-analysis failed to demonstrate superiority of open-entry or closed-entry techniques in terms of mortality, rates of vascular injury, visceral injury, or failed entry into the abdomen. Evidence suggests lower rates of extraperitoneal insufflation with the open-entry technique compared with the closed-entry technique (Veress needle), which remains apparent after sensitivity analysis. Evidence shows a reduction in rates of omental injury with the open-entry technique compared with the closed-entry technique, which remains evident after sensitivity analysis.

In the updated review, ten RCTs looking at Veress needle entry reported vascular injury as an outcome. There was a total of 1086 participants and 10 events of vascular injury were reported. Four RCTs looking at open entry technique reported vascular injury as an outcome. There was a total of 376 participants and 0 events of vascular injury were reported. This was not a direct comparison. In the direct comparison of Veress needle and Open-entry technique, there was insufficient evidence to determine whether there was a difference in rates of vascular injury.

Evidence suggests a reduced rate of failed entry into the abdomen with use of a direct trocar compared with a Veress needle for primary port entry. Evidence is insufficient to show a difference in rates of vascular injury, visceral injury, or solid organ injury when direct trocar entry is compared with Veress needle entry. Reductions in rates of both extraperitoneal insufflation and omental injury with use of a direct trocar compared with a Veress needle remain evident after sensitivity analysis.

Evidence is insufficient to suggest that radially expanding trocars are more or less safe in reducing major complications during primary or secondary port placement. However, researchers noted a reduction in trocar site bleeding with radially expanding (STEP) trocars for primary port insertion compared with non-expanding trocars. This result should be interpreted with caution because of substantial heterogeneity and dependence on the choice of a statistical model.

We found insufficient evidence of a difference in minor or major complications in comparisons between direct vision and Veress needle entry and direct vision and open entry.

Overall completeness and applicability of evidence

It must be noted that studies were limited to small numbers and low-quality data. Many studies excluded patients with previous abdominal surgery or a raised body mass index. These patients are likely to have higher complication rates, and their exclusion could be interpreted as a form of selection bias. Thus the strict inclusion criteria of these trials require that results be interpreted with caution in terms of relevance to the general population.

Open-entry versus closed-entry technique (primary port entry)

Given restraints for data quality and sample size, trial results show no advantage for major complication rates – mortality, visceral injury, or vascular injury. None of the included studies were sufficiently powered to detect major complications. Retrospective studies have reported that an open technique to establish pneumoperitoneum is safer than a blind technique, with avoidance of both visceral and major vascular injury.

No definition of failed entry has been universally accepted. Akbar defined failed entry as failure to aspirate following Veress needle insertion on three consecutive attempts ([Akbar 2008](#)). Angioli defined failed entry as entry requiring more than three consecutive attempts ([Angioli 1 2013](#)). Both of these study authors reported a high rate of failed entry in the Veress needle group. This is not consistent with routine practice, which classifies failed entry after two attempts of Veress needle insertion ([RCOG 2008](#)). In contrast, [Zaman 2015](#) reported a high rate of failed entry in the open entry group. It is difficult to draw any conclusions as to why this might be the case, as study authors did not attempt to define failure of technique.

Unlike the other four studies, [Cogliandolo 1998](#) had no exclusion criteria based on past medical/surgical history. [Bemelman 2000a](#) excluded patients with a midline laparotomy scar and body weight less than 40 kg. [Akbar 2008](#) excluded patients with previous upper abdominal surgery and paraumbilical hernia. [Zaman 2015](#) excluded all those with pregnancy, history of laparotomy, umbilical hernia, granuloma or abscess, and severe systemic illness. [Angioli 1 2013](#) was the most restrictive study in excluding all those with previous abdominal surgery by laparoscopy or laparotomy, history of pelvic inflammatory disease, irritable bowel syndrome, or suspicion of malignancy or malignancy at histological examination. Caution is required when results of these studies are interpreted, as patient populations often do include aforementioned excluded comorbidities.

Direct trocar entry versus Veress needle entry (primary port entry)

Direct trocar placement and Veress needle insertion are blind procedures with potential for serious injury. Because of their low incidence, any study investigating major complications occurring during primary port entry would require a large number of patients to be included. [Molloy 2002](#) concluded that 828,204 patients would be required to show a reduction in bowel injury rates from 0.3% to 0.2%. The RCTs included in this meta-analysis had insufficient power to effectively demonstrate a difference in most major complications. Nine of the studies in this subgroup failed to undertake any power calculation. [Agresta 2004](#) performed a power calculation that was based upon the incidence rate of failed entry (12%), which is substantially higher than those of other

entry-related complications. [Ertugrul 2015](#) also performed a power calculation, but study authors did not report how this was done.

Although several studies describe a similar approach for Veress needle insertion using a 45° angle at the level of the umbilicus, not all studies within this review state the exact technique used for insertion of the Veress needle. Thus, no conclusions can be reached concerning the optimal method of Veress needle insertion.

A reduction in the rates of extraperitoneal insufflation and omental injury was associated with use of direct trocar entry compared with Veress needle entry. Extraperitoneal insufflation can result in failed laparoscopy and increases the risk of gas embolism. Two RCTs reported gas embolism as an outcome and described no events in either arm ([Agresta 2004](#); [Borgatta 1990](#)).

It is difficult to interpret these results in the context of the general population, as several studies excluded patients on the basis of previous abdominal surgery ([Agresta 2004](#); [Angioli 1 2013](#); [Bemelman 2000](#); [Borgatta 1990](#); [Ertugrul 2015](#); [Karaca 2014](#); [Prieto-Díaz-Chávez 2006](#); [Tansatit 2006](#)), obesity ([Agresta 2004](#); [Borgatta 1990](#)), or medical comorbidities ([Angioli 1 2013](#); [Imran 2014](#)). [Byron 1993](#), [Gunenc 2005](#), and [Zakerah 2010](#) did not state exclusion criteria.

As most of these studies selected for low-risk patients, we performed sensitivity analysis to determine whether exclusion of studies selecting for high-risk patients changed the results. Sensitivity analysis performed by restricting eligibility to studies that either selected for non-obese adult patients or did not specify a body mass index (BMI) threshold showed a reduction in the rate of vascular injury associated with use of direct trocar entry versus Veress needle entry. This may be explained by the need for greater force to penetrate the subcutaneous fat of the obese abdomen, which in turn may increase the risk of vascular injury in this cohort with the direct trocar entry technique.

Radially expanding (STEP) trocars versus standard trocars (primary port entry)

Meta-analysis did not show an advantage in reduction of visceral or vascular injury rates. As the dilator and the cannula in the STEP device radially expand the tissue tract created by the Veress needle, defects in the abdominal wall are about 50% narrower, and the incidence of trocar site bleeding is considerably less with STEP use ([Feste 2000](#)). In addition, the STEP device separates rather than cuts the tissue, leaving a slit-like defect that forms along the muscle fibres, as opposed to the clover-leaf defect left by the cutting styles of a conventional trocar ([Bhoyrul 2000](#)). Although results show an advantage for reduction of trocar site bleeding, the reliability of this conclusion was undermined by both a high degree of heterogeneity ($I^2 = 60\%$) and lack of statistical significance with use of a Mantel-Haenszel odds ratio and/or a random-effects model.

Lifting or not lifting the abdominal wall before Veress needle insertion (primary port entry)

Abdominal wall lifting is aimed at increasing skin resistance to facilitate cutaneous perforation with the Veress needle. The Royal College of Obstetricians and Gynaecologists currently recommends stabilising the lower abdominal wall when inserting the Veress needle perpendicular to the skin incision ([RCOG 2008](#)).

Analysis demonstrated increased risk of failed entry in the lifting group as compared to the group that did not lift ([Briel 2000](#)). These results need to be interpreted with caution, as failed entry has been defined as a single attempt. This is not consistent with routine practice, as discussed above for open-entry versus closed-entry technique (primary port entry).

SILS versus Hasson technique and Veress needle insertion for port entry (primary port)

As single-port surgery continues to grow in popularity and surgeons have become more expert in performing it, a greater number of RCTs have been conducted to compare SILS versus other surgical techniques. The theoretical benefits of SILS techniques over more traditional laparoscopic entry techniques include reduction in wound site complications such as infection and bleeding by virtue of reducing the total number of incisions made in the abdominal wall.

Results show no advantage in reduction of any of the primary or secondary outcomes when SILS was compared with the Hasson technique or Veress needle entry. Evidence was of low or very low quality, and no studies were sufficiently powered to detect a difference in complication rates. One study comparing SILS with the Hasson technique enrolled a paediatric population from 3 to 15 years of age ([Perez 2013](#)). This study reported no events, thus precluding sensitivity analysis.

Quality of the evidence

Most available evidence is of very low quality. The main limitations are imprecision associated with very low event rates and suboptimal sample sizes, and risk of bias associated with poor reporting of study methods. Most studies failed to describe methods of randomisation or to provide sufficient details about blinding or allocation concealment.

Only 14 RCTs attempted blinding. No universal definition of a "single-blinded" study is known. [He 1 2015](#) failed to specify whether patients or outcome assessors were blinded. [Zaman 2015](#) described this study as a "prospective randomized double blind study" in the study abstract but did not mention blinding in the main body of the paper.

Blinding of the surgeon is not possible in these studies, so to some extent performance bias is unavoidable, but this is unlikely to have substantially affected intraoperative events. Although single-blinding of patients to treatment to minimise any Hawthorne effect and detection bias would be important for assessment of delayed subjectively reported postoperative complications, such as pain and scarring, we did not consider these outcomes when conducting this systematic review.

The potential for loss to follow-up is relevant, as delayed recognition of bowel injury and minor complications such as wound infection following patient discharge may have been missed. [Feste 2000](#) and [Schulze 1999](#) reported participants as losses to follow-up because of intraoperative complications that required conversion to a different technique. [Bisgaard 2007](#) stated loss of one participant due to loss of the study diary. [Chang 2015](#) reported loss to follow-up of three participants in the SILS group and four in the Hasson group. Six of these losses were due to lost contact, and one to postoperative withdrawal of consent. In [Carter 2013](#), eight participants were lost to long-term follow-up,

as they did not attend outpatient clinics. [Youssef 2015](#) reported 13 participants lost to follow-up: seven elected to follow up with their local doctors, four had travelled abroad, and available phone numbers were incorrect for two. [Guo 2015](#) reported 36 losses to follow-up due to relocation or changes in contact information. Only seven trials specifically described an intention-to-treat approach ([Agresta 2004](#); [Bhoyrul 2000](#); [Carter 2013](#); [Chang 2015](#); [Ertugrul 2015](#); [Feste 2000](#); [Partelli 2016](#)).

From the 'Summary of findings' tables ([Summary of findings for the main comparison](#); [Summary of findings 2](#); [Summary of findings 3](#); [Summary of findings 4](#); [Summary of findings 5](#)), it is evident that the quality of evidence for most outcomes was deemed to be very low. As discussed, the conclusions drawn by this review are limited due to lack of high-quality evidence.

Potential biases in the review process

Several outcomes reported within this review are variable with respect to their definitions. For example, failed entry, wound infection, and trocar site bleeding are assigned different definitions in different reviews. No definition of failed entry has been universally agreed upon. Study definitions have ranged from two to three attempts of Veress needle insertion before abandoning the procedure or converting to a different entry technique. [Zaman 2015](#) does not offer a definition for "failure of technique".

Twelve of the trials included within the review did not measure the complication rate as a primary outcome; therefore study authors did not predefine the complications that would be measured and the methods used to do so. None of the included studies defined the method of identifying wound infection, for example, clinical diagnosis or microbiological confirmation. Also, if power calculations were based upon the reduction in reported complication rates, a larger number of participants would be required if results are to be regarded as statistically significant.

As detailed above, feedback from the last update pointed out the need to describe trocar information to make results more comparable ([Feedback 1](#)). No 'standard' trocar has been universally accepted, and papers are not uniform in their reporting of trocar type. Seven studies provided no trocar information. Study authors considered that in all studies that described their choice of trocars, the equipment used could be considered standard. Omissions have been followed up through email. Information on individual trocar types has been added to the 'Intervention' section of each [Characteristics of included studies](#) table, with omissions highlighted. No RCTs have reported an advantage of any individual trocar type for primary port entry. However, a recent review concluded that blunt tip trocars are preferable to cutting trocars for cannulation of the abdominal wall under laparoscopic vision (i.e. secondary and further ports), as they are associated with lower risks of abdominal wall bleeding and overall complications ([Antoniou 2013](#)). As all trocar safety profiles meet industry standards, it could be postulated that, in the current climate of limited resource allocation and budgeting difficulties, cost is the deciding factor when trocar type is selected.

Agreements and disagreements with other studies or reviews

Current guidelines of the Royal College of Obstetricians and Gynaecologists do not recommend a specific laparoscopic entry

technique. However, for extremes of body mass index (BMI), these guidelines recommend the open-entry ([Hasson](#)) technique. This review has not demonstrated any major safety advantage with use of either an open-entry or a closed-entry technique; however, this review was not designed to specifically identify the preferred entry technique for women at extremes of BMI ([RCOG 2008](#)).

A meta-analysis in [Song 2013](#) was unable to demonstrate differences between SILS and standard four-port laparoscopy entry for perioperative complication rates, conversion rates, or length of operation. Review authors did not further delineate the term "perioperative complications" in the paper, and conversion included both addition of trocars and/or conversion to laparotomy. Outcomes reported in this review for the SILS technique were corroborated by another recent meta-analysis ([Antoniou 2014](#)), which concluded that there was insufficient evidence to demonstrate differences between SILS and standard four-port entry techniques, other than prolonged operative time with SILS.

Results of this systematic review are consistent with the results of three other reviews of randomised and non-randomised data ([Antoniou 2013](#); [Merlin 2003](#); [Molloy 2002](#)).

AUTHORS' CONCLUSIONS

Implications for practice

Overall, evidence is insufficient to support the use of one laparoscopic entry technique over another. Results show an advantage of direct trocar entry over Veress needle entry for failed entry. Most of the evidence is of very low quality, and the main limitations were imprecision (due to small sample sizes and very low event rates) and risk of bias associated with poor reporting of study methods.

Implications for research

Randomised controlled trials (RCTs) of adequate power are required to detect differences in risks of major complications. To increase cohort size enough to gain the statistical power needed to detect rare major complications, the number of participants required would have to be in the hundreds of thousands, and it is unlikely that these studies could be performed. [Cuss 2014](#) recently explored this dilemma and suggested that the evidence for laparoscopic surgery may be at the limit of what is possible. To address this issue, we suggest creation of a centralised national register. Although this would not produce RCT-level evidence, it would enable collation of all information on laparoscopic complications and thus would provide cohort sizes large enough that major complications could be reliably identified. This register could be modelled on existing maternal mortality databases. The onus would be on individual surgeons to be transparent in their reporting of complications.

Additional well-designed RCTs of sufficient power are needed to determine the optimal entry technique for patients with extreme body mass index (BMI) and for those with previous abdominal and pelvic surgery.

Future meta-analyses ought to consider using individual patient data (IPD) analysis. Performing aggregate data meta-analysis means accepting the reporting methods of each individual study and using their outcomes for analysis. Therefore, any selection bias, publication bias, or flaws in reporting protocol will influence

outcomes of the meta-analysis. Although it is much more resource intensive, as all raw data from individual studies must be obtained and reanalysed via advanced statistical methods, IPD analysis would allow all data analyses to be standardised and reported consistently.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Agresta 2004

Methods	Randomised controlled trial
Participants	<p>Included were non-obese paediatric and adult patients referred for urgent or scheduled laparoscopic and gynaecological procedures: 275 in the direct trocar group and 323 in the Veress needle group. No participants lost to follow-up</p> <p>Exclusion criteria: BMI > 27 kg/m², presence of massive bowel distension, history of 2 or more abdominal operations</p> <p>Power calculation performed</p>
Interventions	Veress needle (technique unclear) insertion vs direct trocar insertion (zero degree tilt on the table, umbilical incision, shielded trocars). No co-intervention. Standardised operative training in both interventions, especially for the study. Standardised operative technique was deployed by all operators. For the direct trocar insertion, a 5-mm shielded trocar (dilating tip trocar; Endopath; Ethicon Endo-Surgery, Cincinnati, OH, USA) was used. Information on this brand of Veress needle was not supplied
Outcomes	<p>Aim: to assess technical feasibility and safety</p> <p>Primary complications: mortality, visceral and solid organ injury</p> <p>Secondary complications: extraperitoneal insufflation, failed entry, gas embolism</p>

Laparoscopic entry techniques (Review)

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Agresta 2004 (Continued)

Notes Single centre at Veneto, Italy

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation unclear
Allocation concealment (selection bias)	Low risk	"Because of an 8% post hoc deviation of patient allocation due to the sealed-envelope randomisation method adopted, the level of significance was set at 0.01"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Unclear; no reference made
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up nor exclusions reported
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases and percentages; no data converted. P values stated as non-significant for outcomes as opposed to actual values. No omission of outcomes and no subsets of data. Power calculation performed
Other bias	Low risk	No other bias identified

Akbar 2008

Methods	Randomised controlled trial
Participants	Inclusion criteria: patients with symptomatic gallstones with normal common bile duct scheduled for laparoscopic cholecystectomy Exclusion criteria: paraumbilical hernia, history of upper abdominal surgery, uncontrolled systemic illness
Interventions	In group A, pneumoperitoneum was created by the closed method (infraumbilical transverse incision, Veress needle) compared to the open method in group B (supraumbilical incision). No co-intervention. Standardised operative approach. Detailed information on type and make of trocars was not provided
Outcomes	Hospital stay, operating time, complications Injury during induction, failure of technique, and port site infection were reported
Notes	Single-centre study at the Ayub Hospital Complex, Abbottabad

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Selected patients were randomised into group A and B using sealed envelopes containing questionnaire. Seventy ProForma, 35 for each group, were prepared and sealed in blank envelopes. Each envelope contained one out of these seventy ProForma. After informed consent, an envelope was randomly fetched and opened"

Laparoscopic entry techniques (Review)

Akbar 2008 (Continued)

Allocation concealment (selection bias)	Low risk	"Selected patients were randomised into group A and B using sealed envelopes containing questionnaire. Seventy ProForma, 35 for each group, were prepared and sealed in blank envelopes. Each envelope contained one out of these seventy ProForma. After informed consent, an envelope was randomly fetched and opened"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	"All the patients were operated upon under general anaesthesia by the same anaesthesia team. The surgical team consisted of a surgeon (principal author), two assistants, and one scrub nurse"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No losses to follow-up or lost data reported. However, some participants excluded if operation was converted to open cholecystectomy - figures not given
Selective reporting (reporting bias)	Low risk	No power calculation; therefore power calculation set at 33%. Data presented as numbers of cases and percentages; no data conversion. P values stated for outcomes. No omission of outcomes and no subsets of data
Other bias	Low risk	No other source of bias identified

Angioli 1 2013

Methods	Randomised controlled trial with 3 arms. Patients presenting between February 2007 and May 2011; duration 4 years and 4 months
Participants	<p>656 patients were assessed for eligibility: 57 did not meet inclusion criteria or refused to be randomised; 599 were randomised</p> <p>Inclusion criteria: non-obese adults (BMI < 30 kg/m²) referred for scheduled laparoscopic gynaecological procedures for benign pathology</p> <p>Exclusion criteria: previous abdominal surgery by laparoscopy or laparotomy, history of pelvic inflammatory disease, irritable bowel syndrome, suspicion of malignancy, malignancy at histological examination</p> <p>Age of participants ranged from 18 to 70 years. 187 participants in the direct trocar entry group and 218 in the open-entry group. 3 participants from the open-procedure group were excluded from analysis after randomisation because malignancy was found at histological examination</p>
Interventions	<p>Direct trocar entry vs open entry</p> <p>A sharp direct trocar was inserted at 90° through an infraumbilical skin incision aided by manual lifting of the abdominal wall by towel clips placed 3 cm on either side of the umbilicus</p> <p>For open entry, a 1-cm incision was made through the skin at the lower edge of the umbilical fossa, followed by retraction of subcutaneous skin and adipose tissue with Zimmerman dissectors, incision of the anterior rectus fascia, incision of the peritoneum, and insertion of the trocar under direct vision. No information on the make of the trocars was provided</p>
Outcomes	Study was powered to detect the rate of minor complications (extraperitoneal insufflation, trocar site bleeding, omental injury, surgical site infection). Failed entry and time of entry of the main trocar were evaluated. Major complications were also considered
Notes	Single-centre study at University of Rome Campus Bio-Medico

Risk of bias
Laparoscopic entry techniques (Review)

Angioli 1 2013 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to 1 of 3 groups based on computer-generated sequence
Allocation concealment (selection bias)	Low risk	Allocation codes were kept in opaque sealed envelopes and were broken after randomisation
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding was not mentioned in the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	3 participants from the open-procedure group were excluded from analysis after randomisation because malignancy was found at histological examination. Outcomes were unlikely to be affected by small number of exclusions
Selective reporting (reporting bias)	Low risk	No data conversion. P values stated for each outcome. No omission of outcomes and no subsets of data
Other bias	Low risk	No other sources of bias identified in the text

Angioli 2 2013

Methods	Randomised controlled trial with 3 arms. Patients presenting between February 2007 and May 2011; duration 4 years and 4 months
Participants	<p>656 participants were assessed for eligibility: 57 did not meet inclusion criteria or refused to be randomised; 599 were randomised</p> <p>Inclusion criteria: non-obese adults (BMI < 30 kg/m²) referred for scheduled laparoscopic gynaecological procedures for benign pathology</p> <p>Exclusion criteria: previous abdominal surgery by laparoscopy or laparotomy, history of pelvic inflammatory disease, irritable bowel syndrome, suspicion of malignancy, malignancy at histological examination</p> <p>Age of participants ranged from 18 to 70 years. 194 participants in the Veress needle entry group and 218 in the open-entry group. 1 participant from the Veress needle group and 3 from the open-procedure group were excluded from analysis after randomisation because malignancy was found at histological examination</p>
Interventions	<p>Veress needle entry vs open entry</p> <p>Veress needle was inserted at 45° at the level of the umbilicus to establish pneumoperitoneum; this was followed by insertion of the first transumbilical trocar into the sagittal plane at an angle of 90° to the horizontal</p> <p>For open entry, a 1-cm incision was made through the skin at the lower edge of the umbilical fossa, followed by retraction of subcutaneous skin and adipose tissue with Zimmerman dissectors, incision of the anterior rectus fascia, incision of the peritoneum, and insertion of the trocar under direct vision. No information was provided on the make of the trocars used</p>
Outcomes	Study was powered to detect the rate of minor complications (extraperitoneal insufflation, trocar site bleeding, omental injury, and surgical site infection). Failed entry and time of entry of the main trocar were evaluated. Major complications were also considered
Notes	Single-centre study at University of Rome Campus Bio-Medico

Laparoscopic entry techniques (Review)

