



Setting standards to improve women's health

PREVENTING ENTRY-RELATED GYNAECOLOGICAL LAPAROSCOPIC INJURIES

This is the first edition of this guideline.

1. Purpose and scope

Approximately 250 000 women undergo laparoscopic surgery in the UK each year. The majority are without problems but serious complications occur in about one in 1000 cases. Laparoscopic injuries frequently occur during the blind insertion of needles, trocars and cannulae through the abdominal wall and, hence, the period of greatest risk is from the start of the procedure until visualisation within the peritoneal cavity has been established. This guideline aims to highlight strategies to reduce these complications.

2. Background

Over the past 50 years, developments in electronic and optical technologies have meant that it has become possible to perform many gynaecological operations laparoscopically. The unique feature distinguishing laparoscopic from open abdominal or vaginal surgery is the need to insert needles, trocars and cannulae for initial entry into the abdomen. This may result in bowel or vascular injury. There is wide variation in the techniques used by laparoscopic surgeons and this guideline concentrates the evidence for different entry techniques.

One of the difficulties of bowel damage associated with laparoscopic surgery is the likelihood that it may not be immediately recognised and could present some time later, often after discharge from hospital. This potentially serious complication may require major abdominal reparative surgery and sometimes a temporary colostomy.¹ It is essential, therefore, that women and attending staff understand that the recovery from laparoscopic procedures is usually rapid and, where this is not the case, that early diagnosis and treatment are essential and should involve senior medical staff. The relative infrequency of these accidents prevents any individual laparoscopic surgeon from gaining a true appreciation of their importance or frequency.

3. Incidence of complications

The incidence of complications associated with laparoscopic procedures varies considerably between reports, depending on the experience of the surgeons and the complexity of operations undertaken; figures range between 1.0/1000 and 12.5/1000 for all complications. In Finland, 256 complications were reported to the National Patient Insurance Association following 70 607 laparoscopic procedures (3.6/1000). The rate of major complications was 1.4/1000 procedures comprising intestinal injuries (0.6/1000), urological injuries (0.3/1000) and vascular injuries (0.1/1000).² Jansen *et al.* reported the results of a prospective multicentre study of 72 hospitals in the Netherlands in which there were 145 complications from 25 764 laparoscopies (5.7/1000).³ There were two fatalities and 84 women (3.3/1000) required a laparotomy because of

Evidence
level
IIb-III

complications. There were 29 cases of gastrointestinal damage (1.13/1000) and 27 lesions of intra-abdominal vessels (1.05/1000); 57% of the injuries were attributed to problems with laparoscopic entry. Women with a previous laparotomy were also found to be particularly at risk.

Evidence level
IIb-III

In a French prospective study, the rate of severe complications was 12.5/1000 cases after advanced laparoscopic surgery.⁴ This study, which was a snapshot of laparoscopic surgery over a 2-week period throughout all French hospitals, reported the rate of major complications to be two to three times higher than in a previous study from France, which reported only complications from specialised referral centres.⁵

Although the RCOG instigated a confidential inquiry in the early days of laparoscopy,⁶ there has not been a recent national audit of complications of laparoscopic surgery in the UK. A prospective observational study of all gynaecological laparoscopies performed by all grades of staff during a calendar year in a teaching hospital reported bowel damage three times in 836 laparoscopies (3.6/1000).⁷ In a similar study from a district general hospital of 470 patients operated during a single calendar year there were two bowel injuries (4.3/1000).⁸ The bowel injuries in these studies occurred during procedures for diagnostic or sterilisation purposes where the pressure method recommended for safe entry in the Middlesbrough Consensus was not employed.⁹

Evidence level III

4. Identification and assessment of evidence

The Cochrane Library (including the Cochrane Database of Systematic Reviews, DARE and EMBASE), HTA, TRIP, Medline and PubMed (electronic databases) were searched for relevant randomised controlled trials, systematic reviews and meta-analyses. The search was restricted to articles published in English from 1966 to January 2006. The databases were searched using the relevant MeSH terms, including all subheadings, and this was combined with a keyword search. Main keywords included: 'laparoscopic injury', 'laparoscopic entry', 'laparoscopic complications', 'closed laparoscopy', 'open laparoscopy' and 'direct-entry laparoscopy'.

