A systematic review of the methods used to establish laparoscopic pneumoperitoneum

Authors' objectives
The objective was to determine which of the various peritoneal access methods used to establish pneumoperitoneum in laparoscopy was the safest and most effective. The review tested three hypotheses:

1. the 'visual/open' access method is safer and/or more effective than 'blind/closed' or 'hybrid visual/close' access methods;

2. 'hybrid visual/closed' access methods are safer and/or more effective than 'blind/closed' methods; and

3. for 'blind/closed' methods, the direct trocar technique is safer and/or more effective than the Veress needle/primary trocar technique.

Searching
MEDLINE, Current Contents, the Cochrane Library, EMBASE, HealthStar and the Science Citation Index (via ISI Web of Science) were searched from inception to May 2001; the search strategies used were provided in the report. In addition, the Internet was searched, recent conference proceedings of specialist societies were handsearched, and the reference lists of the included studies were checked. No language or publication restrictions were applied. However, the relevance of non-English language studies was established on the basis of their English abstract and they were only translated in full if they were RCTs. Excluded Non-English language studies that had data on relevant outcomes were summarised (based on the abstract) and tabulated.

Study selection
Study designs of evaluations included in the review
Systematic reviews of randomised controlled trials (RCTs), randomised, quasi-randomised and non-randomised trials, or cohort studies (prospective or retrospective) were considered for inclusion. Case series and audit studies with a minimum of 1,000 patients were also considered for the assessment of rare adverse effects.

Specific interventions included in the review
Five access methods used in laparoscopic surgery for establishing pneumoperitoneum were considered for inclusion. They were divided into the following three categories.

'Visual/open' methods: open laparoscopy using the Hasson or modified Hasson technique involving peritoneal cut-down followed by direct insertion of a trocar, gas insufflation and then the laparoscope.

'Blind/closed' methods: closed laparoscopy using either a needle (Veress or other) followed by insufflation, insertion of primary trocar and then the laparoscope (needle/trocar), or direct trocar insertion with insufflation after laparoscope insertion (direct trocar).

'Hybrid visual/closed' methods: closed laparoscopy using either endoscopically-guided optical trocar followed by gas insufflation, or optical needle where the trocar is then inserted after gas insufflation (optical trocar).

There was no restriction on the type of access site used, whether the laparoscopy was therapeutic or exploratory, or the type of surgery that was performed. The type of surgery in the included studies was either general or gynaecological.

Participants included in the review
All patients that had undergone laparoscopic surgery were considered for inclusion.

Outcomes assessed in the review
In this review the safety outcomes were the primary outcomes. Relevant safety outcomes were peri- and post-operative mortality, major and minor complication rates, and conversion to laparotomy. Data on the prevalence of rare complications (e.g. death or major blood vessel injury) were collected from included case series. Relevant efficacy outcomes were: the ability to establish pneumoperitoneum, the average time taken to establish pneumoperitoneum, the mean operating time (by surgical procedure), gas usage and cost.

How were decisions on the relevance of primary studies made?
Two reviewers independently assessed the studies for inclusion, initially using the reference citation abstract and then, where necessary, using the retrieved article. Inter-rater agreement was assessed using the kappa statistic and any disagreements were resolved by discussion or by consulting a third party.

Assessment of study quality
The quality of comparative studies was assessed using an adaptation of a checklist produced by Downs and Black, which considered aspects of both internal and external validity. The checklist produced an overall quality index score ranging from 0 to 27. The influence of any confounders (identified a priori) on the safety outcomes was also assessed. One reviewer assessed the validity of the included studies.

Data extraction
One reviewer extracted the data using tables developed a priori, in conjunction with the outcome definitions provided in the review protocol.

Methods of synthesis
How were the studies combined?
The results of RCTs and non-RCTs (plus observational cohort studies) were pooled in separate meta-analyses. The binary outcomes were pooled using a fixed-effect model (Mantel-Haenszel), while continuous outcome measures were pooled using the inverse variance method. Where statistical heterogeneity could not be explained, a random-effects model (DerSimonian and Laird) was used. The pooled relative risks (RRs) and weighted mean differences (WMDs) were presented along with their respective 95% confidence intervals (CIs). Publication bias was investigated graphically using funnel plots (Begg) and statistically using Egger's weighted regression method. Studies not included in the meta-analyses were pooled in a narrative synthesis.

How were differences between studies investigated?
The results were presented in forest plots and statistical heterogeneity was investigated using the Q statistic (with a significance level of 0.10). Reasons for heterogeneity were investigated by stratifying the studies on the known confounders of prior abdominal surgery, patient weight, patient position, access site, surgical skill, age and gender. Sensitivity analyses were conducted, where possible, to investigate the influence of individual studies on the pooled effect estimate.