Angioli 2 2013 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to 1 of 3 groups based on computer-generated sequence
Allocation concealment (selection bias)	Low risk	Allocation codes were kept in opaque sealed envelopes and were broken after randomisation
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding was not mentioned in the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 participant from the Veress needle group and 3 from the open-procedure group were excluded from analysis after randomisation because malignancy was found at histological examination. Outcomes were unlikely to be affected by small number of exclusions
Selective reporting (reporting bias)	Low risk	All outcomes reported with accompanying significance values
Other bias	Low risk	No other sources of bias identified

Angioli 3 2013

Methods	Randomised controlled trial with 3 arms. Patients presenting between February 2007 and May 2011; duration 4 years and 4 months
Participants	<p>656 participants were assessed for eligibility: 57 did not meet inclusion criteria or refused to be randomised; 599 were randomised</p> <p>Inclusion criteria: non-obese adults (BMI < 30 kg/m²) referred for scheduled laparoscopic gynaecological procedures for benign pathology</p> <p>Exclusion criteria: previous abdominal surgery by laparoscopy or laparotomy, history of pelvic inflammatory disease, irritable bowel syndrome, suspicion of malignancy, malignancy at histological examination</p> <p>Age of participants ranged from 18 to 70 years. 194 participants in the Veress needle entry group and 187 in the direct trocar entry group. 1 participant from the Veress needle group was excluded from analysis after randomisation because malignancy was found at histological examination</p>
Interventions	<p>Veress needle entry vs direct trocar entry</p> <p>Veress needle was inserted at 45° at the level of the umbilicus to establish pneumoperitoneum; this was followed by insertion of the first transumbilical trocar in the sagittal plane at an angle of 90° to the horizontal</p> <p>Sharp direct trocar inserted at 90° through an infraumbilical skin incision aided by manual lifting of the abdominal wall by towel clips placed 3 cm on either side of the umbilicus. No information on the make of trocars used was provided</p>
Outcomes	Study was powered to detect the rate of minor complications (extraperitoneal insufflation, trocar site bleeding, omental injury, and surgical site infection). Failed entry and time of entry of the main trocar were evaluated. Major complications were also considered

Angioli 3 2013 (Continued)

Notes Single-centre study at University of Rome Campus Bio-Medico

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to 1 of 3 groups based on computer-generated sequence
Allocation concealment (selection bias)	Low risk	Allocation codes were kept in opaque sealed envelopes and were broken after randomisation
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding was not mentioned in the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 participant from the Veress needle group was excluded from analysis after randomisation because malignancy was found at histological examination. Outcomes were unlikely to be affected by small number of exclusions
Selective reporting (reporting bias)	Low risk	All outcomes reported with P values
Other bias	Low risk	No other source of bias identified

Bemelman 2000

Methods	Randomised controlled trial that was single-blinded, with 3 arms. Patients presented between June and December 1999; duration 7 months
Participants	62 patients eligible for laparoscopic surgery were enrolled in the study Exclusion criteria: age < 18 years, prior midline laparotomy or laparoscopy, body weight < 40 kg. Exclusion criteria were not based upon age, sex, and procedures performed 20 participants were included in the Veress needle group, 20 in the Hasson trocar group, and 20 in the modified blunt trocar (TrocDoc) group. Two were lost to follow-up. The TrocDoc trocar was derived from a sharp trocar (Storz, Tübingen, Germany)
Interventions	Hasson trocar vs direct trocar. No co-intervention. Standardised operative training in both interventions, especially for the study. Standardised operative technique was deployed by all operators
Outcomes	Aim: to assess technical feasibility. Participant mortality reported as an outcome
Notes	Single centre in Amsterdam, the Netherlands

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation unclear
Allocation concealment (selection bias)	Low risk	"After informed consent was obtained, the sealed envelope method was used to reveal the method of establishment of the pneumoperitoneum for that pa-

Laparoscopic entry techniques (Review)

Bemelman 2000 (Continued)

		tient after induction of anesthesia. Patients were thereby randomly allocated into three groups"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participants reported as lost to follow-up because of intraoperative complications, which required conversion to a different technique; therefore an intention-to-treat analysis may have been of value "Two patients were withdrawn from inclusion during surgery, and no time-motion analysis was performed"
Selective reporting (reporting bias)	Low risk	Data were presented as numbers of cases; no data conversion. P values stated for outcomes. No omission of outcomes and no subsets of data
Other bias	Low risk	No other bias identified

Bhoyrul 2000

Methods	Randomised controlled trial that was double-blinded
Participants	Included were all adult patients under the care of the 16 participating laparoscopic general surgeons Exclusion criteria: acute inflammatory conditions and conversion to laparotomy not due to an entry complication. Exclusion criteria were not based on age, sex, or type of procedure 119 participants in the radially expanding (STEP) trocar group and 125 in the Veress needle group. None lost to follow-up
Interventions	Radially expanding (STEP) (technique unclear) trocars vs standard trocars (technique unclear). No co-intervention. Standardised operative technique was deployed by all operators
Outcomes	Aim: to assess safety Primary complications: vascular, visceral, and solid organ injury Secondary complications: incisional hernias, wound site bleeding Control group used cutting trocars made by US Surgical Corp., Norwalk, CT, USA; Ethicon Endo-Surgery, Cincinnati, OH, USA; and Origin Inc., Sunnyvale, CA, USA STEP group used radially expanding trocars produced by InnerDyne, Inc., Sunnyvale, CA, USA
Notes	Single centre in San Francisco, CA, USA

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was determined from randomization tables before patient enrolment was begun"
Allocation concealment (selection bias)	Unclear risk	No reference made to allocation concealment

Bhojrul 2000 (Continued)

Blinding (performance bias and detection bias) All outcomes	Low risk	Double-blinded - participants and observers "Patients and postoperative observers were blinded to the choice of trocar used in the operations"
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Five participants converted to laparotomy" "One participant who originally consented to participate and later refused was removed from the study"
Selective reporting (reporting bias)	Low risk	Data were presented as numbers of cases and percentages; no data conversion. P values stated for outcomes. No omission of outcomes and no subsets of data. Power calculation performed
Other bias	Low risk	No other bias identified

Bisgaard 2007

Methods	Randomised controlled trial
Participants	Patients undergoing elective cholecystectomy were enrolled in the study "The criteria of exclusion specified ASA physical class 4, age younger than 18 and older than 75 years, and pregnancy. Patients with postoperative complications were included in the analysis. Patients were not invited to participate in the study if they had chronic pain diseases other than gallstone disease, if they received opioids or tranquillizers (treatment for more than 1 week before laparoscopic cholecystectomy), if they spoke a foreign language, if they had a mental disorder, or if they had a history of alcohol or drug abuse. Patients were excluded from the study (study data were not collected) if the operation was converted from a laparoscopic to an open procedure" 39 participants in the cutting group and 38 in the radial group; 3 participants excluded
Interventions	Laparoscopic cholecystectomy was performed with two 10-mm and two 5-mm trocars In the radially expanding group (radial group), the 4 trocars constituted the VersaStep system (Auto Suture, Radially Expanding Access (REA) system; Tyco Healthcare, Copenhagen, Denmark), and in the conventional cutting group (cutting group), the 4 trocars were cutting bladed trocars (Endopath II; Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA). Standardised general anaesthesia and analgesia were provided. Standardised operative technique was performed or supervised by experienced surgeons
Outcomes	Primary outcomes: incisional pain, pain 6 hours after the operation, postoperative pain on days 1 and 2 Secondary outcomes: need for fascial incision, active surgical haemostasis, supplementary need for opioids, moderate or severe nausea, bruising at the trocar site
Notes	Single-centre trial at University Hospital, Denmark

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were consecutively enrolled in the trial by the medical staff in the surgical unit several days before the operation. After induction of anaesthesia, the surgeon randomised the patients to laparoscopic cholecystectomy using radially expanding trocars (radial group) or conventional cutting trocars (cutting group) by the sealed envelope method based on a block-randomised computer-generated list"

Laparoscopic entry techniques (Review)

Bisgaard 2007 (Continued)

Allocation concealment (selection bias)	Low risk	"Patients were consecutively enrolled in the trial by the medical staff in the surgical unit several days before the operation. After induction of anaesthesia, the surgeon randomised the patients to laparoscopic cholecystectomy using radially expanding trocars (radial group) or conventional cutting trocars (cutting group) by the sealed envelope method based on a block-randomised computer-generated list"
Blinding (performance bias and detection bias) All outcomes	Low risk	"The trial was patient- and observer-blinded. At the end of the operation, the incisions were covered with nontransparent standard dressings (5.5 cm), and the patients were instructed to keep the dressings on for the first 2 postoperative days. The patient and the surgical staff, including the nurses, were 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 patients"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	3 exclusions from the trial "One of the three excluded patients underwent conversion to an open procedure (radial group) and the remaining two patients (one from each surgical group) had no study data available due to loss of their study diary"
Selective reporting (reporting bias)	Unclear risk	Some data subgrouped (e.g. little, moderate, and severe suppuration). No omission of outcomes nor selective use of data. No data conversion
Other bias	Low risk	P values not stated for some outcomes (i.e. moderate and severe bruising). No other risk of bias identified

Borgatta 1990

Methods	Randomised controlled trial that was single-blinded
Participants	Inclusion criteria: women undergoing elective laparoscopic sterilisation under general anaesthetic at an out-of-hospital surgical unit Exclusion criteria: not stated Patients were not excluded on the basis of previous abdominal surgery (including caesarean section), presence of intra-abdominal adhesions, age, weight, height, or parity. 110 in the Veress needle group and 102 in the direct trocar group. None lost to follow-up
Interventions	Veress needle insertion (technique unclear) vs direct trocar insertion (technique unclear). No co-intervention. Information on the type and make of trocars was not accessible
Outcomes	Aim: to assess technical feasibility and complications Secondary complications: extraperitoneal insufflation, omentum injury and wound site infection, failed entry
Notes	Single centre in New York, NY, USA

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method not explicitly stated; "assigned randomly"

Laparoscopic entry techniques (Review)

Borgatta 1990 (Continued)

Allocation concealment (selection bias)	Unclear risk	Not referred to within paper
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not referred to within paper
Incomplete outcome data (attrition bias) All outcomes	Low risk	No data issues identified
Selective reporting (reporting bias)	Low risk	No reporting issues identified
Other bias	Low risk	No evidence of additional bias

Briel 2000

Methods	Randomised controlled trial that was single-blinded
Participants	150 consecutive patients scheduled for laparoscopy Exclusion criteria: previous abdominal surgery and obesity (BMI > 40 kg/m ²) Exclusion not based upon age or sex. 75 in the lifting group and 75 in the non-lifting group. None lost to follow-up
Interventions	Lifting of the abdominal wall before Veress needle insertion (abdominal wall lifted with 2 hands; the decision to reinsert the needle was made when insufflation pressure was greater than 10 mmHg) vs non-lifting (technique unclear). No co-intervention. Trocar make and model not stated in the paper
Outcomes	Aim: to assess technical feasibility and safety Secondary complications: extraperitoneal insufflation, failed entry
Notes	Single centre in Rotterdam, the Netherlands

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method not stated but described as 'randomised'
Allocation concealment (selection bias)	Unclear risk	Not referred to within the paper
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not referred to within the paper
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up nor exclusions reported

Laparoscopic entry techniques (Review)

Briel 2000 (Continued)

Selective reporting (re-reporting bias)	Low risk	Data were presented as numbers of cases; no data conversion. No omission of outcomes and no subsets of data
Other bias	Low risk	P values not stated for failed entry but stated for all other outcomes. No power calculation performed. No other sources of bias identified

Byron 1993

Methods	Randomised controlled trial that was single-blinded. Between September 1988 and June 1989; 10 months' duration	
Participants	Patients presenting between September 1988 and June 1989: 111 in the direct trocar group and 141 in the Veress needle group. None lost to follow-up	
Interventions	Veress needle insertion vs direct trocar insertion. No co-intervention. No standardised operative technique nor training stated. Information on type and make of trocars was not accessible	
Outcomes	Aim: to assess technical feasibility and complications Secondary complications: extraperitoneal insufflation, failed entry	
Notes	Single centre in Tripler Army Medical Center, Honolulu, Hawaii, USA	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Truly randomised - random number tables
Allocation concealment (selection bias)	Unclear risk	Not referred to within paper
Blinding (performance bias and detection bias) All outcomes	Low risk	Single-blinded; patients only
Incomplete outcome data (attrition bias) All outcomes	Low risk	No incomplete data issues identified
Selective reporting (re-reporting bias)	Low risk	No selective reporting issues identified
Other bias	Low risk	No other sources of bias identified

Carter 2013

Methods	Randomised controlled trial with 2 study arms running from May 2010 to November 2012; 2 years and 7 months' duration	
Participants	Participants consisted of patients who presented to the emergency department and received diagnosis of acute appendicitis on the basis of clinical and radiographic evaluation	

Laparoscopic entry techniques (Review)

Carter 2013 (Continued)

Exclusion criteria: phlegmon, mass, peri-appendiceal abscess or diffuse peritonitis; earlier open laparotomy with incision through the umbilicus; BMI > 35 kg/m²; age < 18 years; mental illness, dementia; inability to provide informed consent; chronic pain requiring daily medication; long-term opiate use; pregnancy; serving time in prison; alternative diagnosis found by diagnostic laparoscopy (post randomisation)

75 participants were randomised: 37 in the single-incision laparoscopic surgery (SILS) appendectomy group, and 38 in the 3-port appendectomy group

Interventions	<p>SILS appendectomy vs conventional 3-port laparoscopic appendectomy</p> <p>For SILS, the base of the umbilical stalk was everted and an incision was made within the stalk. The fascia was then retracted and incised. The peritoneum was entered with a gloved finger, a Kelly clamp, or scissors. An SILS device (SILS Port; Covidien Plc, Dublin, Ireland) was then inserted as the incision was retracted anteriorly. 5-mm trocars were placed and the abdomen was insufflated, followed by diagnostic laparoscopy and appendectomy if indicated</p> <p>For 3-port laparoscopy, an incision was made in the umbilical stalk, the fascia was retracted and incised, and a 12-mm Hasson port was placed through the fascia into the abdomen. The abdomen was inflated, and diagnostic laparoscopy was performed</p>
Outcomes	<p>Primary outcomes: mean pain score during first 12 hours, hydromorphone use during first 12 hours</p> <p>Secondary outcomes: length of stay, wound infection, deep space infection, wound seroma, return to work, date of last opiate pain medication use, readmission within 30 days, body image score at 6 months, cosmetic appearance scale at 6 months</p>
Notes	<p>Single-centre study at the Department of Surgery, University of California, San Francisco, CA, USA. Study was stopped after the first 75 patients were enrolled because the SILS technique showed inferiority to the conventional 3-port technique for the primary outcome - postoperative pain</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were assigned to each study arm in a 1:1 ratio by a computerised random number generator
Allocation concealment (selection bias)	Low risk	"the patient was unaware of the randomisation until after the completion of the operation"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Study was unblinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed short-term follow-up. 6 out of 37 participants in the SILS group lost to follow-up after 6 months. 2 out of 38 participants in the 3-port group lost to follow-up after 6 months. Intention-to-treat analysis was performed
Selective reporting (reporting bias)	Low risk	All outcome results published with corresponding P values
Other bias	Low risk	No other source of bias identified

Chang 2015

Methods	Randomised double-blinded controlled trial
Participants	<p>Included were 101 patients aged 21 to 80 with symptomatic gallstones</p> <p>Exclusion criteria: acute cholecystitis, previous open upper abdominal surgery, ASA grade 3 or 4, bleeding disorders</p> <p>50 participants were randomised to receive 4PLC, and 51 to receive SILC. Participant demographics (including age, BMI, gender, ethnicity, ASA score, and comorbidities) did not differ significantly between the 2 groups</p>
Interventions	<p>SILS: after the umbilicus was everted, a longitudinal 2-cm incision was made without extension beyond the umbilical folds. The Covidien (Norwalk, CT, USA) SILS™ port was then inserted with the use of a curved clamp. The Olympus EndoEYE™ (Olympus, Tokyo, Japan) 5-mm laparoscope was used in view of the in-line profile of its light/camera cables. To improve triangulation, the AutoSuture Roticulator™ Endo Grasp™ (Covidien, Norwalk, CT, USA), a disposable articulating laparoscopic instrument, was used.</p> <p>4PLC: 10-mm port (Genicon, Winter Park, FL, USA) was first inserted at the umbilical site via the Hasson technique. Pneumoperitoneum was thence established, and 5-mm laparoscopic ports were introduced at the right flank, right hypochondrium, and epigastrium under visualisation via a rigid 10-mm 30° laparoscope</p>
Outcomes	<p>Primary outcome: postoperative pain measured at specific time points</p> <p>Secondary outcomes: incisional hernia and wound infection recorded, analgesia use, time to regain function</p>
Notes	Single-centre trial conducted at the National University Health System, Singapore

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Unclear risk: "Each patient was randomized to one of two study arms by the closed envelope technique"</p> <p>No method of random sequence generation provided in the text</p>
Allocation concealment (selection bias)	Unclear risk	<p>"Each patient was randomized to one of two study arms by the closed envelope technique"</p> <p>Participants consented before randomisation, but no information was provided regarding whether envelopes were sealed or folded shut, and whether or not envelopes were serially numbered</p>
Blinding (performance bias and detection bias) All outcomes	Low risk	<p>"Both patients and post-operative assessors were blinded as to the assigned study arm"</p> <p>Risk of performance bias was unavoidable due to intervention</p>
Incomplete outcome data (attrition bias) All outcomes	Low risk	One post-randomisation exclusion in SILC group; reason given: participant withdrew consent at analysis stage. No post-randomisation exclusions in 4PLC group. Attrition rate was low and was similar in both groups. 3 in SILC group and 4 in 4PLC group. Reasons given in all cases. Data analysed on an intention-to-treat basis
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers and percentages when appropriate. All significance values attached

Chang 2015 (Continued)

Other bias	Low risk	No other source of bias identified
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Channa 2009

Methods	Randomised controlled trial of 12 months' duration, running from January to December 2007. Trial had 2 study arms
Participants	Included were patients requiring laparoscopic cholecystectomy Exclusion criteria: < 20 years old or > 65 years old with comorbid conditions of chronic liver disease, chronic renal failure, and malignancy 120 participants in total, with 60 participants randomised to each study arm
Interventions	Laparoscopic cholecystectomy with Hasson cannula or Veress needle entry. Details of the operative technique used were not included in the text. No mention of a standardised operative technique. Details of the type and make of trocars were not included in the paper
Outcomes	Access time, minor complications (gas leak, extraperitoneal insufflation, port site haematoma, port site wound infection, port site hernia), major complications (visceral injury, vascular injury, need for conversion, mortality). No power calculation was mentioned in the text
Notes	Study was conducted at a single centre at the Jinnah Post Graduate Medical Centre (JPMC), Karachi

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised to 1 of 2 groups via a random numbers table
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment in the text
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding of participants or assessors in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants excluded after randomisation, and no participants dropped out
Selective reporting (reporting bias)	Low risk	No selective reporting issues present, but significance values not attached to all outcomes when an event happened
Other bias	Low risk	No other source of bias identified in the text

Cogliandolo 1998

Methods	Randomised controlled trial that was single-blinded
Participants	Included were 150 patients, aged 16 to 77, who were undergoing laparoscopic cholecystectomy Inclusion and exclusion criteria not specified

Laparoscopic entry techniques (Review)

Cogliandolo 1998 (Continued)

75 in the blind (Veress needle) group, and 75 in the open-trocar (Hasson trocar) group. None lost to follow-up

Interventions	Open-entry (Veress needle) technique vs closed-entry (Hasson trocar) technique. No co-intervention. Standardised operative training in both interventions, especially for the study. Standardised operative technique was deployed by all operators. The technique of pneumoperitoneum has not been specified in terms of use of pressure or volume of gas for Veress needle entry. Standard Hasson trocar entry. Information on type and make of trocars was not included in the text
Outcomes	Aim: to assess technical feasibility and complications Primary complications: vascular and visceral injuries Secondary complications: extraperitoneal insufflation, wound site bleeding and infection
Notes	Single centre at Messina, Italy

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"All patients were entered into two groups according to a computerized random number selection"
Allocation concealment (selection bias)	Unclear risk	"All patients were entered into two groups according to a computerized random number selection"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No blinding mentioned within the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions or dropouts. However, 3 cases converted to open surgery because of difficulty in recognising the location of anatomical structures, and in 2 cases, conversion was due to major complications related to introduction of the first trocar
Selective reporting (reporting bias)	Low risk	Data were presented as numbers of cases and percentages; no data conversion. P values stated for total major complications. No omission of outcomes and no subsets of data
Other bias	Low risk	No power calculation mentioned. No other selective bias issues identified

Cravello 1999

Methods	Randomised controlled trial that was single-blinded
Participants	All patients seen on an outpatient or emergency basis who presented with an indication for laparoscopic surgery were given the option to be included in the trial Excluded were patients with intra-abdominal malignancy 103 participants in insufflation with carbon dioxide gas group, and 51 in gasless abdominal wall retractor group
Interventions	Laparoscopic surgery via insufflation of carbon dioxide gas vs a gasless abdominal wall retractor. No co-intervention. Standardised operative technique was deployed by all operators. Trocars used were

Cravello 1999 (Continued)

customised 10- to 12-mm-long trocars equipped with balloons - blunt tip trocar (Origin Medsystems, Santa Clara, CA, USA)

Outcomes	Aim: to assess technical feasibility and complications
Notes	Single-centre study at Hospital de la Conception, Marseille, France

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomized by a random number table before the induction of anesthesia"
Allocation concealment (selection bias)	Unclear risk	No reference to allocation concealment was made within the text of the paper
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Absent
Incomplete outcome data (attrition bias) All outcomes	Low risk	9 participants converted from gasless laparoscopy technique - reasons given for all exclusions
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases and percentages; no data conversion. No omission of outcomes and no subsets of data
Other bias	Low risk	P values not stated for each outcome. Power calculation not stated. No other bias concerns identified

Deveci 2013

Methods	Randomised controlled trial with 2 study arms. Patients were recruited between January 2010 and January 2012; duration 2 years and 1 month
Participants	Included were patients with gallbladder disease requiring laparoscopic cholecystectomy Exclusion criteria: ASA score > 3; prior abdominal surgery; choledocholithiasis and/or abnormal cholestasis enzyme values; pregnancy; ongoing peritoneal dialysis; presence of pancreatitis 100 participants were randomised, with 50 undergoing single-incision laparoscopic surgery (SILS) cholecystectomy, and 50 receiving 3-port conventional laparoscopic cholecystectomy (3PLC)
Interventions	SILS cholecystectomy vs 3PLC For SILS, a vertical incision was made through the skin and fascia of the umbilicus to allow passage of the SILS port (Covidien Inc., Norwalk, CT, USA) and cholecystectomy For 3PLC, pneumoperitoneum was created with a Veress needle, followed by 10-mm trocar placement in the umbilicus and mid-epigastrium, and 5-mm trocar placement in the right upper abdomen. Cholecystectomy was then performed in standard fashion
Outcomes	Operating time, blood loss, success rate, conversion to open surgery, conversion to 4-port laparoscopy, complications (bile leakage, wound infection, hospital readmission, hernia), postoperative pain at 6 hours, postoperative pain at 1 day, tramadol use, duration of hospital stay, cosmetic satisfaction