Additionally, enquires were made with researchers and Council members of the British Society for Gynaecological Endoscopy (BSGE) and our suggestions were critically appraised at a 1-day study meeting entitled 'Avoiding complications of laparoscopic surgery' held on 7 July 2006 at the University of Surrey Postgraduate Medical School.

5. Assessment, counselling and consent

How should women be counselled prior to laparoscopic surgery?

Women must be informed of the risks and potential complications associated with laparoscopy. This should include discussion of the risks of the entry technique used: specifically, injury to the bowel, urinary tract and major blood vessels, and later complications associated with the entry ports: specifically, hernia formation.



Surgeons must be aware of the increased risks in women who are obese or significantly underweight and in those with previous midline abdominal incisions, peritonitis or inflammatory bowel disease. These factors should be included in patient counselling where appropriate.



Most laparoscopic procedures in gynaecology are performed electively for benign conditions. The understanding and acceptance of the risk associated with the procedure may be different from that of women having procedures for life-threatening conditions.¹⁰ Women must be informed of the associated risks with laparoscopy. Evidence from women undergoing laparoscopy for pelvic pain suggests that they do want to know all complications.¹¹ Potential complications should be discussed according to the principles of counselling described in the RCOG Clinical Governance Advice No. 6 *Obtaining Valid Consent*.

6. Safe surgical techniques and training

How should surgeons be trained in safe laparoscopic techniques?

Surgeons intending to perform laparoscopic surgery should have appropriate training, supervision and experience.



Surgeons undertaking laparoscopic surgery should be familiar with the equipment, instrumentation and energy sources they intend to use.



Surgeons undertaking laparoscopic surgery should ensure that nursing staff and surgical assistants are appropriately trained for the roles they will undertake during the procedure.



The safe practice of any surgical technique lies in effective structured training and supervised practice. The basic elements of this training are covered in the RCOG core training portfolio (www.rcog.org.uk/index.asp?PageID=1959).

For surgeons intending a career with a significant gynaecological surgical role, including intermediate level laparoscopic procedures, the Advanced Training Skills Module (ATSM) on benign gynaecological surgery – laparoscopy would also be an essential requirement. (www.rcog.org.uk/resources/public/pdf/ATSM_Benign_gynae_surg_laparoscopy_010807.pdf). For those surgeons intending to undertake even more complex laparoscopic procedures, this training will need to be supplemented by a process of mentorship, performing surgery of increasing complexity with the support of an experienced laparoscopic surgeon.

7. Laparoscopic entry techniques

The most effective way to reduce complications of laparoscopic entry is to optimise insertion of the primary trocar and cannula, although there is controversy as to the safest technique for achieving this. Gynaecologists have tended to favour the closed or Veress needle entry technique, whereby the abdominal cavity is insufflated with carbon dioxide gas before introduction of the primary trocar and cannula. The Royal College of Surgeons of England recommends that the open (Hasson) approach be used in all circumstances.¹² This latter method uses a small incision to enter the peritoneal cavity under direct vision.

Evidence level IV

In a meta-analysis of over 350 000 closed laparoscopic procedures, the risk of bowel damage was 0.4/1000 and of major vessel injuries was 0.2/1000.¹⁵ It might be anticipated that the open (Hasson) technique would be less likely to cause major vessel injury than the closed method: if a segment of adherent bowel were injured, it might be more likely that this would be recognised at the time, allowing immediate repair. However, a study of 10 840 open procedures found six cases of bowel damage (0.6/1000), four of which were recognised immediately but, in two of them, the diagnosis was later and reparative surgery was delayed.¹⁴

Evidence level III

Hasson reviewed a number of series using the open method and found no cases of major vessel injury and a rate of bowel injury of only 0.1%.¹⁵ The most authoritative comparative review of the safety of open and closed methods of laparoscopic entry was conducted by the Australian College of Surgeons,¹⁶ which found a higher risk of bowel injury associated with open access (relative risk 2.17; 95% CI 1.57–4.63). The risk of vessel damage was so low in both groups that no statistical difference was observed.¹⁷

Evidence level IIa-III

Two randomised trials have compared the open and closed entry techniques. A meta-analysis does not indicate a significant safety advantage to either technique.¹⁸⁻²⁰

Evidence level Ia

7.1 Veress needle (closed) laparoscopic entry technique

How should the closed laparoscopic entry technique be performed?

In most circumstances the primary incision for laparoscopy should be vertical from the base of the umbilicus (not in the skin below the umbilicus). Care should be taken not to incise so deeply as to enter the peritoneal cavity.