Results of the review
Forty-three studies met the inclusion criteria. Seven studies were included in the meta-analyses of RCTs: 4 investigated hypothesis one (n=302) and 3 investigated hypothesis two (n=665). Eleven studies were included in the meta-analyses of non-RCTs: 9 investigated hypothesis one (n=20,364) and 2 investigated hypothesis two (n=1,575). Twenty-five studies were included in a narrative synthesis. These comprised 19 case series, (2 looking at open-Hasson access (n=2,506), 9 looking at closed-needle/trocar access (n=80,885) and 8 looking at closed-direct/trocar access (n=19,740)); 4 abstracts (3 non-English language (n=3,434) and 1 grey-literature (n=2,975)); one historically controlled trial (n=300) relevant to the first hypothesis; and one cohort study (n=100) relevant to the second hypothesis.

'Visual/open' versus 'blind/closed' access.

Four RCTs (quality score: 16 to 24), 9 non-RCTs (quality score: 11 to 20) and one historically controlled trial (quality
score 12) not included in the meta-analyses looked at open versus needle/trocar access. Further information was also provided by 8 case series (2 of open access and 6 of needle/trocar access). None of the included studies looked at open versus direct trocar access.

Safety: studies contributing data on major complications showed both clinical and statistical heterogeneity (chi-squared 11.12, d.f. = 5, P = 0.049). Stratification showed possible differences relating to patient selection. Non-randomised prospective studies on patients with similar levels of prior abdominal surgery in both groups indicated a trend towards a reduced risk of major complications during open access (RR 0.30, 95% CI: 0.09, 1.03). Open access was also associated with a trend towards a reduced risk of access-site herniation (RR 0.21, 95% CI: 0.04, 1.03) and, in non-obese patients, a 57% reduction in minor complications (RR 0.43, 95% CI: 0.04, 1.17). The risk of bowel injury was higher with open access than with needle/trocar access (RR 2.17, 95% CI: 1.14, 4.10), although selection bias may have influenced the results.

Efficacy: pooled estimates from RCTs showed that both the total time to establish pneumoperitoneum (WMD -0.78 minutes, 95% CI: -1.46, -0.10) and the operating time (WMD -6.42 minutes, 95% CI: -6.95, -5.90) were slightly reduced during open access.

'Visual/open' versus 'hybrid visual/close'.

None of the included studies looked at open versus optical trocar access.

'Hybrid visual/close' versus 'blind/closed'.

Only one retrospective cohort study (with only 4 out of 100 patients operated on using optical trocar; quality score 17) and one grey literature abstract looked at optical trocar versus needle/trocar access; the data were inconclusive. None of the included studies looked at optical trocar versus direct trocar access.

'Blind/closed' methods: direct trocar versus needle/trocar access.

Three RCTs (quality score for all: 17) and 2 non-RCTs (quality score: 13 to 17) compared direct trocar with needle/trocar access. Further information was provided by 8 case series looking at direct trocar and 8 case series looking at needle/trocar access.

Safety: the data on major complications were inconclusive, whereas the minor complications reported in RCTs were fewer with direct trocar access (RR 0.19, 95% CI: 0.09, 0.40), predominantly owing to a reduction in extraperitoneal insufflation.

Efficacy: the pooled outcomes relating to the ability to establish pneumoperitoneum were inconsistent; information on the other efficacy outcomes was not reported.

Cost information
Only one study, an RCT comparing open versus closed (needle/trocar) laparoscopy, reported cost outcomes. Based on 2000 to 2001 prices, a Bluntport 10-mm Hasson trocar cost US$127 compared with US$160 for the total package of a 120-mm Surgineedle and Versaport 10-mm sharp trocar. No other comparative costs were reported.

Authors' conclusions
Based on averagely good evidence, definitive differences in safety and efficacy could not be determined for open access versus needle/trocar access, for needle/trocar access versus open access or direct trocar access, or for direct trocar access versus needle/trocar access. There was only poor evidence for the comparison of optical trocar access and needle/trocar access.

CRD commentary
This was a well-conducted review. It addressed an appropriate question using clear inclusion and exclusion criteria.
The literature search was comprehensive and the possibility of publication bias was investigated. Two reviewers were involved in assessing the relevance of individual studies, but only one reviewer was involved in the data extraction and quality assessment processes. It was not stated whether another reviewer checked these procedures; this may have introduced some reviewer bias. Relevant information about the included studies were clearly presented in summary tables and figures, and the results were analysed and pooled appropriately. The authors' conclusions are supported by the review findings.

**Implications of the review for practice and research**

Practice: Due to the lack of firm clinical evidence, the authors recommended that the relevant professional societies (General Surgeons Australia/GSA and New Zealand Association of General Surgeons) should develop training and practice guidelines, with indications, for the various techniques available for primary access in laparoscopic surgery.

Research: The authors recommended that the following studies be carried out. First, large prospective cohort studies that adequately control for patient history of abdominal surgery and body mass index. Second, controlled trials comparing direct trocar and/or optical trocar access with open access. Finally, randomised trials specifically looking at efficacy outcomes comparing direct trocar and needle/trocar access.

**Bibliographic details**


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