Laparoscopic entry techniques (Review)

Deveci 2013 (Continued)

Notes Single-centre study, Department of Surgery, Maltepe University School of Medicine, Istanbul, Turkey

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to undergo SILS or 3PLC cholecystectomy according to a computer-generated table of random numbers
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment in text
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants lost to follow-up and no dropouts
Selective reporting (reporting bias)	Low risk	No reporting bias identified
Other bias	Low risk	No other source of bias identified

Ertugrul 2015

Methods	Randomised controlled trial
Participants	<p>Included were 81 patients aged 18 to 60 receiving bariatric surgery for BMI > 40 kg/m² or BMI 35 to 40 kg/m² plus comorbidities related to obesity, who had failed to lose weight with diet and/or physical exercise</p> <p>Excluded were patients with history of abdominal surgery</p> <p>39 participants were randomised for direct trocar entry (insertion) (DTI) with a bladed retractable non-optical trocar, and 42 were randomised for Veress needle insertion (VNI). Participant demographics (including age, BMI, gender, ASA score, and comorbidities) did not differ significantly between the 2 groups</p>
Interventions	<p>DTI: 12-mm bladed retractable non-optical trocar (Versaport Plus, AutoSuture, Covidien, Mansfield, MA) used for initial access from 4 cm left lateral of the midline and 20 cm down from the xiphoid process. Abdominal wall lifted by clamps and trocar inserted slowly by rotational controlled movements until second click sound heard</p> <p>VNI: Veress needle inserted perpendicular to abdominal wall 1 cm below left subcostal margin on mid-clavicular line, saline drop test performed after second click sound heard. Both used CO₂ insufflation to 14 mmHg</p>
Outcomes	Laparoscopic entry time, successful entry rates at first attempt, CO ₂ consumption, failed attempt rates, intraoperative complication rates (abdominal wall bleeding, visceral injury, conversion to open surgery), length of hospital stay
Notes	Turgut Ozal Medical Centre Gastroenterology Surgery Clinic of Inonu University, Malatya, Turkey

Risk of bias
Laparoscopic entry techniques (Review)

Ertugrul 2015 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomized with the sealed envelope technique" No method for random sequence generation provided in the text
Allocation concealment (selection bias)	Unclear risk	"All patients were informed about the operation, and detailed consent forms were taken before surgery" Unclear whether participant consent was obtained after allocation. No information available as to whether envelopes were serially numbered or sealed shut
Blinding (performance bias and detection bias) All outcomes	High risk	"The limitations of our study are that it was not a blinded study"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No post-randomisation exclusions or losses to follow-up in either group. 2 participants switched to VNI in DTI group, and 1 switched to DTI in VNI group. In all instances, this was due to failed access with the original entry technique. Data were analysed on an intention-to-treat basis
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers with significance values attached
Other bias	Low risk	No other source of bias identified

Feste 2000

Methods	Randomised controlled trial that was single-blinded
Participants	Various operative and diagnostic laparoscopic procedures were performed by 7 different surgeons on 87 consecutive women Exclusion criteria: not stated Exclusion was not based upon age and weight. Results show a significant difference in weight favouring the STEP trocar group (higher): 45 in the radially expanding (STEP) trocar group and 42 in the Veress needle group. None lost to follow-up
Interventions	Radially expanding (STEP) trocars (technique not stated) vs standard trocars (technique not stated). No co-intervention. The STEP device consisted of an access-insufflation needle, a radially expandable bio-compatible polymeric sleeve, and a tapered blunt dilator/cannula. No specific information was provided on the cutting trocars
Outcomes	Aim: to assess safety Primary complications: vascular and visceral injuries
Notes	Multi-centre at Greifswald, Germany; Houston, TX, USA; and Santa Barbara, CA, USA

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation unclear

Laparoscopic entry techniques (Review)

Feste 2000 (Continued)

"Patients were randomized to treatment"		
Allocation concealment (selection bias)	Unclear risk	Not referred to within the paper
Blinding (performance bias and detection bias) All outcomes	Low risk	Double-blinded: patients and observers only "Patients were blinded as to which type of instrument was used" "A blinded, trained observer assessed the operative wounds"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participants reported as lost to follow-up as required conversion to a different technique
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases; no data conversion. No omission of outcomes and no subsets of data
Other bias	Low risk	P values not stated for each outcome. Power calculation not mentioned. No additional bias issues identified

Fonollosa 2012

Methods	Randomised controlled trial with 2 arms. Patients were recruited between October 2009 and June 2011; duration 1 year and 9 months
Participants	A total of 50 patients were enrolled in the study: 26 into the single-incision laparoscopic surgery (SILS) cholecystectomy group, and 24 into the 4-port laparoscopic cholecystectomy group (4PLC) Inclusion criteria: symptomatic cholelithiasis confirmed on ultrasonography Exclusion criteria: obesity (BMI > 35 kg/m ²), hepatitis, alcoholism, pregnancy, acute pancreatitis, cholecystitis, choledocholithiasis, previous surgery in the upper abdomen, prior ERCP
Interventions	SILS cholecystectomy vs 4-port laparoscopic cholecystectomy (4PLC) For SILS, an infraumbilical transverse incision was made, followed by dissection of subcutaneous tissue and the anterior rectus fascia, entry into the peritoneal cavity, and introduction of the SILS port (Covidien, Norwalk, CT, USA) 4PLC was performed by standard technique with the participant in the French position
Outcomes	Operative time, morbidity, conversion between surgical approaches, failure of entry, reoperation, post-operative pain, postoperative analgesic requirement, postoperative nausea and vomiting
Notes	This single-centre trial was conducted at University Hospital Mutua de Terrassa, University of Barcelona

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants randomised via a computer-generated random number table
Allocation concealment (selection bias)	Unclear risk	No mention of concealment in the text

Laparoscopic entry techniques (Review)

Fonollosa 2012 *(Continued)*

Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts or exclusions after enrolment and randomisation
Selective reporting (reporting bias)	Low risk	All outcomes fully reported with significance values attached
Other bias	Low risk	No other sources of bias identified

Ghezzi 2005

Methods	Randomised controlled trial that was single-blinded; conducted from March 2004 to October 2004. 8 months' duration. Both ports were inserted into the same participant with the side of insertion randomised	
Participants	<p>Inclusion criteria: consecutive patients undergoing operative laparoscopy because of a suspected benign adnexal mass at a university hospital from March 2004 through October 2004 were enrolled in the study</p> <p>Exclusion criteria: intra-abdominal malignancy</p> <p>50 participants were included in the 3-mm trocar group, and 52 in the 5-mm trocar group for secondary port entry. No participants lost to follow-up. No further information provided on the type and make of trocars used</p>	
Interventions	5-mm trocars vs 3-mm trocars for secondary port entry. No co-intervention. Standardised operative technique reported	
Outcomes	Trocars site bleeding	
Notes	Single-centre trial at the Department of Obstetrics and Gynaecology, University of Insubria	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomised according to a computer-generated list"
Allocation concealment (selection bias)	Unclear risk	Not referred to within the paper
Blinding (performance bias and detection bias) All outcomes	Low risk	<p>Single-blinded; patients only</p> <p>"The patients were blinded with respect to the surgical technique assignment"</p>
Incomplete outcome data (attrition bias) All outcomes	Low risk	5 exclusions; 5 participants converted to laparotomy - reasons stated
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases; no data conversion. No omission of outcomes and no subsets of data

Laparoscopic entry techniques (Review)

Ghezzi 2005 (Continued)

Other bias	Low risk	P values stated for each outcome. No power calculation stated. No sources of additional bias identified
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Gunenc 2005

Methods	Randomised controlled trial that was single-blinded	
Participants	Inclusion and exclusion criteria: not stated Study authors contacted for clarification. 277 participants in the direct trocar group and 301 in the Veress needle group. None lost to follow-up	
Interventions	Direct trocar (elevation of rectus sheath and 12- to 13-mm transfers; subumbilical incision was made through the sheath, and the sheath was grasped and elevated with the use of 2 towel clips) vs Veress needle (10-mm transverse umbilical incision; needle inserted pointing towards the uterus, and 10 to 15 mmHg intra-abdominal pressure used as a guide to place the primary trocar). No co-intervention. Standardised operative technique was deployed by all operators. Direct entry was conducted with a 10-mm disposable shielded trocar. No further information was provided on the type or make of trocars	
Outcomes	Aim: to assess complication rates Secondary complications: extraperitoneal insufflation, failed entry	
Notes	Single centre in Ankara, Turkey	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated as randomised within the paper; exact method not stated
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not referred to within the paper
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding not referred to within the paper
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions nor loss to follow-up stated
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases; no data conversion. P values stated for each outcome. No omission of outcomes and no subsets of data
Other bias	Low risk	No other bias issues identified

Guo 2015

Methods	Randomised controlled trial	
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Guo 2015 (Continued)

Participants	<p>Included were 552 patients aged 18 to 75 with symptomatic gallstones or polyps documented by imaging with good performance status (KPS $\geq$ 70) and non-obese status (BMI < 30 kg/m²): 138 in SILS group, 414 in VNI group</p> <p>Exclusion criteria: acute cholecystitis, previous upper abdominal surgery, current/anticipated pregnancy, current breastfeeding, preoperative indication for endoscopic retrograde cholangiopancreatography, indication for intraoperative imaging of the biliary tract</p> <p>In addition, discretion was given to surgeons to exclude otherwise eligible patients according to their judgement of contraindications for laparoscopy - no further details given with regards to these contraindications</p>
Interventions	<p>SILS: with participant in Trendelenburg position, a 2.5-cm semicircular incision was made in the upper half of the umbilicus. Pneumoperitoneum was generated in the abdominal cavity by adding 12 mmHg of insufflation pressure; two 5-mm trocars and one 10-mm trocar were inserted through the umbilical incision at different fascial levels and in a triangular fashion. Then, a 5-mm, rigid, 30° laparoscope was introduced through the upper trocar; the remaining 2 trocars were used to introduce various other instruments required for the procedure</p> <p>VNI: with participant in Trendelenburg position, a 10-mm subumbilical incision was made. Then, 12 mmHg insufflation of the abdominal cavity was performed. A 10-mm trocar was inserted to introduce a 30° laparoscope</p>
Outcomes	<p>Primary endpoint: postoperative pain, evaluated by a visual analogue scale (VAS) and assessed at 6 hours, 24 hours, and 7 days, as well as at 1, 3, and 6 months, after surgery</p> <p>Secondary endpoints: KPS, wound-related complications, operative time, duration of hospital stay, cost</p>
Notes	Duration of trial unclear. No conflicts of interest declared. Study funded by a grant from Beijing Municipal Science and Technology Commission

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>"Enrolled patients were assigned to receive SILC or TLC using a 1:3 ratio randomization scheme. The complete randomization sequence was generated by a statistician who had no other role in this RCT"</p> <p>Method of random sequence generation not specified</p>
Allocation concealment (selection bias)	Low risk	"The allocation sequence was delivered in sealed opaque envelopes to a nurse within the operating room (who was not otherwise engaged in the study) immediately before surgery"
Blinding (performance bias and detection bias) All outcomes	Low risk	"Identical opaque dressings were used on all patients regardless of the surgical procedure. The dressings remained in place and unopened until [...] the first postdischarge visit (postoperative day [POD] 7). Thus, the randomization allocation was concealed from participants and investigators until the first postdischarge visit"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No post-randomisation exclusions. 11 lost to follow-up in SILS group. 25 lost to follow-up in VNI group. Reasons given in all cases. Data analysed according to the intention-to-treat principle
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers and percentages when appropriate. All significance values attached
Other bias	Low risk	Unequal allocation ratio - reason not stated. Power calculation performed and recruitment target achieved

Laparoscopic entry techniques (Review)

Hamade 2007

Methods	Randomised controlled trial that was single-blinded
Participants	Included were adults undergoing elective laparoscopic surgery, aged 16 to 80 years Other exclusion criteria: not stated 15 participants in the cutting trocar group and 15 in the blunt trocar group. No losses to follow-up
Interventions	Primary port insertion was accomplished with a direct blunt-tipped trocar at a site other than the umbilicus and without prior peritoneal insufflation, as we have previously described. Secondary port insertion was then accomplished under direct laparoscopic vision with a reusable cutting metal trocar (Mantis Surgical Limited, Newbury, Berkshire, UK), which had 3 sharp fixed blades, or a reusable blunt-tipped metal trocar (Mantis Surgical Limited), which had a conical blunt tip. No co-intervention. Standardised operative technique
Outcomes	Port stability and traction forces required at beginning and at completion of surgery Number of ports dislodged spontaneously, abdominal wall bleeding at trocar site
Notes	Single-centre trial at Manchester Royal Infirmary, UK

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computer-generated randomisation list was produced by an independent statistician and was opened by an independent person who produced envelopes containing the number of the study patient and a card labelled "blunt" or "sharp". Envelopes were sealed and were placed in the operating theatre
Allocation concealment (selection bias)	Low risk	A computer-generated randomisation list was produced by an independent statistician and was opened by an independent person who produced envelopes containing the number of the study patient and a card labelled "blunt" or "sharp". Envelopes were sealed and were placed in the operating theatre
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not stated within the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Complications not predefined by the study; however, primary aim consisted of port stability and friction forces. No losses to follow-up or lost data reported
Selective reporting (reporting bias)	Low risk	No data conversion. P values stated for each outcome. No omission of outcomes and no subsets of data
Other bias	Low risk	No other risk of bias identified

He 1 2015

Methods	Randomised controlled trial with 3 arms
Participants	Included were 300 patients aged 18 to 85 admitted for laparoscopic cholecystectomy with gallstones or gallbladder polyps were randomised to 3 groups of 100: single-incision 3-device group, single-incision X-cone group, conventional laparoscopy group

Laparoscopic entry techniques (Review)

He 1 2015 (Continued)

Exclusion criteria: CBD or intrahepatic bile duct stones; cholecystitis; BMI ≥ 35 kg/m²; drug addiction; ASA > 3; previous upper abdominal surgery; pregnancy; presence of umbilical hernia; previous umbilical hernia repair

No significant differences in terms of age, sex, BMI, and ASA between the 3 groups. No reported losses to follow-up

Interventions	<p>Single-incision 3-device group: 2-cm umbilical incision, 3 trocars (one 10 mm and two 5 mm) placed directly into the incision</p> <p>Conventional laparoscopy group: curved incision of 1 cm at lower umbilical edge, 1- to 1.2-cm incision below the xiphoid, 0.5-cm incision above the right clavicular line at the umbilical level, two 10-mm trocars and one 5-mm trocar inserted into 3 incisions</p>
Outcomes	<p>Primary endpoints: intraoperative and postoperative adverse events up to 1 month, operative time, intraoperative blood loss. Adverse events included conversion to multiple-incision conventional laparoscopy, incision contusion, wound infection, bile duct injury, bile leakage, and abdominal infection</p> <p>Secondary endpoints: postoperative pain (10-point scale, 1 day, 2 days, 1 week, and 1 month postop), cosmetic score, length of hospitalisation, comparison of hospital costs. Follow-up duration was 1 month</p>
Notes	Multi-centre trial across 2 clinical centres in China

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"They [patients] were randomly assigned to three groups of 100" No method for random sequence generation was provided in the text
Allocation concealment (selection bias)	Unclear risk	Not clear whether participants consented before or after allocation. No attempt made to describe allocation concealment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Study authors state in the discussion that this was a single-blinded study. They do not state whether patients or outcome assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No reported post-randomisation exclusions or losses to follow-up. 1 in the X-cone group converted to multiple-incision surgery, 2 in the 3-device method group converted to multiple-incision surgery. No reference made to intention-to-treat principle
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers with significance values attached
Other bias	Low risk	No other source of bias identified

He 2 2015

Methods	Randomised controlled trial with 3 arms
Participants	Included were 300 patients aged 18 to 85, admitted for laparoscopic cholecystectomy with gallstones or gallbladder polyps and randomised to 3 groups of 100: single-incision 3-device group, single-incision X-cone group, and conventional laparoscopy group

He 2 2015 (Continued)

Exclusion criteria: CBD or intrahepatic bile duct stones; cholecystitis; BMI ≥ 35 kg/m²; drug addiction; ASA > 3; previous upper abdominal surgery; pregnancy; presence of umbilical hernia; previous umbilical hernia repair

No significant differences in terms of age, sex, BMI, and ASA between the 3 groups

Interventions	<p>Single-incision X-cone group: 3-cm curved incision around upper or lower edge of umbilicus, X-cone device inserted, pneumoperitoneum up to 12 mmHg established and 5-mm laparoscope inserted</p> <p>Conventional laparoscopy group: curved incision of 1 cm at lower umbilical edge, 1- to 1.2-cm incision below xiphoid, 0.5-cm incision above right clavicular line at umbilical level, two 10-mm trocars and one 5-mm trocar inserted into 3 incisions</p>
Outcomes	<p>Primary endpoints: intraoperative and postoperative adverse events up to 1 month, operative time, intraoperative blood loss. Adverse events included conversion to multiple-incision conventional laparoscopy, incision contusion, wound infection, bile duct injury, bile leakage, and abdominal infection</p> <p>Secondary endpoints: postoperative pain (10-point scale 1 day, 2 days, 1 week, and 1 month postop), cosmetic score, length of hospitalisation, comparison of hospital costs. Follow-up duration was 1 month</p>
Notes	Multi-centre trial across 2 clinical centres in China

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"They [patients] were randomly assigned to three groups of 100" No method of random sequence generation was provided in the text
Allocation concealment (selection bias)	Unclear risk	Not clear whether participants consented before or after allocation. No attempt made to describe allocation concealment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Study authors state in discussion that it was a single-blinded study. They do not state whether patients or outcome assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No post-randomisation exclusions or losses to follow-up reported. 1 converted to multiple-incision surgery in X-cone group, and 2 converted to multiple-incision surgery in 3-device method group. No reference made to intention-to-treat principle
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers with significance values attached
Other bias	Low risk	No other source of bias identified

He 3 2015

Methods	Randomised controlled trial with 3 arms
Participants	Included were 300 patients aged 18 to 85, admitted for laparoscopic cholecystectomy with gallstones or gallbladder polyps and randomised to 3 groups of 100: single-incision 3-device group, single-incision X-cone group, and conventional laparoscopy group

He 3 2015 (Continued)

Exclusion criteria: CBD or intrahepatic bile duct stones; cholecystitis; BMI ≥ 35 kg/m²; drug addiction; ASA > 3; previous upper abdominal surgery; pregnancy; presence of umbilical hernia; previous umbilical hernia repair

No significant differences in terms of age, sex, BMI, and ASA between the 3 groups. No reported losses to follow-up

Interventions	<p>Single-incision 3-device group: 2-cm umbilical incision, 3 trocars (one 10 mm and two 5 mm) placed directly into incision</p> <p>Single-incision X-cone group: 3-cm curved incision around upper or lower edge of umbilicus, X-cone device inserted, pneumoperitoneum up to 12 mmHg established, 5-mm laparoscope inserted</p>
Outcomes	<p>Primary endpoints: intraoperative and postoperative adverse events up to 1 month, operative time, intraoperative blood loss. Adverse events included conversion to multiple-incision conventional laparoscopy, incision contusion, wound infection, bile duct injury, bile leakage, abdominal infection</p> <p>Secondary endpoints: postoperative pain (10-point scale 1 day, 2 days, 1 week, and 1 month postop), cosmetic score, length of hospitalisation, hospital costs compared Follow-up duration was 1 month</p>
Notes	Multi-centre trial across 2 clinical centres in China

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"They [patients] were randomly assigned to three groups of 100" No method of random sequence generation provided in the text
Allocation concealment (selection bias)	Unclear risk	Not clear whether participants consented before or after allocation. No attempt made to describe allocation concealment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Study authors state in discussion that this was a single-blinded study. They do not state whether patients or outcome assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No reported post-randomisation exclusions or losses to follow-up. 1 converted to multiple-incision surgery in X-cone group, 2 converted to multiple-incision surgery in 3-device method group. No reference made to intention-to-treat principle
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers with significance values attached
Other bias	Low risk	No other source of bias identified

Huang 2012

Methods	Randomised controlled trial with 2 arms. Patients presenting between October 2009 and May 2011; duration 1 year and 8 months
Participants	<p>Included were 91 consecutive patients undergoing elective laparoscopic cholecystectomy for gallbladder disease</p> <p>Inclusion criteria: 18 to 85 years old with normal basic hepatic function tests</p>

Huang 2012 (Continued)

Exclusion criteria: pregnancy, immunosuppressive drug therapy within previous 6 months, immunosuppressive condition including acquired immunodeficiency syndrome, autoimmune disorders, organ transplantation, radiation therapy or chemotherapy within previous 6 months, insulin-dependent diabetes mellitus

47 participants in the control (bladed trocar) group and 44 in the bladeless trocar group

Interventions	Control (bladed trocar) vs bladeless trocar. All 91 participants received general anesthesia with the same protocol from one of the study authors (Lin CC, anaesthesiologist). Laparoscopic cholecystectomy with 4 ports was conducted for all patients, including two 12-mm trocars and two 5-mm trocars. In the bladeless group, the two 12-mm trocars were bladeless (Ethicon; Endo-Surgery, Cincinnati, OH, USA), whereas in the control group, the 12-mm trocars were bladed (179771P-12 mm; Covidien, Norwalk, CT, USA). The same 5-mm trocars were applied in both groups (301601TP 5-6 mm diameter, Karl Storz). Participants in both groups received 1.0% ropivacaine 20 mL at port sites after wound closure
Outcomes	Level of pain using the VAS at 1 hour, 6 hours, and 24 hours post procedure and at time of discharge; analgesia use (meperidine and acetaminophen) 1, 6, and 24 hours post procedure
Notes	Single-centre study at the Department of Surgery, Chang Gung Memorial Hospital, Taiwan

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"91 consecutive patients were included in the study and allocated into a control group or bladeless trocar application group according to random number table"
Allocation concealment (selection bias)	Unclear risk	No reference to allocation concealment was made within the text of the paper
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding was not mentioned in the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions or dropouts reported. Conversion rate of zero
Selective reporting (reporting bias)	Low risk	No data conversion. P values stated for each outcome. No omission of outcomes and no subsets of data
Other bias	Low risk	No other sources of bias identified

Imran 2014

Methods	Randomised controlled trial with 2 arms. Patients recruited from August 2012 to July 2014; duration 2 years
Participants	<p>Patients admitted to the surgical ward for laparoscopic cholecystectomy were screened for enrolment</p> <p>Exclusion criteria: patients < 20 or > 65 years of age, coexisting chronic liver disease, chronic renal failure, malignancy</p> <p>30 participants were randomised to the direct trocar entry group, and 30 to the Veress needle entry group</p>