C

The Veress needle should be sharp, with a good and tested spring action. A disposable needle is recommended, as it will fulfil these criteria.

C

The operating table should be horizontal (not in the Trendelenburg tilt) at the start of the procedure. The abdomen should be palpated to check for any masses and for the position of the aorta before insertion of the Veress needle.

C

The lower abdominal wall should be stabilised in such a way that the Veress needle can be inserted at right angles to the skin and should be pushed in just sufficiently to penetrate the fascia and the peritoneum. Two audible clicks are usually heard as these layers are penetrated.

C

Excessive lateral movement of the needle should be avoided, as this may convert a small needlepoint injury in the wall of the bowel or vessel into a more complex tear.

C

A consensus document on safe laparoscopic entry was made in 1999, following an international meeting of gynaecologists and general surgeons with a special interest in laparoscopic surgery to critically evaluate the available published evidence on entry techniques.⁹

Evidence level IV

In a review by the Council of the Association of Surgeons it was suggested that, after two failed attempts to insert the Veress needle, either the open Hasson technique or Palmer's point entry should be used.

A single randomised trial has investigated elevating and not elevating the abdominal wall before insertion of the Veress needle. The latter was associated with a reduced rate of failed entry.^{20,21} Several tests have been advocated to check that the tip of the needle is free in the peritoneal cavity and has not penetrated the omentum or any other organ. There is no evidence that these tests are 100% accurate and, indeed, a recent study evaluated some of these tests and concluded that it is probably of most value to observe that the initial insufflation pressure is relatively low (less than 8 mmHg) and is flowing freely.²²

Evidence level Ib

What intra-abdominal pressure should be achieved to safely insert the primary trocar?

An intra-abdominal pressure of 20–25 mmHg should be used for gas insufflation before inserting the primary trocar.

B

The distension pressure should be reduced to 12–15 mmHg once the insertion of the trocars is complete. This gives adequate distension for operative laparoscopy and allows the anaesthetist to ventilate the patient safely and effectively.

B

It is necessary to achieve a pressure of 20–25 mmHg before inserting the trocar, as this results in increased splinting and allows the trocar to be more easily inserted through the layers of the abdominal wall. The increased size of the 'gas bubble' and this splinting effect has been shown to be associated with a lower risk of major vessel injury. If a constant force of 3 kg is applied to the abdominal wall at the umbilicus to an abdominal cavity insufflated to a pressure of 10 mmHg, the depth under the 'indented' umbilicus is only 0.6 cm. When the same force is applied to an abdomen

Evidence level Iib

distended to 25 mmHg, the depth is 5.6 cm (range 4–8 cm). The mean volume of CO₂ required to reach this pressure was 5.58 litres.²³ No adverse effect on circulation or respiratory function was observed as long as the patient is lying flat.²⁴ It is suggested that all gynaecologists should consider using the pressure technique, insufflating the abdomen to 20–25 mmHg before inserting the primary trocar. Further evidence to support this practice is awaited from randomised controlled trials.

Evidence level IIb

Where should the primary trocar be inserted?

The primary trocar should be inserted in a controlled manner at 90 degrees to the skin, through the incision at the thinnest part of the abdominal wall, in the base of the umbilicus. Insertion should be stopped immediately the trocar is inside the abdominal cavity.

C

Once the laparoscope has been introduced through the primary cannula, it should be rotated through 360 degrees to check visually for any adherent bowel. If this is present, it should be closely inspected for any evidence of haemorrhage, damage or retroperitoneal haematoma.

C

If there is concern that the bowel may be adherent under the umbilicus, the primary trocar site should be visualised from a secondary port site, preferably with a 5-mm laparoscope.

C

On completion of the procedure, the laparoscope should be used to check that there has not been a through-and-through injury of bowel adherent under the umbilicus by visual control during removal.

C

7.2 Hasson (open) entry technique

How should the open entry technique be performed?

When the Hasson open laparoscopic entry is employed, confirmation that the peritoneum has been opened should be made by visualising bowel or omentum before inserting the blunt tipped cannula.

C

The Hasson technique of open laparoscopic entry is an alternative to closed laparoscopy that avoids the use of sharp instruments after the initial skin incision. It allows the insertion of a blunt-ended trocar under direct vision.