Laparoscopic entry techniques (Review)

Imran 2014 (Continued)

Interventions	Direct trocar entry vs Veress needle entry for laparoscopic cholecystectomy. Description of the techniques used is not included in the text. No information on type and make of trocars is included in the text
Outcomes	Access time, gas leak, extraperitoneal insufflation, vascular injury, visceral injury, port site haematoma, port site infection, port site hernia
Notes	Single-centre study at Akhtar Saeed Trust Teaching Hospital, Lahore

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised to each group via a random number table
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment in the text
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants dropped out and none were lost to follow-up
Selective reporting (reporting bias)	Low risk	Data for all outcomes published
Other bias	Low risk	P values not published alongside outcome results. No other source of bias identified

Johnson 1997

Methods	Randomised controlled trial that was single-blinded
Participants	Included were women presenting for sterilisation and over the age of 21. Women weighing more than 100% of their ideal body weight were excluded. No other exclusion criteria stated. 10 participants were assigned to the gasless laparoscopy group, and 8 to the CO ₂ laparoscopy group. None were lost to follow-up
Interventions	Laparoscopic surgery using insufflation of carbon dioxide gas (technique unclear) vs a gasless abdominal wall retractor (technique unclear). No co-intervention. Standardised operative training in both interventions, especially for the study. Inability to access information on the type and make of trocars
Outcomes	Aim: to assess technical feasibility, ventilatory parameters, haemodynamic stability, and postoperative pain and nausea. No outcome measures reported. Study authors were contacted Outcome measures: ease of operative technique, participant pain and nausea
Notes	Single-centre study in North Carolina, USA

Laparoscopic entry techniques (Review)

Johnson 1997 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A randomization protocol consisting of a randomization block design"
Allocation concealment (selection bias)	Unclear risk	No reference to allocation concealment
Blinding (performance bias and detection bias) All outcomes	Low risk	Single-blinded; patients only "The subjects were not informed of their treatment group"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No outcome measures reported; study authors contacted to request clarification. No dropouts or exclusions stated
Selective reporting (reporting bias)	High risk	Data presented as numbers of cases; no data conversion. Not all outcomes reported and no subsets of data
Other bias	Low risk	Power calculation not stated. P values not stated for each outcome. No other sources of bias identified

Karaca 2014

Methods	Randomised controlled trial with 2 arms. Patients presenting between January 2007 and July 2009; duration 2 years and 7 months
Participants	Included were 400 patients undergoing laparoscopic cholecystectomy Exclusion criteria: patients who had undergone previous abdominal surgery 200 people were in the Veress needle entry group, and 200 were in the direct trocar entry group
Interventions	Veress needle entry vs direct trocar entry Veress needle (Tyco or Ethicon) was inserted through a subumbilical incision to establish pneumoperitoneum Direct trocar (Tyco or Ethicon) was inserted into the peritoneal cavity after a 10-mm subumbilical incision was made; entry was aided by lifting of the abdominal wall with towel clamps
Outcomes	Aim: to assess complication rates Major complications requiring open surgery (mesenteric laceration, bleeding, organ perforation, solid organ injury, blood vessel injuries) and minor complications (subcutaneous emphysema, phison, extraperitoneal insufflation)
Notes	Single-centre study at the Bartın National Hospital, Turkey

Risk of bias

Bias	Authors' judgement	Support for judgement
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Karaca 2014 (Continued)

Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described. Study author contacted for clarification
Allocation concealment (selection bias)	Unclear risk	No reference to allocation concealment was made within the text of the paper
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding of participants, personnel, or outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants lost to follow-up and no dropouts recorded
Selective reporting (reporting bias)	Low risk	P values stated for minor and major complications as groups. No omission of outcomes and no subsets of data
Other bias	Low risk	No other source of bias identified

Kitano 1993

Methods	Randomised controlled trial that was single-blinded; April to August 1991; study duration 5 months
Participants	<p>Included were patients referred for treatment of gallstones from April to August 1991</p> <p>Exclusion criteria were based upon previous abdominal surgery, concomitant common bile duct stones, and gallbladder cancer</p> <p>Exclusion was not based upon age and sex</p> <p>82 in the pneumoperitoneum group and 41 in the U-shaped retractor elevation group. None lost to follow-up</p>
Interventions	Laparoscopic surgery with insufflation of carbon dioxide gas (technique unclear) vs a gasless abdominal wall retractor (technique unclear). No co-intervention Standardised operative training in both interventions, especially for the study. Standardised operative technique was deployed by all operators. Information on type and make of the trocar was not provided
Outcomes	<p>Aim: to assess technical feasibility</p> <p>Primary complications: vascular and solid organ injuries</p> <p>Secondary complications: extraperitoneal insufflation, wound infection</p>
Notes	Multi-centre study in Kitakyushu, Japan, and Fukuoka, Japan

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Forty-two patients were randomly allocated to the pneumoperitoneum (P) group and 41 to the U-shaped retractor (U) group by using a system of randomized numbers"
Allocation concealment (selection bias)	Unclear risk	No reference to allocation concealment

Laparoscopic entry techniques (Review)

Kitano 1993 (Continued)

Blinding (performance bias and detection bias) All outcomes	Unclear risk	No reference to blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions or dropouts stated
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases and percentages; no data conversion. No omission of outcomes and no subsets of data
Other bias	Low risk	P values not published for each outcome. No power calculation mentioned. No further bias issues identified

Köstü 1 2016

Methods	Prospective randomised controlled trial with 3 arms
Participants	Included were 65 patients undergoing laparoscopy for benign gynaecological indications Exclusion criteria: patients requiring direct entry due to 3 unsuccessful attempts at Veress needle entry, patients requiring Palmer's point entry or with any evident adhesions on anterior abdominal wall 22 participants at IAP 15 mmHg + umbilical clip group, 21 participants at IAP 25 mmHg + umbilical clip group. Participant demographics (including age, gravidity, parity, BMI, preoperative and postoperative haemoglobin concentrations, number of previous surgeries, procedure type) did not differ significantly between the 2 groups
Interventions	Entry to abdomen achieved with 10-mm vertical incision in the umbilical region up to the fascia, through which a Veress needle was passed into the abdomen. In Group 1 (n = 22), IAP 15 mmHg achieved with CO ₂ insufflation, abdominal wall lifted with clip on each side of umbilicus, and main trocar inserted. In Group 2 (n = 21), same as Group 1 but IAP 25 mmHg achieved by CO ₂ insufflation
Outcomes	Pneumoperitoneum distance, amount of CO ₂ used to achieve pneumoperitoneum, operation onset-to-trocar entry interval, complications (omental injury, incision site bleeding, preperitoneal insufflation, open entry)
Notes	Kahramanmaraş Sutcuimam University Hospital - tertiary level reference hospital

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Simple randomization was conducted using computer-generated sequence"
Allocation concealment (selection bias)	High risk	"Allocation concealment was not performed"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	No reported post-randomisation exclusions or losses to follow-up. No reference made to intention-to-treat principle

Laparoscopic entry techniques (Review)

Köstü 1 2016 (Continued)

Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers and percentages when appropriate, with significance values attached
Other bias	Low risk	No other source of bias identified

Köstü 2 2016

Methods	Prospective randomised controlled trial with 3 arms
Participants	<p>Included were 65 patients undergoing laparoscopy for benign gynaecological indications</p> <p>Exclusion criteria: patients requiring direct entry due to 3 unsuccessful attempts at Veress needle entry, patients requiring Palmer's point entry or any evident adhesions on anterior abdominal wall</p> <p>22 participants in external compression at IAP 25 mmHg group, and 21 at IAP 25 mmHg + umbilical clip group. Participant demographics (including age, gravidity, parity, BMI, preoperative and postoperative haemoglobin concentrations, number of previous surgeries, and procedure type) did not differ significantly between the 2 groups</p>
Interventions	Entry to abdomen achieved with 10-mm vertical incision in umbilical region up to the fascia, through which Veress needle was passed into the abdomen. After this step, participants were recruited into 3 groups. In Group 2 (n = 22), CO ₂ insufflation was used to obtain IAP 15 mmHg, but then surgeon applied external compression on supraumbilical region until IAP 25 mmHg was achieved, then placed main trocar into abdominal cavity. In Group 3 (n = 21), IAP 25 mmHg achieved with CO ₂ insufflation, abdominal wall lifted with clip on each side of umbilicus, and main trocar inserted
Outcomes	Pneumoperitoneum distance, amount of CO ₂ used to achieve pneumoperitoneum, operation onset-to-trocar entry interval, complications (omental injury, incision site bleeding, preperitoneal insufflation, open entry)
Notes	Kahramanmaras Sutcuimam University Hospital - tertiary level reference hospital

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Simple randomization was conducted using computer-generated sequence"
Allocation concealment (selection bias)	High risk	"Allocation concealment was not performed"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	No reported post-randomisation exclusions nor losses to follow-up. No reference made to intention-to-treat principle
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers and percentages when appropriate, with significance values attached
Other bias	Low risk	No other source of bias identified

Köstü 3 2016

Methods	Prospective randomised controlled trial with 3 arms
Participants	<p>Included were 65 patients undergoing laparoscopy for benign gynaecological indications</p> <p>Exclusion criteria: patients requiring direct entry due to 3 unsuccessful attempts at Veress needle entry, patients requiring Palmer's point entry or with evident adhesions on anterior abdominal wall</p> <p>22 participants at IAP 15 mmHg + umbilical clip group, 22 participants in external compression at IAP 25 mmHg group. Participant demographics (including age, gravidity, parity, BMI, preoperative and postoperative haemoglobin concentrations, number of previous surgeries, and procedure type) did not differ significantly between the 2 groups</p>
Interventions	Entry to abdomen achieved with 10-mm vertical incision in umbilical region up to the fascia, through which a Veress needle was passed into the abdomen. After this step, participants were recruited into 3 groups. In Group 1 (n = 22), IAP 15 mmHg achieved with CO ₂ insufflation, abdominal wall lifted with clip on each side of umbilicus, and main trocar inserted. In Group 2 (n = 22), CO ₂ insufflation used to obtain IAP 15 mmHg, but then surgeon applied external compression on supraumbilical region until IAP 25 mmHg achieved, then placed main trocar into abdominal cavity
Outcomes	Pneumoperitoneum distance, amount of CO ₂ used to achieve pneumoperitoneum, operation onset-to-trocar entry interval, complications (omental injury, incision site bleeding, preperitoneal insufflation, open entry)
Notes	Kahramanmaras Sutcuimam University Hospital - tertiary level reference hospital

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Simple randomization was conducted using computer-generated sequence"
Allocation concealment (selection bias)	High risk	"Allocation concealment was not performed"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	No reported post-randomisation exclusions nor losses to follow-up. No reference made to intention-to-treat principle
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers and percentages when appropriate, with significance values attached
Other bias	Low risk	No other source of bias identified

Lai 2011

Methods	Randomised controlled trial
Participants	Invited to participate in the study were patients from 18 to 80 years of age with preoperative diagnosis of symptomatic gallstones or gallbladder polyps, requiring elective cholecystectomy

Laparoscopic entry techniques (Review)

Lai 2011 (Continued)

Exclusion criteria: patients with: ASA class 4 and 5; contraindications for laparoscopy; Mirizzi syndrome; suspected presence of common bile duct stones; suspected malignancy; previous upper abdominal surgery; long-term anticoagulation; previous history of cholangitis or cholecystitis; large gallstone (> 3 cm); imaging diagnosis of contracted gallbladder or chronic cholecystitis

27 participants were randomised to both the single-incision laparoscopic surgery (SILS) cholecystectomy group and the conventional 4-port laparoscopic cholecystectomy group (4PLC)

Interventions	<p>SILS cholecystectomy vs 4PLC</p> <p>For SILS cholecystectomy, a 20-mm umbilical incision was made by open technique, through which the SILS Port (Covidien Inc., Norwalk, CT, USA) was inserted. Pneumoperitoneum was generated, laparoscopic instruments were inserted into the peritoneal cavity, and cholecystectomy was performed</p> <p>For conventional 4PLC, a subumbilical incision was made and the abdominal cavity was insufflated. Once pneumoperitoneum was established, a laparoscope was inserted through the subumbilical incision and three 5-mm trocars were inserted into the right subcostal region under direct vision. Surgical techniques were standardised among participating surgeons before the protocol was started</p>
Outcomes	<p>Primary outcomes: pain score at 6 hours after surgery and at 7 days after surgery</p> <p>Secondary outcomes: open conversion rate, complications, mortality, length of hospital stay, interval for resumption of normal physical activities, cosmetic satisfaction of surgical scar</p>
Notes	Single-centre study at the Department of Surgery, Pamela Youde Nethersole Eastern Hospital, Hong Kong

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants randomised via computer-generated random numbers
Allocation concealment (selection bias)	Low risk	Computer-generated random numbers were stored in sealed opaque envelopes
Blinding (performance bias and detection bias) All outcomes	Low risk	Patients were not blinded from the study, but outcome assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	From the SILS group, 3 participants refused to participate after randomisation. We felt this small number would have no effect on results. No participants were lost to follow-up
Selective reporting (reporting bias)	Low risk	Data for all outcome measures were published alongside significance values
Other bias	Low risk	No other sources of bias were identified

Lam 2000

Methods	Randomised controlled trial that was single-blinded
Participants	<p>Included were patients over the age of 18 who were likely to benefit from laparoscopic cholecystectomy</p> <p>Exclusion criteria: presence of inflammatory conditions and malignancy</p>

Laparoscopic entry techniques (Review)

Lam 2000 (Continued)

30 in the radially expanding (STEP) trocar group and 31 in the standard trocar group. Seven lost to follow-up

Interventions	Radially expanding (STEP) 10-mm trocars vs standard metal 10-mm trocars for secondary port entry. No co-intervention. No further information provided on type or make of trocars
Outcomes	Major complications (specific complications not stated). Trocar site bleeding and wound infection
Notes	Single-centre trial at the Department of Surgery, United Christian Hospital, Hong Kong

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Truly randomised
Allocation concealment (selection bias)	Unclear risk	Not referred to within the paper
Blinding (performance bias and detection bias) All outcomes	Low risk	Single-blinded study (patients only)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants dropped out or were lost to follow-up
Selective reporting (reporting bias)	Unclear risk	Major complications (specific complications not stated) not recorded; study authors have been contacted
Other bias	Low risk	No other sources of bias identified

Luna 2013

Methods	Prospective randomised controlled trial with 2 study arms. Patients were recruited between January 2010 and December 2010 (duration 12 months)
Participants	<p>Patients were invited to take part in the study if they had symptomatic cholelithiasis, diagnosed clinically and confirmed by abdominal ultrasound</p> <p>Exclusion criteria: BMI > 36 kg/m²</p> <p>40 patients were enrolled in the study: 20 in the single-incision laparoscopic surgery (SILS) cholecystectomy group, and 20 in the 4-port laparoscopic cholecystectomy (4PLC) group</p>
Interventions	<p>SILS cholecystectomy vs 4PLC. For SILSC, a SITRACC device (EDLO, Rio Grande do Sul, Brazil), containing one 10-mm and three 5-mm working ports, was used. The SILS cholecystectomy intervention was not described in the text</p> <p>4PLC was done with conventional technique</p>
Outcomes	Primary outcomes: IL-6 levels, C-reactive protein, postoperative pain. Surgical site infection and the need for extra ports were also recorded for the SILS group

Luna 2013 (Continued)

Notes Single-centre study at the Division of General Surgery, Federal Hospital of Servidores do Estado, Rio de Janeiro, Brazil

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not mentioned in the text
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment in the text
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of allocation concealment in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants dropped out or were lost to follow-up
Selective reporting (reporting bias)	Low risk	All primary outcomes reported with corresponding significance values
Other bias	Unclear risk	No other sources of bias identified in the text

Mettler 2000

Methods	Randomised controlled trial that was single-blinded
Participants	Three surgeons at 2 centres enrolled 100 patients undergoing elective laparoscopic gynaecological surgical procedures Exclusion criteria: acute inflammatory conditions 49 participants in the radially expanding (STEP) trocar group and 51 in the Veress needle group. None lost to follow-up
Interventions	Radially expanding (STEP) trocars (technique not stated) vs standard trocars (technique not stated). No co-intervention. Standardised operative training in both interventions, especially for the study. Standardised operative technique was deployed by all operators. The control device - the conventional trocar - was non-disposable and had a sharp, cutting stylet or a blunt obturator. The STEP device consisted of an access insufflation needle, a radially expandable polymeric sleeve, and a tapered blunt dilator/cannula. No further information on trocars was provided
Outcomes	Aim: to assess complications Primary complications: vascular and visceral injuries Secondary complications: failed entry, wound bleeding
Notes	Multi-centre study at Kiel, Germany, and Victoria, Australia

Risk of bias

Bias	Authors' judgement	Support for judgement
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Laparoscopic entry techniques (Review)

Mettler 2000 (Continued)

Random sequence generation (selection bias)	Low risk	"Patients were randomised into either Step (S; n = 49) or conventional technique (C; n = 51) groups according to which kind of laparoscopic access device was assigned from the randomisation table"
Allocation concealment (selection bias)	Unclear risk	No reference to allocation concealment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No reference to blinding within paper
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up nor exclusions stated
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases; no data conversion. P values stated for each outcome. No omission of outcomes and no subsets of data
Other bias	Low risk	Power calculation not stated. No evidence of further bias identified

Minervini 2008

Methods	Randomised controlled trial
Participants	Included were patients admitted for transperitoneal laparoscopic procedures for renal pathology Exclusion criteria: none 27 participants in the open group and 33 in the bladeless group. No losses to follow-up stated
Interventions	Hasson trocar inserted by standard technique vs a 12-mm bladeless trocar (Ethicon Endo-Surgery, Cincinnati, OH, USA). No co-intervention. Standardised surgical technique deployed
Outcomes	Mean time to closure, failed entry, gas leak, intra-abdominal injury, port site herniation
Notes	Single-centre trial at University of Florence, Italy

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not clearly stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions or dropouts stated

Minervini 2008 (Continued)

Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases and percentages; no data conversion. No omission of outcomes and no subsets of data
Other bias	Low risk	P values not stated for each outcome. Power calculation not performed. No other sources of bias identified

Ostrzenski 1999

Methods	Randomised controlled trial that was single-blinded; between January 1992 and January 1995; study duration 3 years	
Participants	<p>Patients were recruited between January 1992 and January 1995. Elective diagnostic and/or operative laparoscopic cases were included</p> <p>Exclusion criteria: previous abdominal surgery, abdominal or pelvic adhesions, severe endometriosis, fistulae formation, IBS, diaphragmatic herniae, cardiopulmonary disease, abdominopelvic organ enlargement</p> <p>Exclusion was not based upon age and BMI</p> <p>50 participants in the closed technique group and 50 in the parallel technique group. None lost to follow-up</p>	
Interventions	<p>Closed (technique unclear) vs parallel (Trendelenburg position, incision made at the lower end of the umbilicus, no abdominal wall elevation, Veress needle advanced through the abdominal wall aiming towards the sacral hollow) technique of Veress needle insertion. No co-intervention. Standardised operative training in both interventions, especially for the study. Standardised operative techniques were deployed by all operators. A 20-cm Veress needle was used in patients weighing < 81 kg, and a 50-cm Veress needle was used in patients weighing ≥ 81 kg. No further information on Veress needle or trocar make was provided</p>	
Outcomes	<p>Aim: to assess safety and efficacy</p> <p>Primary complications: vascular and visceral injuries</p> <p>Secondary complications: extraperitoneal insufflation</p>	
Notes	Multicentre study across several facilities in Washington, D.C., USA.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"To prevent bias related to preoperative expectations, patients were randomized by sealed envelope in the operating room after the induction of anesthesia"
Allocation concealment (selection bias)	Unclear risk	"To prevent bias related to preoperative expectations, patients were randomized by sealed envelope in the operating room after the induction of anesthesia"
Blinding (performance bias and detection bias) All outcomes	Low risk	Single-blinded; patients only
Incomplete outcome data (attrition bias)	Low risk	No exclusions or dropouts reported

Laparoscopic entry techniques (Review)

Ostrzenski 1999 (Continued)

All outcomes

Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases; no data conversion. No omission of outcomes and no subsets of data
Other bias	Low risk	P values not stated for each outcome. Power calculation not stated. No other sources of bias identified

Partelli 2016

Methods	Prospective double-blinded randomised controlled trial	
Participants	<p>Included were 59 patients, aged 18 to 75, who were undergoing laparoscopic cholecystectomy for cholelithiasis demonstrated by ultrasound</p> <p>Exclusion criteria: pregnancy, inability to provide informed written consent, BMI > 30 kg/m², ASA grade > 2, previous umbilical hernia repair, previous abdominal surgery, acute cholecystitis, obstructive jaundice, acute pancreatitis</p> <p>30 randomised to undergo single-incision laparoscopic cholecystectomy (SILC), 29 to traditional laparoscopic cholecystectomy (TLC). No difference in participant demographics (age, sex, and BMI) between groups</p>	
Interventions	<p>All participants operated on by the same first surgeon. Three other surgeons responsible for postoperative care and medical ward nursing staff were all blinded to the type of operation</p> <p>TLC: Veress needle through umbilicus with 10-mm optical trocar, 5-mm epigastric trocar, 10-mm right subcostal trocar, and 5-mm left subcostal trocar</p> <p>SILC: 15- to 25-mm skin incision, single-site laparoscopic access system (Johnson and Johnson Medical Spa) placed in peritoneal cavity</p>	
Outcomes	<p>Primary endpoint: level of pain after surgery (VAS pain score at 2, 4, 6, 12, 24 hours postoperatively)</p> <p>Secondary endpoints: complications, median operative time, cosmetic outcomes (scars, erythema, induration, skin retraction), patient satisfaction</p> <p>Complications included biliary fistula (defined as ≥ 30 mL biliary fluid output/d for > 7 days) and haemorrhage (defined as requirement for 1 or more unit RBC within 48 hours of operation)</p>	
Notes	Department of Surgery, Ospedale, Verona, Italy	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was done the day before the operation using computer-generated random numbers"
Allocation concealment (selection bias)	Low risk	Participants consented before allocations, as exclusion criteria included the following: "inability to provide written informed consent"; and "allocation to the SILC group or the TLC group was communicated to the operating surgeon on the day of surgery"
Blinding (performance bias and detection bias) All outcomes	Low risk	Double-blinded RCT: patients, postoperative assessors, and ward nurses were blinded to the intervention group

Laparoscopic entry techniques (Review)

Partelli 2016 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	No post-randomisation exclusions nor losses to follow-up in either group. Data analysed on an intention-to-treat basis
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers and percentages when appropriate, with significance values attached
Other bias	Low risk	No other source of bias identified

Peitgen 1997

Methods	Randomised controlled trial with 2 study arms. Study ran from July to November 1996; duration 5 months
Participants	<p>Included were adult patients 21 to 89 years of age requiring laparoscopic interventions (18 cholecystectomy; 12 staging laparoscopy; 9 gastrostomy; 6 splenectomy; 2 liver cyst; 1 double cholecyst/splenectomy; 1 colostomy deviation; 1 explorative)</p> <p>Excluded were 14 patients who had undergone previous abdominal surgery. No other exclusion criteria were stated</p> <p>24 participants were randomised to the Veress needle entry group, and 26 to the open laparoscopic entry group</p>
Interventions	<p>Veress needle entry vs open laparoscopic entry</p> <p>For Veress needle entry, a 1-cm subumbilical transverse incision was made, followed by Veress needle entry and insufflation of the peritoneum</p> <p>For open entry, a subumbilical 1- to 1.5-cm incision was made through the linea alba, and the peritoneum was incised with Lang scissors, followed by insufflation. No further information on Veress needle or trocar model or make was provided</p>
Outcomes	Time from incision to introduction of the laparoscope, total operation time, use of gas, subjective reporting of gas leakage at first injection site, number of attempts to insert Veress needle or trocar, complications
Notes	Single-centre study in Essen, Germany

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No mention of method used for randomisation
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	14 participants excluded before randomisation due to previous abdominal surgery. No participants lost to follow-up

Laparoscopic entry techniques (Review)

Peitgen 1997 (Continued)

Selective reporting (reporting bias)	Low risk	All outcomes clearly reported
Other bias	Low risk	Not all P values published alongside outcomes. Power calculation not mentioned. No other source of bias identified

Perez 2013

Methods	Single-blind randomised controlled trial with 2 treatment arms, running from June 2009 to January 2011; duration 1 year and 8 months
Participants	Included were children presenting with a diagnosis of appendicitis, from 3 to 15 years of age Exclusion criteria: not included in the text 50 patients were enrolled in the study: 25 to the single-incision laparoscopic surgery (SILS) appendectomy group, and 25 to the standard 3-port laparoscopic appendectomy (3PLA) group
Interventions	SILS appendectomy vs 3PLA For SILS, a single supraumbilical incision was made, subcutaneous tissue was removed, three 5-mm fascial incisions were produced, and ports were inserted into the peritoneal cavity (5-mm 30° laparoscope through the middle port, and 5-mm dissector and 5-mm grasper through the lateral ports). The appendix was then dissected free LAPA procedures were performed in standard 3-port fashion with 3 separate skin incisions. Details of the laparoscopic instruments used are not included in the text. No further information on trocar make or model was provided
Outcomes	Operative time, operative conversions, analgesic usage, hospital length of stay, complications, participant follow-up evaluation
Notes	Single-centre study at the Division of Pediatric Surgery, Children's Medical Center of Dallas, University of Texas Southwestern Medical Center (Dallas, TX, USA)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised via Random Allocation Software 1.0, through random number generation
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment in the text
Blinding (performance bias and detection bias) All outcomes	Low risk	Hospital staff and patients blinded to each procedure, with similar dressings used in each group
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants lost to follow-up or dropped out after randomisation
Selective reporting (reporting bias)	Low risk	No selective reporting bias identified in the text
Other bias	Low risk	No other sources of bias identified

Laparoscopic entry techniques (Review)

Phillips 2012

Methods	Randomised controlled trial with 2 arms
Participants	<p>Invited to enrol in the study were patients presenting with biliary colic (radiographic diagnosis of gallstones or polyp), biliary dyskinesia with an ejection fraction < 30%, between 18 and 85 years of age, of either gender, and with BMI < 45 kg/m²</p> <p>Exclusion criteria: pregnancy, acute cholecystitis, previous right subcostal or upper midline incision, preoperative indication for endoscopic retrograde cholangiopancreatography, indication for intraoperative biliary imaging, ASA classification > 3, ongoing peritoneal dialysis, presence of umbilical hernia or umbilical hernia repair</p> <p>117 participants were randomised to the single-incision laparoscopic surgery (SILS) cholecystectomy group, and 80 to the 4-port laparoscopic cholecystectomy (4PLC) group</p>
Interventions	<p>SILS cholecystectomy vs 4PLC</p> <p>For SILS, the umbilicus was inverted and incised through the fascia, and the SILS port was placed into the peritoneal cavity with the assistance of a curved clamp</p> <p>For 4PLC, two or three 5-mm ports and one or two 10-mm or 12-mm ports were placed under the discretion of the surgeon. No further information on trocar make or model was provided</p>
Outcomes	<p>Primary aims of the study: assessment of the feasibility and safety of SILS cholecystectomy vs 4PLC as indicated by intraoperative and postoperative adverse events up to 1 year, operative time, estimated blood loss</p> <p>Secondary outcomes: pain post procedure and at specific points at follow-up, analgesic use post procedure, cosmetic scar evaluation, quality of life before and after the procedure, time required for insertion of SILS port vs 4 standard ports</p>
Notes	Multi-centre study conducted at 10 hospital sites, based at Western Reserve University, Cleveland, OH, USA

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants randomised to SILS cholecystectomy and 4PLC at a 1.5:1 ratio
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment in the text
Blinding (performance bias and detection bias) All outcomes	Low risk	Patients blinded up to a week after the procedure
Incomplete outcome data (attrition bias) All outcomes	Low risk	Patients dropped out from long-term follow-up, but no one dropped out immediately post surgery
Selective reporting (reporting bias)	Low risk	All outcome data published with corresponding P values
Other bias	Low risk	No other source of bias identified

Porta 2017

Methods	Prospective randomised controlled trial
Participants	Included were 130 patients who were receiving laparoscopic sleeve gastrectomy: 65 in single-incision group, 65 in VNI group Exclusion criteria: BMI > 50 kg/m ² , presence of hiatal hernia and gastroesophageal reflux disease, previous abdominal surgery, younger than 18 or older than 70 years
Interventions	VNI: with participants in supine position, pneumoperitoneum was inflated at 15 mmHg with a Veress needle. Five ports were placed (10 mm in mesogastrium for the camera, 15 mm and 12 mm, respectively, in the right and left flanks for the operating surgeon, 5 mm in the right hypochondrium, and 5 mm in the sub-xiphoid region) SILS: 2.5-cm umbilical incision done and anterior rectus fascia incised. The SILS device (Covidien, Norwalk, CT, USA) was positioned with three 5-mm ports in place, and pneumoperitoneum was inflated at 15 mmHg
Outcomes	Complications (oliguria, fever, vomiting, chest pain, hypertensive crisis, wound haematoma, wound infection, bleeding from cutting line, intraluminal bleeding, compression injury (shoulder), incisional hernia, leaks), hospital stay, time to passage of flatus, resumption of oral intake, cosmesis, postoperative pain and nausea, mortality, quality of life
Notes	January 2009 to December 2014. No conflicts of interest declared. Source of funding not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation method not specified
Allocation concealment (selection bias)	Unclear risk	No method of allocation concealment specified
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No reference made to blinding in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Follow up rate was 100% in both groups at 12 months. Four-year follow up was completed in 96% of patients in the SI group compared to 95% in the CL group" No reasons given but similar losses in each group and unlikely to affect our outcome measures. No reference made to intention-to-treat principle
Selective reporting (reporting bias)	High risk	Absolute significance values often not quoted (i.e. P value given as "NS" or "< 0.05")
Other bias	Unclear risk	No other source of bias identified

Prieto-Díaz-Chávez 2006

Methods	Randomised controlled trial with 2 arms, running from December 1997 to July 1999; duration 1 year and 8 months
Participants	Inclusion criteria: calculous cholecystitis requiring cholecystectomy

Laparoscopic entry techniques (Review)

Prieto-Díaz-Chávez 2006 (Continued)

Exclusion criteria: previous superior or high abdominal surgery

42 people were randomised to the direct trocar insertion group, and 42 to the Veress needle insertion group

Interventions	<p>Laparoscopic cholecystectomy with direct trocar entry vs laparoscopic cholecystectomy with Veress needle insertion</p> <p>For the direct trocar insertion group, the umbilical stalk was clamped and incised; this was followed by incision of the rectus aponeurosis, blunt dissection of the aponeurosis with the index finger, and entry into the abdominal cavity. The abdominal wall was then elevated and the first trocar was inserted</p> <p>For the Veress needle group, the abdominal wall was elevated and the Veress needle was introduced at a 45° angle towards the pelvis. Pneumoperitoneum was then established. No further information on trocar or Veress needle make or model was provided</p>
Outcomes	Procedure complications (epigastric vessel bleeding, more than 3 attempts at establishing pneumoperitoneum, wall infection, preperitoneal insufflation), laparoscopic insertion time, duration of surgery
Notes	Single-centre study at the General Hospital and Familiar Medicine No.1, Colima, Mexico

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were assigned to 2 treatment groups via a random number table
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment in the text
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants lost to follow-up, and none dropped out after randomisation
Selective reporting (reporting bias)	Low risk	All outcomes stated with corresponding significance values
Other bias	Low risk	No other sources of bias identified in the text

Santala 1999

Methods	Randomised controlled trial that was single-blinded
Participants	<p>Included were 100 consecutive women with BMI > 25 kg/m² attending clinic for sterilisation who were enrolled into the trial</p> <p>Exclusion criteria: history of pelvic inflammatory disease, adhesions obliterating the cul-de-sac, uterine fibroids, uterine cavity larger than 10 cm</p> <p>Exclusion criteria were not based upon age, BMI, height, or weight</p>

Santala 1999 (Continued)

50 participants in the transfundal group and 50 in the infraumbilical group. None lost to follow-up

Interventions	Transfundal insertion vs infraumbilical insertion of the Veress needle. No co-intervention. Standardised operative training in both interventions, especially for the study Standardised operative technique was deployed by all operators. No further details on Veress needle make or model were provided
Outcomes	Aim: to assess efficacy and safety Secondary complications: uterine bleeding, failed entry
Notes	Single-centre study in Oulu, Finland

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"For allocation into study groups, we used sealed envelopes prepared in blocks of 20"
Allocation concealment (selection bias)	Low risk	"For allocation into study groups, we used sealed envelopes prepared in blocks of 20"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not stated within the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions, dropouts, or losses to follow-up stated
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases; no data conversion No omission of outcomes and no subsets of data
Other bias	Low risk	P values not stated for each outcome. Power calculation not stated. No other sources of bias identified

Schulze 1999

Methods	Randomised controlled trial that was not blinded
Participants	22 participants provided informed consent and entered the study Exclusion criteria: extensive tumour growth and rectal surgery Participants were randomised to gasless (n = 9) or conventional CO ₂ (n = 8) surgery; 5 were lost to follow-up
Interventions	Gasless (technique published elsewhere) vs conventional surgery (technique published elsewhere). No co-intervention. Standardised operative technique was deployed by all operators For gasless operations, retraction of the abdominal wall was achieved by the plantar lifting technique (Laparolift; Oregon Medical Systems, San Jose, CA). No further information on trocar make or model was provided
Outcomes	Aim: to assess cardiopulmonary and systemic changes Complications that occurred: pneumonia, brachial artery embolism, incarcerated inguinal hernias

Laparoscopic entry techniques (Review)

Schulze 1999 (Continued)

Study authors reported changes in cardiovascular and respiratory function

Notes	Single-centre study in Copenhagen, Denmark	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation unclear
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not discussed within the paper
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reported participants as lost to follow-up because of conversion to a different technique; therefore an intention-to-treat analysis may have been of value "Five patients were excluded because of conversion from laparoscopic to open surgery (2 in the gasless group and 3 in the CO2 group)"
Selective reporting (reporting bias)	Low risk	Data were presented as numbers of cases; no data conversion. P values stated for each outcome. No omission of outcomes and no subsets of data
Other bias	Low risk	Power calculation not stated. No other source of bias identified

Tansatit 2006

Methods	Randomised controlled trial that was single-blinded	
Participants	<p>Included were patients referred from the infertility clinic for laparoscopic diagnosis</p> <p>Exclusion criteria: based upon suspicion of adhesions, prior abdominal surgery, midline vertical scars, history of peritonitis, and large pelvic/abdominal masses</p> <p>Exclusion was not based upon age and BMI</p> <p>50 in the missile trocar group and 50 in the Veress needle group; none lost to follow-up</p>	
Interventions	Direct trocar (missile trocar) vs Veress needle (reusable pyramidal trocar). All operators had learnt the technique on cadavers. No co-intervention. Standardised operative training in both interventions, especially for the study. Standardised operative technique was deployed by all operators. Unable to access information on trocar or Veress needle make or model	
Outcomes	<p>Aim: to assess technical feasibility</p> <p>Stated no carbon dioxide leakage, abdominal wall haematoma, nor serious complications occurred</p>	
Notes	Single-centre study in Bangkok, Thailand	
Risk of bias		
Bias	Authors' judgement	Support for judgement

Tansatit 2006 (Continued)

Random sequence generation (selection bias)	Unclear risk	Method of randomisation unclear "Allocated by simple randomisation"
Allocation concealment (selection bias)	Unclear risk	"Allocated by simple randomisation"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Unclear, as not stated in the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions or dropouts included
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases and means; no data conversion. P values stated for each outcome. No omission of outcomes and no subsets of data
Other bias	Low risk	No other source of bias identified

Tinelli 2009

Methods	Prospective randomised controlled trial
Participants	<p>Included were 186 postmenopausal women undergoing laparoscopic surgery for simple ovarian cysts: 89 were assigned to direct optical access (DOA), and 97 to classic closed Veress needle approach, pneumoperitoneum, and trocar entry</p> <p>Inclusion criteria: existence of a simple unilateral ovarian cyst 4 to 8 cm in diameter, with no evidence of echographic malignancy features; normal CA-125 levels; BMI between 20 and 28 kg/m²; normal speculum examination; no use of hormonal therapy in last year</p> <p>Exclusion criteria: history of open abdominal surgery; large ovarian cysts (≥ 9 cm in diameter); previous periumbilical surgery</p>
Interventions	<p>DOA technique: 10-mm infraumbilical incision was made and the abdominal wall was lifted; an optical bladeless trocar (Endopath Trocars; Ethicon, Johnson & Johnson, Somerville, NJ) with a laparoscope was introduced directly into the abdominal cavity by a constant axial penetrating force applied under direct visual identification of abdominal wall layers, starting from subcutaneous fat tissue to the rectus sheath and the peritoneum; intra-abdominal contents were also examined. This was followed by secondary creation of a pneumoperitoneum</p> <p>Veress needle: VN was guided steadily in an even 45° angle position through the umbilicus; a midsagittal infraumbilical incision was made, with the scalpel angled at 30° to the woman's abdominal wall. The Veress needle perforated the abdominal wall layers to the abdominal cavity, and surgeons performed the injection-aspiration test before insufflation</p>
Outcomes	Time needed for entry into the abdomen, occurrence of vascular and/or bowel injury, blood loss
Notes	January 2004 to October 2008. No financial disclosures/reported conflicts of interest

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random sequence generation method not specified

Laparoscopic entry techniques (Review)

Tinelli 2009 (Continued)

"All participants were randomized to two groups by clinicians"

Allocation concealment (selection bias)	Unclear risk	No reference to allocation concealment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No reference to blinding of outcome assessors or patients
Incomplete outcome data (attrition bias) All outcomes	Low risk	All 186 participants accounted for in results - no losses to follow-up. No reference to intention-to-treat principle
Selective reporting (reporting bias)	Low risk	All outcomes reported as numbers and percentages when appropriate. All significance values attached
Other bias	Low risk	No other source of bias identified

Tinelli 2010

Methods	Randomised controlled trial from January 2004 to October 2008. Study duration 4 years and 9 months Investigation of direct optical access vs Veress needle entry
Participants	Included were 194 participants undergoing laparoscopy for simple, persistent ovarian cysts at multiple gynaecological centres Exclusion criteria: preceding open abdominal surgery, presence of large ovarian cysts (larger than 9 cm in diameter), previous periumbilical surgery, together with those reporting the following ultrasound pattern of malignancy: BMI between 20 and 28 kg/m ² 93 participants in direct optical access group and 101 in Veress needle entry group. No losses to follow-up
Interventions	Standardised operative technique applied. Participants were randomised for direct optical access or Veress needle entry and pneumoperitoneum before operative laparoscopy 10-mm infraumbilical incision was made, and the abdominal wall was lifted upwards to enable the introduction of an optical conical blunt-tipped trocar into the abdomen. Second, an optical bladeless trocar, called "Endopath" Trocars (Ethicon, Johnson & Johnson, Somerville, NJ, USA), with a 08 illuminated laparoscope (Karl Storz, Tuttlingen, Germany) inside, was inserted directly into the abdominal cavity through application of a constant axial penetration force, under direct visual identification of abdominal wall layers, starting from subcutaneous fat tissue to rectus sheath and peritoneum, until final verification of intra-abdominal contents The classical closed method was performed via the Veress needle (by Karl Storz Endoscopy, Germany); this was followed by pneumoperitoneum with insertion of a single-use, conical, blind, blunt-tipped trocar (Ethicon, Johnson & Johnson, Somerville, NJ, USA)
Outcomes	Duration of entry, blood loss, vascular injuries, visceral injuries
Notes	Multi-centre trial at Vito Fazzi Hospital, Lecce, Italy; Santa Maria Hospital, Bari, Italy; Harvard Medical School, Boston, MA, USA; LKH, Villach, Austria; The New European Surgical Academy (NESA), Berlin, Germany; University Hospitals Schleswig-Holstein, Campus Kiel, Germany

Risk of bias
Laparoscopic entry techniques (Review)

Tinelli 2010 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Study provided, at every suitable gynaecological centre, allocation of all suitable consecutive patients with ovarian cysts to either of the 2 procedures, with a randomisation ratio of 1:1
Allocation concealment (selection bias)	Unclear risk	Study provided, at every suitable gynaecological centre, allocation of all suitable consecutive patients with ovarian cysts to either of the 2 procedures, with a randomisation ratio of 1:1
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Unclear - not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcomes reported. No exclusions stated
Selective reporting (reporting bias)	Low risk	All P values stated. No data conversion. No subgroups of data
Other bias	Low risk	No other sources of bias identified

Tinelli 2011

Methods	Randomised controlled trial. Patients presenting from June 2005 to November 2009 were assessed; duration of study 4 years and 6 months
Participants	<p>Included were 168 women eligible for laparoscopic surgery</p> <p>Inclusion criteria: women of reproductive age, utero-ovarian benign disease, previous abdominopelvic surgery by laparoscopy or by laparotomy, with transverse or midline incision</p> <p>Exclusion criteria: patients with a pelvic mass larger than 10 cm</p> <p>86 participants were assigned to the direct optical entry group, and 82 to the open-entry (Hasson technique) group</p>
Interventions	<p>Direct optical entry vs open-entry (Hasson) technique</p> <p>For direct optical entry, a 10-mm infraumbilical incision was made and extended to the fascia, followed by axial penetration of the fascia with an optical bladeless trocar (12-mm diameter; Endopath or Endopath Xcel; Ethicon Endo-Surgery, Cincinnati, OH, USA) with a zero-degree illuminated laparoscope (Karl Storz, Tuttlingen, Germany)</p> <p>For open-entry technique: classic Hasson technique was performed as described in the literature with Hasson's trocar (Ethicon Endo-Surgery, Cincinnati, OH, USA)</p>
Outcomes	Time required for entry into the abdomen, blood loss, occurrence of vascular and/or bowel injury
Notes	<p>Multi-centre study at Vito Fazzi Hospital, Lecce, Italy</p> <p>; Santa Maria Hospital, Bari, Italy</p> <p>; University of Salento, Lecce, Italy</p> <p>; Mount Sinai Hospital of Queens, New York, NY, USA; Department of Gynecology and Obstetrics at Wilhelminenspital der Stadt, Wien, Austria; The New European Surgical Academy (NESA), Berlin, Germany;</p> <p>The USP Hospital, Mallorca, Spain</p> <p>; University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany</p>

Laparoscopic entry techniques (Review)

Tinelli 2011 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The method of randomisation was in parallel assignment, at a randomisation ratio of 1:1"
Allocation concealment (selection bias)	Unclear risk	Allocation concealment techniques not mentioned in the text
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding not mentioned in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions or dropouts reported. No conversion between intervention groups or to laparotomy
Selective reporting (reporting bias)	Low risk	No data conversion. P values not stated for each outcome. No omission of outcomes and no subsets of data.
Other bias	Low risk	No other source of bias identified

Tinelli 2013

Methods	Randomised controlled trial. Participants recruited between January 2006 and December 2010; duration 5 years
Participants	<p>245 patients assessed for eligibility for inclusion; 21 did not meet inclusion criteria, and 224 were randomised</p> <p>Inclusion criteria: women of reproductive age (30 to 40 years old), BMI 30 to 40 kg/m², defined as obesity class I-II, with the presence of benign pelvic mass of uterine and/or ovarian origin</p> <p>Exclusion criteria: primary: postmenopausal age due to differing physiological characteristics, previous abdominal and pelvic surgery(ies) because of scar tissue and postsurgical adhesions; secondary: pelvic mass > 10 cm in diameter on pelvic examination</p> <p>108 participants were randomised to the direct optical entry group, and 116 to the open-entry (Hasson technique) group</p>
Interventions	<p>Direct optical entry vs open-entry (Hasson) technique</p> <p>For direct optical entry, a 10-mm infraumbilical incision was made and extended to the fascia, followed by axial penetration of the fascia with an optical bladeless trocar (12-mm diameter; Endopath or Endopath Xcel; Ethicon Endo-Surgery, Cincinnati, OH, USA) with a zero-degree illuminated laparoscope (Karl Storz, Tuttlingen, Germany)</p> <p>For open-entry technique, umbilical skin was incised and dissected down to the fascia, and the fascia was then incised with a scalpel and bluntly divided, allowing insertion of the Hasson trocar (Ethicon Endo-Surgery, Cincinnati, OH, USA) under direct visualisation aided by elevation of the abdominal wall at points lateral to the original incision</p>
Outcomes	Time required to establish intra-abdominal vision after pneumoperitoneum, blood loss, occurrence of vascular and/or bowel injuries

Tinelli 2013 (Continued)

Notes

Multi-centre study at the Department of Obstetrics and Gynaecology, Vito Fazzi Hospital, Lecce, Italy; Department of Obstetrics and Gynaecology, Santa Maria Hospital, Bari, Italy; Experimental Researches and Modeling Division, Moscow State University of Medicine and Dentistry, Moscow, Russia; Department of Gynecology, Division of Minimal Invasive Endoscopy, The Mount Sinai Hospital of Queens, New York, NY, USA; Hospital Regional de Poza Rica, Sesver, Monterrey, Mexico; Fundacion Hospitalaria, Buenos Aires, Argentina; Department of Gynecology and Obstetrics, University of Perugia, Perugia, Italy; Columbia University College of Physicians and Surgeons, New York, NY, USA; Division of Gynecologic Oncology and Department of Obstetrics and Gynecology, St. Luke's-Roosevelt Hospital Center, New York, NY, USA

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Method of allocation was controlled by a statistician, who assigned participants to surgery using a 1:1 randomisation ratio
Allocation concealment (selection bias)	Low risk	Participants randomised via sealed numbered containers
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding in the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts recorded. Everyone who was randomised was included in the final analysis
Selective reporting (reporting bias)	Low risk	No data conversion. P values stated for all outcomes. Values for all outcomes recorded in the published study
Other bias	Unclear risk	No other source of bias identified

Tsimoyiannis 2009

Methods	Randomised single-blinded trial
Participants	<p>Participants attending for laparoscopic cholecystectomy</p> <p>Exclusion criteria: BMI > 30 kg/m², signs of acute cholecystitis or choledocholithiasis or attacks of acute pancreatitis, ASA grade > 2, lack of written informed consent</p> <p>16 exclusions but no loss to follow-up. 20 participants in each group</p>
Interventions	<p>Standardised operative technique applied. Single-incision laparoscopic surgery (SILS) cholecystectomy vs classic 4-port laparoscopic cholecystectomy. No co-intervention For the classic 4-port approach, an 11-mm umbilical trocar was inserted via the Hasson technique. Another 5-mm trocar was placed into the mid-epigastrium and two 5-mm trocars in the right costal margin at mid-clavicular and mid-axillary lines</p> <p>For SILS cholecystectomy, pneumoperitoneum was induced with a 10-mm atraumatic trocar (VersaStep; Covidien, Norwalk, CT, USA). Second and third trocars of 5 mm (VersaStep; Covidien, Norwalk, CT, USA) were used</p>
Outcomes	Abdominal and shoulder pain, requirement of analgesics, nausea and vomiting

Tsimoyiannis 2009 (Continued)

Notes

Single-centre trial at General Hospital of Ioannina, Greece

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomly assigned to two groups using a closed envelope containing information regarding placement into group A or B"
Allocation concealment (selection bias)	Unclear risk	"Randomly assigned to two groups using a closed envelope containing information regarding placement into group A or B"
Blinding (performance bias and detection bias) All outcomes	Low risk	Single-blinded: "All patients were informed about the intervention technique" "Surgeons were informed about the group of each patient in the operating room. Two other investigators, blinded to the group of each patient, independently recorded postoperative pain score, need for analgesics, and incidences of nausea and vomiting"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up stated. Sixteen participants were excluded after randomisation because of signs of acute cholecystitis (9 participants), clinical and laboratory findings of choledocholithiasis (3 participants; preoperative endoscopic retrograde cholangiopancreatography was performed), attacks of acute pancreatitis (2 participants), and ASA grade 3 classification (2 participants)
Selective reporting (reporting bias)	Low risk	Data were presented in an appropriate manner and were not converted. P values were stated. None of the stated outcomes were omitted
Other bias	Low risk	No other source of bias was identified

Venkatesh 2007

Methods	Randomised controlled trial investigating use of cutting vs dilating disposable trocars in laparoscopic renal surgery
Participants	<p>Patients 18 years old and older undergoing laparoscopic transperitoneal renal procedures were invited to participate in the study</p> <p>Exclusion criteria: no other criteria stated</p> <p>56 participants</p>
Interventions	<p>4 trocar types compared included 2 cutting (single or pyramidal bladed) and 2 dilating (radially or axially dilating) trocar types</p> <p>Reference trocar: standardised lateral 5-mm, non-cutting, metal trocar (Storz EndoTIP, Storz Inc., Tuttlingen, Germany). Cutting trocars included a pyramidal bladed trocar (Ethicon Inc., Cincinnati, OH, USA) and a single-bladed trocar (Ethicon Inc., Cincinnati, OH, USA). Dilating trocars evaluated included an axially dilating trocar (Ethicon Inc., Cincinnati, OH, USA) and a radially dilating STEP system (US Surgical Inc., San Bernardino, CA, USA)</p>
Outcomes	<p>Mean pain scores at 3 hours, 24 hours, and 1 week postoperatively</p> <p>All complications, such as abdominal wall vessel bleeding and intra-abdominal vascular or visceral injuries related to trocar deployment, were documented</p>

Venkatesh 2007 (Continued)

Trocar-related events during the operative procedure, such as gas leakage, trocar dislodgement, problems in handling the reducer mechanism, and failure of trocar seal integrity, were documented

Notes

Multi-centre trial at Washington University School of Medicine, Division of Urology, St. Louis, MO, USA; Indiana University Medical Center, Department of Urology, Indianapolis, IN, USA; University School of Medicine, Medical Statistics, St. Louis, MO, USA; UCI Medical Center, Department of Urology, Irvine, CA, USA; Columbia University Medical Center, Department of Urology, New York, NY, USA

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No exclusions nor losses to follow-up stated
Selective reporting (reporting bias)	Unclear risk	Outcomes reported with number of trocar insertions as opposed to number of participants. Complication outcomes not specifically predefined. No data conversion. Power calculation performed for pain scores
Other bias	Low risk	P values not stated for all outcomes. No other source of bias was identified

Vilallonga 2012

Methods	Randomised controlled trial with 2 arms. Patients enrolled between July 2009 and March 2010; duration 9 months
Participants	Adult patients presenting with gallbladder pathology (all patients had documented gallstones) requiring either elective surgery or urgent surgery in the emergency room 140 patients were enrolled in the study: 69 in the single port access group, 71 in the standard laparoscopy group
Interventions	Single-incision laparoscopic surgery (SILS) cholecystectomy vs standard laparoscopic cholecystectomy For the single-port access group, a 22-mm infraumbilical incision was made, the umbilicus was pulled out and incised longitudinally, and a SILS Port (Covidien, Inc., Norwalk, CT, USA) or TriPort (Advanced Surgical Concepts, Wicklow, Ireland) was introduced into the peritoneal cavity For the standard laparoscopy group, Jason trocars and standard trocars were placed under direct vision
Outcomes	Blood loss, operative time, complications (intraoperative, seroma, hernia), length of stay, pain post procedure, cosmetic satisfaction
Notes	Multi-centre trial; Vall d'Hebron University Hospital (Barcelona, Spain), and Istanbul University, Istanbul Faculty of Medicine (Istanbul, Turkey)

Vilallonga 2012 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Paper states that after surgeons enrolled participants, they randomised them to 2 different groups in an alternative way. The method of randomisation is not explicitly mentioned
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants dropped out, and no participants were lost to follow-up
Selective reporting (reporting bias)	Low risk	All outcomes were published with significance values
Other bias	Low risk	No other source of bias was identified

Villalobos 2014

Methods	Prospective randomised controlled trial from January 2011 to September 2012; duration 1 year and 9 months
Participants	<p>Inclusion criteria: patients presenting with acute appendicitis and onset of symptoms less than 48 hours, 15 to 65 years of age</p> <p>Exclusion criteria: BMI > 30 kg/m², ASA > 1, previous history of abdominal surgery, inability to give informed consent, unavailability of surgeons trained in single-incision laparoscopic surgery (SILS)</p> <p>120 participants were randomised: 60 to the SILS appendectomy group, and 60 to the 3-port laparoscopic appendectomy (3PLA) group</p>
Interventions	<p>SILS appendectomy vs 3PLA</p> <p>For SILS, a 2.5-cm to 3-cm transumbilical incision was followed by insertion of the SILS port (SILS port; Covidien, Norwalk, CT, USA)</p> <p>For CLA, a 1-cm periumbilical incision was made to place the Hasson trocar, and another 5-mm incision and an 11-mm incision were made in the suprapubic region</p>
Outcomes	Surgery duration, start of oral intake, length of hospital stay, amount of postoperative pain, pathological diagnosis on resection, cost of procedure, postsurgery complications (wound infection, intra-abdominal abscess, postsurgery ileus, hernia, other unspecified complication)
Notes	Single-centre trial at the University Hospital Arnau de Vilanova, Lleida, Spain

Risk of bias

Bias	Authors' judgement	Support for judgement
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Laparoscopic entry techniques (Review)

Villalobos 2014 (Continued)

Random sequence generation (selection bias)	Unclear risk	Random selection of outcomes from box containing closed envelopes with different interventions
Allocation concealment (selection bias)	Low risk	Intervention selections stored in closed envelopes
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding in the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts or participants lost to follow-up
Selective reporting (reporting bias)	Low risk	No selective reporting bias identified. All outcomes reported with no data conversion
Other bias	Unclear risk	No other source of bias identified

Vilos 2015

Methods	Prospective patient-blinded randomised controlled trial
Participants	Included 283 women undergoing laparoscopic surgery (type not specified) Exclusion criteria: midline laparotomy, known or suspected abdominal wall adhesions Umbilical group n = 143; LUQ group n = 137
Interventions	For umbilical entry, the assistant used both hands to grasp the skin below the umbilicus and pulled caudally and upwards to maximal displacement. A 1-cm vertical infraumbilical incision was made, and the Veress was inserted at 90° to the umbilicus. The specific technique for LUQ entry was not described in the conference abstract
Outcomes	Number of attempts, conversion to alternate site/entry, minor vessel injury, preperitoneal insufflation
Notes	January to December 2014. No conflicts of interest mentioned. Source of funding not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation method not specified
Allocation concealment (selection bias)	Unclear risk	No reference made to allocation concealment
Blinding (performance bias and detection bias) All outcomes	Low risk	"Patient-blinded randomized control trial"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up nor post-randomisation exclusions. No reference made to intention-to-treat principle.

Laparoscopic entry techniques (Review)

Vilos 2015 (Continued)

Selective reporting (reporting bias)	High risk	All outcomes reported as numbers and percentages when appropriate. Significance values not consistently attached
Other bias	Low risk	No other source of bias identified

Yim 2001

Methods	Randomised controlled trial that was double-blinded between September 1997 and March 1998; study duration 7 months	
Participants	Between September 1997 and March 1998, women scheduled for laparoscopic surgery for adnexal masses at a university teaching hospital were recruited Exclusion criteria: not stated 34 in the radially expanding (STEP) trocar group and 34 in the standard trocar group. No participants lost to follow-up	
Interventions	Radially expanding (STEP) trocars vs standard trocars for secondary port entry. Standardised operative technique applied The STEP device was a 10-mm rapidly expanding access device A size-matched disposable trocar with a linear cutting blade (Endopath; Ethicon Endo-Surgery, Cincinnati, OH, USA) was used for the standard trocar	
Outcomes	Incisional hernia, trocar site bleeding, trocar site infection	
Notes	Single-centre trial at Prince of Wales Hospital, Chinese University of Hong Kong, SAR, Hong Kong	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The allocation of trocars was based on computer-generated random numbers that were put inside consecutively labelled, sealed, opaque envelopes. Numbers were disclosed at surgery"
Allocation concealment (selection bias)	Low risk	"The allocation of trocars was based on computer-generated random numbers that were put inside consecutively labelled, sealed, opaque envelopes. Numbers were disclosed at surgery"
Blinding (performance bias and detection bias) All outcomes	Low risk	Double-blinded: patients and observers "Patients and assessors were masked to trocar assignments"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions or dropouts reported
Selective reporting (reporting bias)	Low risk	Data presented as numbers of cases; no data conversion. No omission of outcomes and no subsets of data. Power calculation performed
Other bias	Low risk	P values not stated for each outcome. No other source of bias identified

Youssef 2015

Methods	Prospective randomised controlled trial
Participants	<p>Included were 80 patients with clinically palpable varicocele who underwent laparoscopic varicoelectomy during the period from June 2010 to June 2012</p> <p>Excluded were patients with recurrent varicoceles and those participating in other trials</p> <p>Indications for surgery were infertility and chronic testicular pain. Varicoceles were diagnosed by clinical scrotal examination and were confirmed by scrotal ultrasound with real-time colour Doppler imaging. When bilateral varicocele was diagnosed, the larger size was reported. Participant age, BMI, ASA score, varicocele side, varicocele grade, and semen parameters were recorded preoperatively</p>
Interventions	<p>SILV: supine low lithotomy position under GA. Transverse 2-cm skin incision through umbilicus; underlying fascia incised vertically with placement of 2 stay sutures at edges. Once the preperitoneal fat was identified, blunt artery forceps were introduced into the peritoneal cavity under direct vision. Next, flexible SILS port (Covidien, Norwalk, CT, USA) folded at the lower edge contralateral to the insufflation system with use of a small artery forceps was advanced under direct vision into the abdomen. Once the bottom half of the port was inside the abdomen, the port was released from artery forceps. After the 3 cannulae (one 10-mm and two 5-mm) provided with the SILS port were introduced through access channels of the SILS port, a pneumoperitoneum was created and maintained at 15 mmHg</p> <p>CTLV: conventional transperitoneal varicoelectomy. Participants were placed in a supine low lithotomy position under GA, and Veress needle was introduced through the umbilicus with CO₂ gas inflation until intraperitoneal pressure 15 mmHg reached</p>
Outcomes	<p>Primary: improvement in semen parameters, resolution of testicular pain</p> <p>Secondary: operating time, postoperative pain scores, time to return to normal activity, patient satisfaction and postoperative complications (persistence, recurrence, hydrocoele, wound infection, epididymitis, surgical emphysema, scrotal oedema, port site hernia)</p>
Notes	June 2010 to June 2012. No conflicts of interest declared. Source of funding not mentioned

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No method given for generating random sequence
Allocation concealment (selection bias)	Unclear risk	<p>"Randomization was simple and achieved using sealed envelopes"</p> <p>No information as to whether envelopes were serially numbered or sealed shut</p>
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No reference made to blinding in the text
Incomplete outcome data (attrition bias) All outcomes	Low risk	13 lost to follow-up: 6 in SILV and 7 in CTLV; reasons given in all cases. No reference made to intention-to-treat principle
Selective reporting (reporting bias)	High risk	Absolute significance values sometimes not quoted (i.e. P value given as "NS" or "< 0.01")
Other bias	Low risk	No other source of bias identified

Zakerah 2010

Methods	Randomised controlled trial investigated the use of direct trocar and Veress needle entry. Duration of study unclear
Participants	One thousand patients scheduled to undergo diagnostic laparoscopy were recruited for the study Exclusion criteria: none stated but demographics examined 500 participants in direct trocar group and 500 participants in Veress needle group. No losses to follow-up stated
Interventions	Standardised operative technique stated "The technique of DT entry started with an infraumbilical skin incision wide enough to accommodate the diameter of a sharp trocar/canal system. The anterior abdominal wall was adequately elevated by hand, and the trocar was inserted directly into the abdominal cavity, aiming towards the pelvic hollow. After removal of the sharp trocar, the laparoscope was inserted to confirm the presence of omentum or bowel in the visual field, then pneumoperitoneum was started" No further information was provided on the make or model of Veress needle or direct trocar
Outcomes	Length of procedure, gas usage, failed entry, minor intraoperative complications
Notes	Single-centre trial at Department of Obstetrics and Gynecology, Women's Health Centre, Assiut University, Assiut, Egypt

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to either direct trocar (group A, n = 500 patients) or Veress needle (group B, n = 500 patients) entry for pneumoperitoneum by a computer-generated randomisation table
Allocation concealment (selection bias)	Low risk	Participants were randomly assigned to either direct trocar (group A, n = 500 patients) or Veress needle (group B, n = 500 patients) entry for pneumoperitoneum by a computer-generated randomisation table
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	No exclusions or dropouts stated. No losses to follow-up stated
Selective reporting (reporting bias)	Unclear risk	All outcomes reported, but different statistical analysis used for outcomes
Other bias	Low risk	P values not stated for demographics. No power calculation performed. No other source of bias identified

Zaman 2015

Methods	Prospective randomised double-blind controlled trial
Participants	Included were 200 patients aged 18 to 70, with uncomplicated cholelithiasis

Laparoscopic entry techniques (Review)

Zaman 2015 (Continued)

Exclusion criteria: pregnancy, history of laparotomy, umbilical hernia, granuloma or abscess, severe systemic illness

170 underwent lap cholecystectomy, 20 lap hernia repair, and 10 lap appendectomy. All participants for each type of operation were divided into 2 equal groups: group A for whom pneumoperitoneum was created by closed technique, and group B for whom it was created by open technique (total 100 in each group). Data on differences in patient demographics between the 2 groups were not reported

Interventions	Group A (closed): blind insertion of Veress needle and bladed trocar via umbilicus Group B (open): small umbilical incision under direct visualisation to enter abdominal cavity followed by introduction of a blunt trocar
Outcomes	Mean time required for successful pneumoperitoneum, total operating time, time needed to close the wound, failure of technique, air leakage, damage to visceral vessels or bladder, port site infection, port site hernia
Notes	Department of General and Minimal Access Surgery, MMIMSR Medical College, Ambala Hararyana

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described in the abstract as "prospective randomized double blind study" No reference to randomisation made in the main body of text. No method of random sequence generation provided
Allocation concealment (selection bias)	Unclear risk	Not clear whether participants consented before or after allocation. No attempt made to describe allocation concealment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Study described in the abstract as "prospective randomized double blind study" No mention of blinding in the main body of the paper
Incomplete outcome data (attrition bias) All outcomes	Low risk	No reported post-randomisation exclusions or losses to follow-up. No reference made to intention-to-treat principle
Selective reporting (reporting bias)	High risk	Individual significance values not given for different complications. Overall significance for complication rates between 2 groups given as $P < 0.05$
Other bias	Low risk	No other source of bias identified

3PLA: 3-port conventional laparoscopic appendectomy.
3PLC: 3-port conventional laparoscopic cholecystectomy.
4PLC: four-port laparoscopic cholecystectomy.
ASA: American Society of Anaesthesiologists.
BMI: body mass index.
CA: cancer antigen.
CBD: common bile duct.
CTLV: conventional transperitoneal varicolectomy.
DOA: direct optical access.
DT: direct trocar.
DTI: direct trocar insertion.
ERCP: endoscopic retrograde cholangiopancreatography.
GA: general anaesthetic.
IAP: intra-abdominal pressure.

Laparoscopic entry techniques (Review)

KPS: Karnofsky Performance Status.
LUQ: left upper quadrant.
NS: not significant.
POD: postoperative day.
RCT: randomised controlled trial.
REA: radially expanding access.
SI: single-incision.
SILC: single-incision laparoscopic cholecystectomy.
SILS: single-incision laparoscopic surgery.
SILV: single incision laparoscopic varicocelelectomy.
STEP: radially expanding trocar.
TLC: traditional laparoscopic cholecystectomy.
TPLC: three-port laparoscopic cholecystectomy.
VAS: visual analogue scale.
VNI: Veress needle insertion.

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

Study	Reason for exclusion
Alekbierzade 2015	Study compared SILS vs multi-port technique but failed to report initial trocar entry method
Artis 2014	Study compared SILS vs multi-port technique but failed to report initial trocar entry method
Cardin 2011	Study compared 2 laparoscopic entry techniques but was not an RCT
Chakravartty 2014	Study compared SILS vs multi-port technique but failed to report initial trocar entry method
Dabbagh 2015	Study compared SILS vs multi-port technique but failed to report initial trocar entry method
Dunne 2011	Study compared 2 laparoscopic entry techniques but was not an RCT
Fagotti 2010	Study compared 2 laparoscopic entry techniques but was not an RCT
Garg 2012	Study compared 2 laparoscopic entry techniques but was not an RCT
Han 2012	Study compared effects of different methods of creating the peritoneal operating field (lifting abdomen, pneumoperitoneum) on stress response as opposed to different entry techniques
Joshi 2009	Study evaluated maintenance of the pneumoperitoneum as opposed to port entry technique
Kim 2009	Study evaluated differences between operative technique as opposed to port entry
Lu 2012	Study compared 2 laparoscopic entry techniques but was not an RCT
Rizwi 2014	Study compared SILS vs multi-port technique but failed to report initial trocar entry method
Sandhu 2009	Study evaluated maintenance of the pneumoperitoneum as opposed to port entry technique
Sangrasi 2011	Studies compared Veress needle entry vs open-entry (Hasson) but was not an RCT
Shayani-Nasab 2013	Study compared 2 laparoscopic entry techniques but was not an RCT
Singh 2014	Study compared SILS vs multi-port technique but failed to report initial trocar entry method
Taye 2016	Study compared 2 laparoscopic entry techniques but was not an RCT

Study	Reason for exclusion
Warle 2013	Study compared different pneumoperitoneum pressures to optimise live donor comfort as opposed to port entry technique
Watanabe 2016	Study compared SILS vs multi-port technique but failed to report initial trocar entry method
Zhao 2015	Study compared 2 laparoscopic entry techniques but was not an RCT

RCT: randomised controlled trial.

SILS: single-incision laparoscopic surgery.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Köstü 2016a

Methods	Randomised controlled trial
Participants	67 patients undergoing gynaecological laparoscopic surgery: 33 in the skin elevation group, 34 in the fascial elevation group
Interventions	In the skin elevation group, the skin was held and elevated by a towel clip on each para-incisional area before Veress needle insertion. In the fascial elevation group, the dissection was made as far as the rectus muscle fascia, which was then held and elevated with Kocher forceps before Veress needle insertion
Outcomes	Mean number of attempts to enter the peritoneal cavity and time taken to access peritoneal cavity
Notes	Abstract only: study compared laparoscopic entry techniques but did not report our outcome measures

Prabakar 2015

Methods	Prospective randomised cross-over study
Participants	27 patients aged 24 to 75 years undergoing gynaecological surgery with conventional or robotic laparoscopy in an academic hospital setting
Interventions	Trocars were placed in the patient's right and left lower quadrants by the same resident using either the "look" or the "feel" method. With the "look" method, the surgeon looked at the video monitor throughout trocar placement. With the "feel" method, the surgeon looked directly at the patient until the fascia was entered, after which the surgeon looked at the monitor for the rest of the placement. Method and site of placement were randomised for each participant (i.e. participants acted as their own controls)
Outcomes	Primary outcome measure: length of the trocar beneath the peritoneum
Notes	Abstract only: study compared laparoscopic entry techniques but did not report our outcome measures

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

NCT00731107

Trial name or title	XCEL Bladeless Trocar Versus Veress Needle: A Randomised Controlled Trial Comparing These Two Entry Techniques in Gynaecological Laparoscopic Surgery
Methods	Single-blinded (participant) randomised controlled trial
Participants	200 women undergoing laparoscopic gynaecological surgery
Interventions	Veress Needle entry vs XCEL bladeless trocar insertion
Outcomes	Time taken to enter the abdomen Number of attempts taken to enter the abdomen Impact of the time taken to enter vs the whole operating time Happiness that the surgeon has entered the abdomen before adding gas, on a scale of 1 to 5
Starting date	September 2008
Contact information	trmanley@hotmail.com
Notes	

NCT02804529

Trial name or title	A Comparison of Three Different Entry Points to Establish the Pneumoperitoneum
Methods	Open-label tripartite randomised controlled trial
Participants	90 patients aged 18 to 80 undergoing gastrointestinal surgery. Patients with previous abdominal surgery will be excluded
Interventions	Periumbilical vs Palmer's point vs Meng's point for insertion of the Veress needle
Outcomes	Complications during entry in laparoscopy Time to enter the abdominal cavity
Starting date	July 2016
Contact information	mengfq75@163.com
Notes	

NCT03306238

Trial name or title	LAParoscopic Entry Technique in RENal Surgery (LAPRES)
Methods	Triple-blinded (participant, investigator, outcomes assessor) randomised controlled trial
Participants	300 participants undergoing laparoscopic renal surgery Exclusions: BMI > 40 kg/m ² , previous laparotomy
Interventions	Hasson (open) technique vs Veress needle (closed) technique
Outcomes	Complications

Laparoscopic entry techniques (Review)

NCT03306238 (Continued)

Time to insertion

Starting date	1 November 2017
Contact information	arun.z.thomas@gmail.com
Notes	

BMI: body mass index.

DATA AND ANALYSES

Comparison 1. Open-entry technique vs closed-entry technique (primary port entry)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality	1	120	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.1 Open entry vs Veress needle entry	1	120	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Vascular injury (major vessels and abdominal wall vessels)	5	915	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 6.82]
2.1 Open entry vs direct trocar entry	1	294	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Open entry vs Veress needle entry	4	621	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 6.82]
3 Visceral injury (bladder or bowel)	5	915	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.61 [0.06, 6.08]
3.1 Open entry vs direct trocar entry	1	294	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 Open entry vs Veress needle entry	4	621	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.61 [0.06, 6.08]
4 Failed entry	4	865	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.45 [0.14, 1.42]
4.1 Open entry vs direct trocar entry	1	294	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.21 [0.00, 12.20]
4.2 Open entry vs Veress needle entry	3	571	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.48 [0.14, 1.60]
5 Extraperitoneal insufflation	6	985	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.26 [0.07, 0.94]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Open entry vs direct trocar entry	1	294	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.2 Open entry vs Veress needle entry	5	691	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.26 [0.07, 0.94]
6 Trocar site bleeding	4	865	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.61 [0.13, 2.83]
6.1 Open entry vs direct trocar entry	1	294	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.21 [0.01, 3.70]
6.2 Open entry vs Veress needle entry	3	571	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.94 [0.15, 5.67]
7 Trocar site infection	7	1185	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.51 [0.69, 3.35]
7.1 Open entry vs direct trocar entry	1	294	Peto Odds Ratio (Peto, Fixed, 95% CI)	15.90 [1.50, 168.43]
7.2 Open entry vs Veress needle entry	6	891	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.12 [0.48, 2.61]
8 Incisional hernia	2	320	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.39 [0.15, 372.38]
8.1 Open entry vs Veress needle entry	2	320	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.39 [0.15, 372.38]
9 Omental injury	3	665	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.20 [0.05, 0.71]
9.1 Open entry vs direct trocar entry	1	294	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.21 [0.02, 2.17]
9.2 Open entry vs Veress needle entry	2	371	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.19 [0.04, 0.90]

Analysis 1.1. Comparison 1 Open-entry technique vs closed-entry technique (primary port entry), Outcome 1 Mortality.

Study or subgroup	Open n/N	Closed n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.1.1 Open entry vs Veress needle entry					
Channa 2009	0/60	0/60			Not estimable
Subtotal (95% CI)	60	60			Not estimable
Total events: 0 (Open), 0 (Closed)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
<div> <div></div> <div>Favours open0.010.1110100Favours closed</div> </div>					

Study or subgroup	Open n/N	Closed n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Total (95% CI)	60	60			Not estimable
Total events: 0 (Open), 0 (Closed)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable

Analysis 1.2. Comparison 1 Open-entry technique vs closed-entry technique (primary port entry), Outcome 2 Vascular injury (major vessels and abdominal wall vessels).

Study or subgroup	Open n/N	Closed n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.2.1 Open entry vs direct trocar entry					
Angioli 1 2013	0/107	0/187			Not estimable
Subtotal (95% CI)	107	187			Not estimable
Total events: 0 (Open), 0 (Closed)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
1.2.2 Open entry vs Veress needle entry					
Angioli 2 2013	0/108	0/193			Not estimable
Channa 2009	0/60	0/60			Not estimable
Cogliandolo 1998	0/75	1/75		100%	0.14[0.6.82]
Peitgen 1997	0/26	0/24			Not estimable
Subtotal (95% CI)	269	352		100%	0.14[0.6.82]
Total events: 0 (Open), 1 (Closed)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1(P=0.32)					
Total (95% CI)	376	539		100%	0.14[0.6.82]
Total events: 0 (Open), 1 (Closed)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1(P=0.32)					
Test for subgroup differences: Not applicable

Analysis 1.3. Comparison 1 Open-entry technique vs closed-entry technique (primary port entry), Outcome 3 Visceral injury (bladder or bowel).

Study or subgroup	Open n/N	Closed n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.3.1 Open entry vs direct trocar entry					
Angioli 1 2013	0/107	0/187			Not estimable
Subtotal (95% CI)	107	187			Not estimable
Total events: 0 (Open), 0 (Closed)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable

Analysis 1.4. Comparison 1 Open-entry technique vs closed-entry technique (primary port entry), Outcome 4 Failed entry.

Analysis 1.5. Comparison 1 Open-entry technique vs closed-entry technique (primary port entry), Outcome 5 Extraperitoneal insufflation.

Analysis 1.6. Comparison 1 Open-entry technique vs closed-entry technique (primary port entry), Outcome 6 Trocar site bleeding.

Analysis 1.7. Comparison 1 Open-entry technique vs closed-entry technique (primary port entry), Outcome 7 Trocar site infection.

Analysis 1.8. Comparison 1 Open-entry technique vs closed-entry technique (primary port entry), Outcome 8 Incisional hernia.

Analysis 1.9. Comparison 1 Open-entry technique vs closed-entry technique (primary port entry), Outcome 9 Omental injury.

Comparison 2. Direct trocar entry vs Veress needle entry (primary port entry)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vascular injury (major vessels and abdominal wall vessels)	6	1603	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.59 [0.18, 1.96]
2 Visceral injury (bladder or bowel)	5	1519	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.02 [0.21, 19.42]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Solid organ injury	3	1079	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.58 [0.06, 5.65]
4 Failed entry	8	3185	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.24 [0.17, 0.34]
5 Extraperitoneal insufflation	9	3564	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.19 [0.14, 0.26]
6 Trocar site infection	4	736	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.52 [0.16, 1.62]
7 Omental injury	4	1673	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.34 [0.19, 0.60]

Analysis 2.1. Comparison 2 Direct trocar entry vs Veress needle entry (primary port entry), Outcome 1 Vascular injury (major vessels and abdominal wall vessels).

Analysis 2.2. Comparison 2 Direct trocar entry vs Veress needle entry (primary port entry), Outcome 2 Visceral injury (bladder or bowel).

Study or subgroup	Direct trocar n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Test for overall effect: $Z=0.61(P=0.54)$					
<div> <div></div> <div>Favours direct trocar</div> <div>0.001</div> <div>0.1</div> <div>1</div> <div>10</div> <div>1000</div> <div>Favours Veress needle</div> </div>					

Analysis 2.3. Comparison 2 Direct trocar entry vs Veress needle entry (primary port entry), Outcome 3 Solid organ injury.

Study or subgroup	Direct trocar n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Agresta 2004	0/275	2/323		66.52%	0.16[0.01,2.53]
Ertugrul 2015	1/39	0/42		33.48%	7.98[0.16,403.24]
Karaca 2014	0/200	0/200			Not estimable
Total (95% CI)	514	565		100%	0.58[0.06,5.65]
Total events: 1 (Direct trocar), 2 (Veress needle)					
Heterogeneity: $\tau^2=0$; $\chi^2=2.57$, $df=1(P=0.11)$; $I^2=61.04\%$					
Test for overall effect: $Z=0.46(P=0.64)$					
<div> <div></div> <div>Favours direct trocar</div> <div>0.01</div> <div>0.1</div> <div>1</div> <div>10</div> <div>100</div> <div>Favours Veress needle</div> </div>					

Analysis 2.4. Comparison 2 Direct trocar entry vs Veress needle entry (primary port entry), Outcome 4 Failed entry.

Study or subgroup	Direct trocar n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Agresta 2004	0/275	4/323		3.4%	0.16[0.02,1.12]
Angioli 3 2013	1/187	4/193		4.26%	0.31[0.05,1.79]
Borgatta 1990	0/102	2/110		1.71%	0.14[0.01,2.33]
Byron 1993	2/111	4/141		4.99%	0.64[0.13,3.27]
Ertugrul 2015	5/39	2/42		5.56%	2.74[0.59,12.8]
Gunenc 2005	2/301	13/277		12.57%	0.2[0.07,0.57]
Prieto-Díaz-Chávez 2006	0/42	5/42		4.1%	0.12[0.02,0.74]
Zakerah 2010	10/500	70/500		63.41%	0.2[0.12,0.31]
Total (95% CI)	1557	1628		100%	0.24[0.17,0.34]
Total events: 20 (Direct trocar), 104 (Veress needle)					
Heterogeneity: $\tau^2=0$; $\chi^2=12.77$, $df=7(P=0.08)$; $I^2=45.16\%$					
Test for overall effect: $Z=7.72(P<0.0001)$					
<div> <div></div> <div>Favours direct trocar</div> <div>0.001</div> <div>0.1</div> <div>1</div> <div>10</div> <div>1000</div> <div>Favours Veress needle</div> </div>					

Analysis 2.5. Comparison 2 Direct trocar entry vs Veress needle entry (primary port entry), Outcome 5 Extraperitoneal insufflation.

Study or subgroup	Direct trocar n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Agresta 2004	0/275	19/323		12.56%	0.15[0.06,0.37]
Angioli 3 2013	0/187	6/193		4.06%	0.14[0.03,0.68]
<div> <div></div> <div>Favours direct trocar</div> <div>0.01</div> <div>0.1</div> <div>1</div> <div>10</div> <div>100</div> <div>Favours Veress needle</div> </div>

Analysis 2.6. Comparison 2 Direct trocar entry vs Veress needle entry (primary port entry), Outcome 6 Trocar site infection.

Analysis 2.7. Comparison 2 Direct trocar entry vs Veress needle entry (primary port entry), Outcome 7 Omental injury.

Comparison 3. Direct vision entry vs Veress needle entry (primary port entry)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vascular injury (major vessels and abdominal wall vessels)	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
2 Visceral injury (bladder or bowel)	2		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
3 Trocar site bleeding	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only

Analysis 3.1. Comparison 3 Direct vision entry vs Veress needle entry (primary port entry), Outcome 1 Vascular injury (major vessels and abdominal wall vessels).

Study or subgroup	Direct vision n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Tinelli 2009	1/89	3/97		0%	0.39[0.05,2.85]
Favours direct vision					Favours VNI

Analysis 3.2. Comparison 3 Direct vision entry vs Veress needle entry (primary port entry), Outcome 2 Visceral injury (bladder or bowel).

Study or subgroup	Direct vision n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Tinelli 2009	0/89	0/97			Not estimable
Tinelli 2010	0/93	2/101		0%	0.15[0.01,2.34]
Favours direct vision					Favours Veress needle

Analysis 3.3. Comparison 3 Direct vision entry vs Veress needle entry (primary port entry), Outcome 3 Trocar site bleeding.

Study or subgroup	Direct vision n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Tinelli 2010	2/93	4/101		0%	0.55[0.11,2.78]
Favours direct vision					Favours Veress needle

Comparison 4. Direct vision entry vs open-entry technique (primary port entry)

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

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Solid organ injury	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
3 Failed entry	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
4 Trocar site bleeding	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only

Analysis 4.1. Comparison 4 Direct vision entry vs open-entry technique (primary port entry), Outcome 1 Visceral injury (bladder or bowel).

Analysis 4.2. Comparison 4 Direct vision entry vs open-entry technique (primary port entry), Outcome 2 Solid organ injury.

Analysis 4.3. Comparison 4 Direct vision entry vs open-entry technique (primary port entry), Outcome 3 Failed entry.

Analysis 4.4. Comparison 4 Direct vision entry vs open-entry technique (primary port entry), Outcome 4 Trocar site bleeding.

Comparison 5. Radially expanding (STEP) trocars vs standard (non-expanding) trocars (primary port entry)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vascular injury (major vessels and abdominal wall vessels)	2	331	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.24 [0.05, 1.21]
2 Visceral injury (bladder or bowel)	2	331	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.13 [0.00, 6.37]
3 Solid organ injury	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
4 Trocar site bleeding	3	421	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.31 [0.15, 0.62]

Analysis 5.1. Comparison 5 Radially expanding (STEP) trocars vs standard (non-expanding) trocars (primary port entry), Outcome 1 Vascular injury (major vessels and abdominal wall vessels). **Analysis 5.2. Comparison 5 Radially expanding (STEP) trocars vs standard (non-expanding) trocars (primary port entry), Outcome 2 Visceral injury (bladder or bowel).**

Analysis 5.3. Comparison 5 Radially expanding (STEP) trocars vs standard (non-expanding) trocars (primary port entry), Outcome 3 Solid organ injury.

Analysis 5.4. Comparison 5 Radially expanding (STEP) trocars vs standard (non-expanding) trocars (primary port entry), Outcome 4 Trocar site bleeding.

Comparison 6. Comparisons of sites of entry

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Transfundal vs infraumbilical insertion of the Veress needle	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
1.1 Failed entry	1	100	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.00, 6.82]
1.2 Uterine bleeding	1	100	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.70 [0.78, 75.76]
2 Left upper quadrant vs caudally displaced umbilical insertion of the Veress needle	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
2.1 Vascular injury (major vessels and abdominal wall vessels)	1	280	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.04 [0.06, 16.78]
2.2 Extraperitoneal insufflation	1	280	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.83 [0.22, 3.13]

Analysis 6.1. Comparison 6 Comparisons of sites of entry, Outcome 1 Transfundal vs infraumbilical insertion of the Veress needle.

Analysis 6.2. Comparison 6 Comparisons of sites of entry, Outcome 2 Left upper quadrant vs caudally displaced umbilical insertion of the Veress needle.

Comparison 7. SILS vs Veress needle entry

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality	1	130	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Visceral injury (bladder or bowel)	1	200	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Trocar site bleeding	2	330	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.97 [0.39, 9.89]
4 Trocar site infection	6	1121	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.10 [0.45, 2.70]
5 Incisional hernia	4	862	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 7.1. Comparison 7 SILS vs Veress needle entry, Outcome 1 Mortality.

Study or subgroup	SILS n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Porta 2017	0/65	0/65			Not estimable
Total (95% CI)	65	65			Not estimable
Total events: 0 (SILS), 0 (Veress needle)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable

Analysis 7.2. Comparison 7 SILS vs Veress needle entry, Outcome 2 Visceral injury (bladder or bowel).

Study or subgroup	SILS n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
He 1 2015	0/100	0/100			Not estimable
Total (95% CI)	100	100			Not estimable
Total events: 0 (SILS), 0 (Veress needle)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable

Analysis 7.3. Comparison 7 SILS vs Veress needle entry, Outcome 3 Trocar site bleeding.

Study or subgroup	SILS n/N	Veress needle n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
He 1 2015	4/100	1/100		83.05%	3.4 [0.58, 20]
Porta 2017	0/65	1/65		16.95%	0.14 [0.6, 82]
Total (95% CI)	165	165		100%	1.97 [0.39, 9.89]
Total events: 4 (SILS), 2 (Veress needle)					
Heterogeneity: Tau ² =0; Chi ² =2.16, df=1 (P=0.14); I ² =53.68%					
Test for overall effect: Z=0.82 (P=0.41)

Analysis 7.4. Comparison 7 SILS vs Veress needle entry, Outcome 4 Trocar site infection.

Analysis 7.5. Comparison 7 SILS vs Veress needle entry, Outcome 5 Incisional hernia.

Comparison 8. SILS vs Hasson entry technique

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality	1	50	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Vascular injury (major vessels and abdominal wall vessels)	1	51	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Failed entry (inability to access the peritoneal cavity)	5	488	Peto Odds Ratio (Peto, Fixed, 95% CI)	6.56 [0.67, 63.96]
4 Trocar site infection	5	387	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.67 [0.19, 2.35]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Incisional hernia	1	101	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.25 [0.14, 365.22]

Analysis 8.1. Comparison 8 SILS vs Hasson entry technique, Outcome 1 Mortality.

Study or subgroup	SILS n/N	Hasson entry technique n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Fonollosa 2012	0/26	0/24			Not estimable
Total (95% CI)	26	24			Not estimable
Total events: 0 (SILS), 0 (Hasson entry technique)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable

Analysis 8.2. Comparison 8 SILS vs Hasson entry technique, Outcome 2 Vascular injury (major vessels and abdominal wall vessels).

Study or subgroup	SILS n/N	Hasson entry technique n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Lai 2011	0/24	0/27			Not estimable
Total (95% CI)	24	27			Not estimable
Total events: 0 (SILS), 0 (Hasson entry technique)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable

Analysis 8.3. Comparison 8 SILS vs Hasson entry technique, Outcome 3 Failed entry (inability to access the peritoneal cavity).

Study or subgroup	SILS n/N	Hasson entry technique n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Fonollosa 2012	1/26	0/24		33.7%	6.84[0.14,345.9]
Lai 2011	0/24	0/27			Not estimable
Perez 2013	0/25	0/25			Not estimable
Phillips 2012	1/117	0/80		32.56%	5.39[0.1,291.4]
Vilallonga 2012	1/69	0/71		33.74%	7.61[0.15,383.49]
Total (95% CI)	261	227		100%	6.56[0.67,63.96]
Total events: 3 (SILS), 0 (Hasson entry technique)

Analysis 8.4. Comparison 8 SILS vs Hasson entry technique, Outcome 4 Trocar site infection.

Analysis 8.5. Comparison 8 SILS vs Hasson entry technique, Outcome 5 Incisional hernia.

Comparison 9. Comparisons of other laparoscopic entry techniques for primary or secondary port insertion

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Lifting vs not lifting the abdominal wall before Veress needle insertion	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
1.1 Visceral injury (bladder or bowel)	1	150	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.2 Failed entry	1	150	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.44 [2.16, 9.13]
1.3 Extraperitoneal insufflation	1	150	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.43 [0.98, 20.10]
2 Carbon dioxide gas insufflation vs gasless abdominal wall retractor	2		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
2.1 Vascular injury	2	186	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.23 [0.45, 115.64]
2.2 Extraperitoneal insufflation	1	83	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.58 [0.77, 74.97]
2.3 Trocar site bleeding	1	103	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.13 [0.00, 6.69]
2.4 Trocar site infection	1	83	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.98 [0.06, 15.87]
3 Closed technique vs a parallel technique of Veress needle insertion	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
3.1 Vascular injury	1	100	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 Visceral injury (bladder or bowel)	1	100	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.3 Extraperitoneal insufflation	1	100	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Cutting trocar vs blunt trocar	3		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
4.1 Mortality	1	91	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.2 Visceral injury (bladder or bowel)	1	165	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.67 [0.15, 386.69]
4.3 Trocar site bleeding	2	195	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.33 [0.09, 1.23]
4.4 Trocar site infection	1	165	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.67 [0.15, 386.69]
5 5-mm vs 3-mm secondary port trocars	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
5.1 Trocar site bleeding	1	102	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.01, 2.24]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6 Radially expanding (STEP) trocars vs standard (non-expanding) trocars (secondary port entry)	2		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
6.1 Trocar site bleeding	1	68	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.13 [0.01, 2.14]
6.2 Trocar site infection	1	61	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.01, 2.21]
7 X-cone vs Veress needle entry	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
7.1 Visceral injury (bladder or bowel)	1	200	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.2 Trocar site bleeding	1	200	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.76 [0.38, 19.89]
7.3 Trocar site infection	1	200	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.36 [0.05, 2.61]
8 X-cone vs SILS	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
8.1 Visceral injury (bladder or bowel)	1	200	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.2 Trocar site bleeding	1	200	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.74 [0.17, 3.35]
8.3 Trocar site infection	1	200	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.0 [0.06, 16.10]
9 IAP 25 mmHg vs IAP 15 mmHg	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
9.1 Extraperitoneal insufflation	1	43	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.12 [0.21, 21.52]
9.2 Trocar site bleeding	1	43	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.75 [0.15, 390.96]
9.3 Omentum injury	1	43	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 IAP 25 mmHg vs IAP 25 mmHg with external compression	1	129	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.97 [0.50, 7.72]
10.1 Extraperitoneal insufflation	1	43	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.02 [0.37, 11.13]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.2 Trocar site bleeding	1	43	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.13 [0.00, 6.51]
10.3 Omentum injury	1	43	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.41 [0.45, 122.53]
11 IAP 15 mmHg vs IAP 25 mmHg with external compression	1	132	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.67 [1.00, 21.76]
11.1 Extraperitoneal insufflation	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.75 [0.60, 23.66]
11.2 Trocar site bleeding	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.3 Omentum injury	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	7.75 [0.47, 128.03]

Analysis 9.1. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 1 Lifting vs not lifting the abdominal wall before Veress needle insertion.

Analysis 9.2. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 2 Carbon dioxide gas insufflation vs gasless abdominal wall retractor.

Analysis 9.3. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 3 Closed technique vs a parallel technique of Veress needle insertion.

Analysis 9.4. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 4 Cutting trocar vs blunt trocar.

Analysis 9.5. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 5 5-mm vs 3-mm secondary port trocars.

Analysis 9.6. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 6 Radially expanding (STEP) trocars vs standard (non-expanding) trocars (secondary port entry).

Analysis 9.7. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 7 X-cone vs Veress needle entry.

Analysis 9.8. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 8 X-cone vs SILS.

Analysis 9.9. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 9 IAP 25 mmHg vs IAP 15 mmHg.

Analysis 9.10. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 10 IAP 25 mmHg vs IAP 25 mmHg with external compression.

Analysis 9.11. Comparison 9 Comparisons of other laparoscopic entry techniques for primary or secondary port insertion, Outcome 11 IAP 15 mmHg vs IAP 25 mmHg with external compression.

APPENDICES

Appendix 1. Cochrane Gynaecology and Fertility Group (CGFG) specialised register search strategy

Searched 25 January 2018

PROCITE platform

Keywords CONTAINS "laparoscopic" or "laparoscopic techniques" or "laparoscopy" or "laparoscopic procedure" or "laparoscopic surgical treatment" or Title CONTAINS "laparoscopic" or "laparoscopic techniques" or "laparoscopy" or "laparoscopic procedure" or "laparoscopic surgical treatment"

AND

Keywords CONTAINS "entry site" or "trocar" or "trocar - dilating-tip" or "trocar - non-shielded-bladed" or "trocar ports" or "Veress needle" or "pneumoperitoneum" or "direct trocar insertion" or "gas" or "gasless" or "carbon dioxide" or "single port" or "port" or "inguinal" or "umbilical port" or Title CONTAINS "entry site" or "trocar" or "trocar - dilating-tip" or "trocar - non-shielded-bladed" or "trocar ports" or "Veress needle" or "pneumoperitoneum" or "direct trocar insertion" or "gas" or "gasless" or "carbon dioxide" or "single port" or "port" or "inguinal" or "umbilical port" (130 hits)

Appendix 2. CENTRAL Register of Studies Online (CRSO) search strategy

Searched 25 January 2018

Web platform

#1 MESH DESCRIPTOR Hand-Assisted Laparoscopy EXPLODE ALL TREES 8

#2 MESH DESCRIPTOR Laparoscopy EXPLODE ALL TREES 4778

#3 laparoscop*:TI,AB,KY 11622

#4 (pelvi* adj2 endoscop*):TI,AB,KY 6

#5 peritoneoscop*:TI,AB,KY 17

#6 videolaparoscop*:TI,AB,KY 22

#7 laparoendoscop*:TI,AB,KY 120

#8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 11644

#9 (entry technique*):TI,AB,KY 20

#10 (Veress or veress-needle*):TI,AB,KY 47

#11 trocar*:TI,AB,KY 502

#12 (open entr*):TI,AB,KY 1

#13 (closed entr*):TI,AB,KY 4

#14 pneumoperiton*:TI,AB,KY 788

#15 MESH DESCRIPTOR Pneumoperitoneum, Artificial EXPLODE ALL TREES 267

#16 MESH DESCRIPTOR Supine Position EXPLODE ALL TREES 583

#17 (supine position*):TI,AB,KY 2227

#18 lithotomy:TI,AB,KY 147

#19 (patient* adj2 position*):TI,AB,KY 1143

#20 (French position*):TI,AB,KY 0

#21 (American position*):TI,AB,KY 0

#22 (side adj2 position*):TI,AB,KY 106

#23 (side adj2 approach*):TI,AB,KY 33

#24 gas:TI,AB,KY 11193

#25 (disposable instrument*):TI,AB,KY 19

#26 (reusable instrument*):TI,AB,KY 14

#27 trendelenburg:TI,AB,KY 267

#28 (radially expanding):TI,AB,KY 9

#29 (direct vision):TI,AB,KY 181

#30 (trans fundal or transfundal):TI,AB,KY 2

#31 (carbon dioxide):TI,AB,KY 5881

#32 gasless:TI,AB,KY 58

#33 infraumbilical:TI,AB,KY 62

#34 (infra umbilical):TI,AB,KY 24

#35 TrocDoc:TI,AB,KY 1

#36 (open approach):TI,AB,KY 183

#37 missile:TI,AB,KY 15

#38 pyramidal:TI,AB,KY 333

#39 (u shaped retractor*):TI,AB,KY 1

#40 (intra abdominal pressure):TI,AB,KY 196

#41 (closed technique*):TI,AB,KY 50

#42 (direct entry):TI,AB,KY 7

#43 (single incision):TI,AB,KY 369

#44 SILS:TI,AB,KY 96

#45 (open technique):TI,AB,KY 211

#46 (lift* adj5 wall):TI,AB,KY 3

#47 (blind* adj2 approach*):TI,AB,KY 93

#48 (blind* adj2 entr*):TI,AB,KY 24

#49 #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 21026

#50 #8 AND #49 1834

Appendix 3. MEDLINE search strategy

Searched from 1946 to 25 January 2018

OID platform

1 exp laparoscopy/ or exp hand-assisted laparoscopy/ (85184)

2 laparoscop\$.tw. (108445)

3 (pelvi\$ adj2 endoscop\$).tw. (61)

Laparoscopic entry techniques (Review)

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4 peritoneoscop\$.tw. (745)
 5 videolaparoscop\$.tw. (391)
 6 laparoendoscop\$.tw. (1073)
 7 or/1-6 (121804)
 8 entry technique\$.tw. (139)
 9 (Veress or veress-needle\$.tw. (447)
 10 trocar\$.tw. (5885)
 11 open entr\$.tw. (43)
 12 closed entr\$.tw. (17)
 13 pneumoperiton\$.tw. (6856)
 14 exp Pneumoperitoneum, Artificial/ (4118)
 15 exp posture/ or exp supine position/ (68388)
 16 supine position\$.tw. (10461)
 17 lithotomy.tw. (1313)
 18 (patient\$ adj2 position\$.tw. (7598)
 19 French position\$.tw. (27)
 20 American position\$.tw. (13)
 21 (side adj2 position\$.tw. (1005)
 22 (side adj approach\$.tw. (117)
 23 direct-trocar\$.tw. (61)
 24 gas.tw. (235146)
 25 disposable instrument\$.tw. (209)
 26 reusable instrument\$.tw. (138)
 27 trendelenburg.tw. (1517)
 28 radially expanding.tw. (85)
 29 direct vision.tw. (2450)
 30 (trans fundal or transfundal).tw. (41)
 31 carbon dioxide.tw. (42178)
 32 gasless.tw. (603)
 33 infra umbilical.tw. (97)
 34 infraumbilical.tw. (358)
 35 TrocDoc.tw. (1)
 36 lift\$.tw. (21798)
 37 blind.tw. (171760)
 38 open approach.tw. (2733)
 39 missile.tw. (1535)
 40 pyramidal.tw. (32233)
 41 u shaped retractor\$.tw. (4)
 42 intra abdominal pressure.tw. (2322)
 43 closed technique\$.tw. (465)
 44 direct entry.tw. (326)
 45 single incision.tw. (2738)
 46 SILS.tw. (1030)
 47 open technique.tw. (1942)
 48 (lift\$ adj5 abdominal wall).tw. (203)
 49 port entry.tw. (26)
 50 or/8-49 (595532)
 51 7 and 50 (15503)
 52 randomized controlled trial.pt. (451646)
 53 controlled clinical trial.pt. (92093)
 54 randomized.ab. (400519)
 55 randomised.ab. (79857)
 56 placebo.tw. (190812)
 57 clinical trials as topic.sh. (182274)
 58 randomly.ab. (283601)
 59 trial.ti. (176663)
 60 (crossover or cross-over or cross over).tw. (75038)
 61 or/52-60 (1183592)
 62 exp animals/ not humans.sh. (4416814)
 63 61 not 62 (1090012)
 64 51 and 63 (2569)

Appendix 4. Embase search strategy

Searched from 1980 to 25 January 2018

OVID platform

- 1 entry technique\$.tw. (270)
- 2 (Veress or veress-needle\$.tw. (792)
- 3 trocar\$.tw. (10736)
- 4 open entr\$.tw. (67)
- 5 closed entr\$.tw. (36)
- 6 pneumoperiton\$.tw. (8327)
- 7 exp body position/ or exp body posture/ (79070)
- 8 supine position\$.tw. (15305)
- 9 lithotomy.tw. (2151)
- 10 (patient\$ adj2 position\$.tw. (11956)
- 11 French position\$.tw. (86)
- 12 American position\$.tw. (17)
- 13 (side adj2 position\$.tw. (1153)
- 14 (side adj approach\$.tw. (150)
- 15 direct-trocar\$.tw. (100)
- 16 (gas adj5 laparoscop\$.tw. (356)
- 17 disposable instrument\$.tw. (271)
- 18 reusable instrument\$.tw. (213)
- 19 trendelenburg.tw. (2188)
- 20 radially expanding.tw. (101)
- 21 direct vision.tw. (3240)
- 22 (trans fundal or transfundal).tw. (47)
- 23 (carbon dioxide adj5 laparoscop\$.tw. (486)
- 24 (gasless adj5 laparoscop\$.tw. (354)
- 25 infra umbilical.tw. (147)
- 26 infraumbilical.tw. (519)
- 27 TrocDoc.tw. (1)
- 28 (lift\$ adj5 laparoscop\$.tw. (163)
- 29 (blind adj5 laparoscop\$.tw. (272)
- 30 open approach.tw. (4301)
- 31 (missile adj5 laparoscop\$.tw. (1)
- 32 (pyramidal adj5 laparoscop\$.tw. (5)
- 33 u shaped retractor\$.tw. (4)
- 34 intra abdominal pressure.tw. (2997)
- 35 or/1-34 (125521)
- 36 exp laparoscopic surgery/ or exp laparoscopy/ (133381)
- 37 laparoscop\$.tw. (167100)
- 38 (pelvi\$ adj2 endoscop\$.tw. (82)
- 39 peritoneoscop\$.tw. (782)
- 40 videolaparoscop\$.tw. (562)
- 41 laparoendoscop\$.tw. (2435)
- 42 or/36-41 (194906)
- 43 35 and 42 (18399)
- 44 Clinical Trial/ (962971)
- 45 Randomized Controlled Trial/ (480356)
- 46 exp randomization/ (76690)
- 47 Single Blind Procedure/ (30087)
- 48 Double Blind Procedure/ (142439)
- 49 Crossover Procedure/ (53781)
- 50 Placebo/ (303058)
- 51 Randomi?ed controlled trial\$.tw. (170383)
- 52 Rct.tw. (26544)
- 53 random allocation.tw. (1712)
- 54 randomly allocated.tw. (28645)
- 55 allocated randomly.tw. (2273)
- 56 (allocated adj2 random).tw. (789)

57 Single blind\$.tw. (20097)
58 Double blind\$.tw. (177696)
59 ((treble or triple) adj blind\$.tw. (730)
60 placebo\$.tw. (259430)
61 prospective study/ (417538)
62 or/44-61 (1841920)
63 case study/ (51494)
64 case report.tw. (343560)
65 abstract report/ or letter/ (1014541)
66 or/63-65 (1401377)
67 62 not 66 (1795019)
68 43 and 67 (2304)

Appendix 5. PsycINFO search strategy

Searched from 1806 to 25 January 2018

OID platform

1 laparoscop\$.tw. (442)
2 entry technique\$.tw. (11)
3 trocar\$.tw. (8)
4 open entr\$.tw. (14)
5 closed entr\$.tw. (4)
6 pneumoperiton\$.tw. (4)
7 exp Posture/ (5310)
8 supine position\$.tw. (477)
9 lithotomy.tw. (12)
10 (patient\$ adj2 position\$).tw. (306)
11 trendelenburg.tw. (21)
12 direct vision.tw. (53)
13 open approach.tw. (89)
14 carbon dioxide.tw. (1605)
15 or/2-14 (7806)
16 1 and 15 (7)

FEEDBACK

Included studies and trocar definitions, 6 July 2014

Summary

Review authors report that two RCTs with a total of 129 participants compared a radially expanding access device with a conventional cutting tip trocar (Summary of findings table 5) ([Lam 2000](#); [Yim 2001](#)). Analysis 10.8 includes only one of these studies ([Yim 2001](#)), although the data are also available for [Lam 2000](#). Furthermore the number of events in Analysis 10.8 extracted for Yim is listed as 4/34, but two of these events were related to another instrument for port site closure, not to trocar placement.

The term "standard trocars" is used but there is no consensus on what a standard trocar is. In most publications, the exact trocar type used is specified as cutting trocars, and these have been put in the category of "standard trocars". Only in one study is the standard trocar a mixture of blunt and sharp trocars ([Mettler 2000](#)).

Most studies compared a specific company product (REA/STEP trocars) with standard trocars. It is unclear what the exact benefit of the STEP trocar is, as less port site bleeding could result from the blunt tip on REA trocars and not the other aspects of the STEP system. We refer you to a recent systematic review: Antoniou SA, Antoniou GA, Koch OO, Pointner R, Granderath FA (2013) Blunt versus bladed trocars in laparoscopic surgery: a systematic review and meta-analysis of randomized trials. *Surg Endosc* 27:2312–2320.

This area is troubled by lack of clear definitions and very poorly designed underpowered studies, and most analyses listed in the review cannot say anything conclusive regarding which types of laparoscopic ports should be used. Yet, we found it troublesome that the analysis compares one specific company product (STEP system) versus older cutting trocars.

We hope you will take these comments for consideration in future reviews on this topic or during updates of this review.

Reply

Thank you for your comments. We have reviewed the Cochrane review and original trial reports and addressed your concerns by topic.

Secondary ports – Trocar site bleeding

The methods stated that we would analyse the data utilising an intention-to-treat basis. The [Lam 2000](#) study recorded no events for trocar site bleeding; we will state this more clearly in future updates. With reference to your query regarding trocar site bleeding, we have reviewed [Yim 2001](#). Trocar site bleeding was reported in four patients; two happened during entry and two happened during insertion of Endoclose. As this review focuses on entry techniques, on reflection we could have excluded these latter two events from the analysis. In future updates, we will clearly state this in the descriptive text.

Description of trocars

There is no international consensus regarding the definition of trocars. Taking on board your comments, in future we will consistently state the broad category, subcategory, and manufacture designation to satisfy the general and special interest audience.

Antoniou et al Systematic Review 2013

The discussion in any Cochrane review will always include discussion of other published systematic reviews. This review was published in 2013 and thus could not have been included in our review, which was published the year before. We will discuss the work of Antoniou et al. in future review updates.

STEP system

We are careful to describe throughout the text the STEP system as radially expanding.

Again, many thanks for your comments.

Contributors

Flemming Bjerrum, MD, PhD Student, Department of Gynecology, The Juliane Marie Centre, University of Copenhagen

Gaity Ahmad, Helena O'Flynn, James MN Duffy, Kevin Phillips, Andrew Watson

Interpretation of safety data in meta-analyses, 29 September 2018

Summary

The feedback received on 29 September refers to the version of this review published in 2015.

In three consecutive iterations of this meta-analysis, the authors state that there was no difference between using the Veress Needle to establish pneumoperitoneum and other methods, particularly vs. the Hasson or open technique. Among the cited studies in the meta-analysis, only one had a major vascular injury, and it was in the Veress arm (1/75 vs. 0/75)). In the first iteration of the meta-analysis, the authors added data from an RCT of 20 subjects in each group (Benelman I) which showed no event, for a total of 95 patients in each arm. Since the estimated incidence of major blood vessel injury using the Veress technique is approximately 1/1000 (FDA estimation is 1.1/1000 and when the authors used all studies which had a Veress arm, the incidence of major blood vessel injury was 8/1000) it is impossible to draw any conclusions from a sample size of 95 patients. In the next two iterations, the authors did not include this study in the analysis (the reason is unclear since they still used this study for other comparisons). They added two other RCT which also had no events, but even with these studies, the sample size was grossly inadequate. Further, according to the Cochrane handbook [http://handbook.cochrane.org/chapter 16.9.3](http://handbook.cochrane.org/chapter_16.9.3)) using studies with no events in each arm in meta-analyses dilute the data without adding information. You may argue that stating that no difference was found is true. It is possible that you as editors understand the correct implications, but the average intelligent person does not and will interpret the meta-analyses as showing that there is really no difference. For most of us, the presented conclusions are only half the truth and therefore misleading because we trust the library and do not look into the details of the published meta-analysis. For example, the authors of the UpToDate chapter on entry technique base their endorsement of Veress for routing cases on the meta-analysis. Finally, if a surgeon is sued for causing major blood vessel injury and base the defense on the meta-analysis, Wiley and the Library may find themselves in court for failure to follow their own publishing guidelines in the review process, and for publishing half-truths and potentially misleading information. I suspect that it will not go well with the fact-finders. The meta-analyses should clearly state, in the abstract, that the sample size was inadequate to form any conclusions or combine all the studies which had a Veress Arm in the analysis (permitted under the guidelines) and show that there is a statistically significant difference against the Veress Arm. It may help if meta-analyses which fail to show a difference use standard sample size calculations to determine if the total sample size was sufficient to show non-inferiority. 1. Cogliandolo, A., et al., Blind versus open approach to laparoscopic cholecystectomy: a randomized study. *Surg Laparosc Endosc*, 1998. 8(5): p. 353-5. 2. Pryor, A. Abdominal access techniques used in laparoscopic surgery. *minimally invasive surgery [Web]* 2013; . Available from: <http://www.uptodate.com/contents/abdominal-access-techniques-used-in-laparoscopic-surgery>.

Reply

We agree that there should be a clear distinction between the two scenarios:

- 1) where there is evidence to show there is no difference/non-inferiority between Veress needle entry vs. open/Hasson entry

2) where there is insufficient evidence to demonstrate a difference between Veress needle entry vs. open/Hasson entry

In the 2018 update of this review, all wording has been amended to clarify this important distinction. For the most part due to low event rates and sample sizes there was insufficient evidence to demonstrate a difference between techniques, and this is reflected in the text of the review.

In the updated review, ten RCTs looking at Veress needle entry reported vascular injury as an outcome. There was a total of 1086 participants and 10 events of vascular injury were reported. Four RCTs looking at open entry technique reported vascular injury as an outcome. There was a total of 376 participants and 0 events of vascular injury were reported. This was not a direct comparison. In the direct comparison of Veress needle and Open-entry technique, there was insufficient evidence to determine whether there was a difference in rates of vascular injury.

We understand your concerns re using studies with no events in each arm, however including studies with no events in either arm does not affect the calculated Peto OR for that comparison group. RCTs are not well suited to detecting differences between interventions when the events rates are very low. We make reference to this in the review and suggest a way forward may be the creation of a centralised national register:

“Randomised controlled trials (RCTs) of adequate power are required to detect differences in risks of major complications. In order to increase cohort size enough to gain the statistical power needed to be able to detect rare major complications, the number of patients required would need to be in the hundreds of thousands and it is unlikely that these studies could be performed. This dilemma has been explored recently by Cuss 2014 who suggest that the evidence for laparoscopic surgery may be at the limit of what is possible. In order to address this issue, we suggest that a centralised national register could be created. Although this would not produce RCT-level evidence, it would enable collation of all information on laparoscopic complications and thus provide cohort sizes large enough to reliably identify major complications. This could be modelled on the existing maternal mortality databases. The onus would be on individual surgeons to be transparent in their reporting of complications”

Bemelman 2000 is listed in the included studies in the current version of the review, as it compares different laparoscopic entry techniques, however we were not able to extract any data for meta-analysis as the paper does not report our outcome measures.

Contributors

Aviel Roy-Shapira, affiliation not stated

Gaity Ahmad, Jade Baker, John Finnerty, Kevin Phillips, Andrew Watson

WHAT'S NEW

Date	Event	Description
4 December 2018	New search has been performed	<p>11 new studies added to the review at this update: 10 from new database searches: Chang 2015, Ertugrul 2015, He 1 2015, Vilos 2015, Youssef 2015, Guo 2015, Zaman 2015, Köstü 1 2016, Partelli 2016, Porta 2017, and 1 from previous searches and not included in previous review versions: Tinelli 2009. Three new entry technique comparisons added: LUQ vs caudally displaced umbilical VNI; SILS vs VNI vs X-cone (3-arm); IAP 15 vs IAP 25 vs IAP 25 with external compression (3-arm).</p> <p>Authorship update: John Finnerty and Jade Baker added.</p> <p>Feedback received 29 September 2018 relating to previous published versions of this review has been addressed: see Feedback 2: Interpretation of safety data in meta-analyses.</p>
4 December 2018	New citation required and conclusions have changed	<p>Evidence is insufficient to show a difference in rates of failed entry between open-entry and closed-entry techniques. Other conclusions remain unchanged.</p>

HISTORY

Protocol first published: Issue 3, 2007

Review first published: Issue 2, 2008

Laparoscopic entry techniques (Review)

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Date	Event	Description
25 March 2015	New citation required but conclusions have not changed	No changes made to the conclusions of this review
25 March 2015	New search has been performed	18 new studies added to the review at this update: Angioli 2013 , Carter 2013 , Channa 2009 , Deveci 2013 , Fonollosa 2012 , Huang 2012 , Imran 2014 , Karaca 2014 , Lai 2011 , Luna 2013 , Peitgen 1997 , Perez 2013 , Phillips 2012 , Prieto-Díaz-Chávez 2006 , Tinelli 2011 , Tinelli 2013 , Vilallonga 2012 , Villalobos 2014 Authorship update - David Gent and Daniel Henderson added
13 August 2014	Feedback has been incorporated	Feedback received (summarised below), which will be addressed in the 2014 update of this review
17 August 2011	New citation required and conclusions have changed	Failed entry now considered a major complication. Implications of failed entry considered (e.g. laparotomy, abandoned surgery). Protocol changed accordingly Three new comparisons included in this update: direct vision vs open-entry technique, 5-mm vs 3-mm secondary port trocars, STEP secondary trocars vs standard trocars 11 new trials included in this update: Akbar 2008 , Bisgaard 2007 , Feste 2000 , Ghezzi 2005 , Hamade 2007 , Minervini 2008 , Tinelli 2010 , Tsimoyiannis 2009 , Venkatesh 2007 , Yim 2001 , Zakerah 2010 New conclusions demonstrated in analysis Authorship updated - Helena O'Flynn added
11 November 2008	Amended	Converted to new review format
27 January 2008	New citation required and conclusions have changed	Substantive amendments made

CONTRIBUTIONS OF AUTHORS

Gaity Ahmad (GA).

Main review author, designed the review. Supervised screening of search results and verified selection against the inclusion criteria, resolved discrepancies, wrote to study authors when required, and supervised JF and JB throughout the process.

John Finnerty (JF).

Updated review co-author, screened search results based on abstracts, retrieved full-text original RCTs, selected RCTs based on inclusion criteria, extracted data from RCTs, interpreted results, and updated the discussion and conclusions.

Jade Baker (JB).

Updated review co-author, screened search results based on abstracts, retrieved full-text original RCTs, selected RCTs based on inclusion criteria, extracted data from RCTs, interpreted results, and updated the discussion and conclusions.

Kevin Philipps (KP).

Helped design the original review and draft the discussion and conclusions.

Andrew Watson (AW).

Helped design the original review, supervised all steps undertaken for the original review, and helped draft the discussion and conclusions.

DECLARATIONS OF INTEREST

None known for any review author.

SOURCES OF SUPPORT

Internal sources

- No sources of support provided, Other.

External sources

- None, Other.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We included in the 2012 update of the review studies reviewing secondary port entry. The new comparisons were 5-mm versus 3-mm trocar for secondary port entry and radially expanding access device versus conventional (non-expanding) cutting tip trocar for secondary port entry.

We changed failed entry from a secondary outcome to a primary outcome in the 2012 update of the review, as review authors deemed it to have serious consequences such as prolonged operative time and increased risk of infection due to further incisions. We added solid organ injury as a primary outcome in the 2012 update of the review.

We defined secondary outcome measures in the 2015 update as extraperitoneal insufflation, trocar site bleeding, trocar site infection, incisional hernia, omentum injury, and uterine bleeding.

For the 2018 update, we added a second sensitivity analysis restricted to studies that either selected for non-obese adult patients or did not specify a BMI threshold.

INDEX TERMS

Medical Subject Headings (MeSH)

*Abdominal Wall; *Intraoperative Complications [prevention & control]; Blood Vessels [injuries]; Gynecologic Surgical Procedures [*adverse effects] [methods]; Intestines [injuries]; Laparoscopy [*adverse effects] [methods]; Peritoneal Cavity; Randomized Controlled Trials as Topic; Urinary Bladder [injuries]

MeSH check words

Female; Humans; Male