Once the fascial edges are incised, they should be held by a lateral stay suture on either side of the incision. Once the peritoneum is opened, the fascial sutures are then pulled firmly into the suture holders on the cannula to produce an airtight seal with the cone of the cannula. Gas is insufflated directly through the cannula to produce the pneumoperitoneum. The blunt trocar is withdrawn only after the abdomen is partially distended. At the end of the procedure, the fascial defect should be closed using the stay sutures (and possibly additional sutures) to minimise the risk of herniation.

Evidence level IV

8. Alternative entry techniques

What alternative entry techniques are available?

8.1 Direct trocar insertion

Direct trocar insertion is an acceptable alternative trocar insertion method.

A

This technique was developed to overcome the difficulty associated with grasping the abdominal wall already distended by the pneumoperitoneum.²⁵ Although in experienced hands it is the most rapid method of entry and can be safely used if the cases are carefully selected, it is not widely used within gynaecological practice. Six randomised controlled trials have compared Veress needle with direct trocar entry.^{19,26–30} Meta-analysis does not show any safety disadvantage from using direct

Evidence level Ia

entry in terms of major complications. There may be an advantage when considering minor complications.²⁰

Evidence
level Ia

8.2 *Alternative entry devices*

There are several ingenious devices that have been introduced during the last decade to try to minimise the risk during primary trocar insertion. These include visual access systems,³¹ radially expanding trocars³² and second-generation Endotip® (Karl Storz, Tutlingen, Germany) systems. A number of randomised controlled trials have demonstrated safety advantage in terms of reduced trocar site bleeding with radially expanding trocars.^{20,33-35}

Further miniaturisation of optical systems has resulted in the invention of an optical Veress needle but despite the theoretical advantages of such a device there is no evidence to demonstrate the superiority of this approach over the conventional Veress needle.³⁶

Evidence
level III

8.3. *Alternative sites for primary trocar or Veress needle insertion*

What alternative sites can be safely used for primary trocar or Veress needle insertion?

Palmer's point is the preferred alternative trocar insertion site, except in cases of previous surgery in this area or splenomegaly.

B

The rate of adhesion formation at the umbilicus may be up to 50% following midline laparotomy and 23% following low transverse incision.³⁷ The umbilicus may not, therefore, be the most appropriate site for primary trocar insertion following previous abdominal surgery. The most usual alternative site is in the left upper quadrant, where adhesions rarely form, although even this may be inappropriate if there had been previous surgery in this area or splenomegaly. The preferred point of entry is 3 cm below the left costal margin in the mid-clavicular line (Palmer's point). A small incision is made and a sharp Veress needle inserted vertically. Testing for correct placement using the pressure/flow test is performed. CO₂ is then instilled to 25 mmHg pressure and a 2-5 mm endoscope is used to inspect the undersurface of the anterior abdominal wall in the area beneath the umbilicus. If this is free of adhesions, the trocar and cannulae can be inserted under direct laparoscopic vision. If there are many adhesions present, it is possible to dissect these free via secondary ports in the lower left abdomen or an alternative entry site can be selected visually.

Evidence
level III

Other sites have been tried but, in general, are to be avoided. Suprapubic insertion of the Veress needle puts the bladder at risk of damage and is associated with the highest rate of failure due to preperitoneal insufflation of gas.⁹ Instillation of gas through the uterine fundus with the Veress needle carries the possibility of introducing infection and can be dangerous if bowel is adherent to the fundus. Similarly, entry through the posterior fornix could cause serious problems if the woman was found to have deep infiltrating endometriosis with obliteration of the cul-de-sac and the rectum adherent to the back of the cervix. A low rectal perforation at this site could be particularly dangerous and it should only be used when imaging techniques have clearly shown that the posterior cul-de-sac is free from deep infiltrating endometriosis and adherent bowel.

9. **Secondary ports**

How should secondary ports be inserted?

Secondary ports must be inserted under direct vision perpendicular to the skin, while maintaining the pneumoperitoneum at 20-25 mmHg.

C

During insertion of secondary ports, the inferior epigastric vessels should be visualised laparoscopically to ensure the entry point is away from the vessels.

C

During insertion of secondary ports, once the tip of the trocar has pierced the peritoneum it should be angled towards the anterior pelvis under careful visual control until the sharp tip has been removed.

C

Secondary ports must be removed under direct vision to ensure that any haemorrhage can be observed and treated, if present.

C

Before placing the lateral ports, it is essential that the inferior epigastric vessels are visualised from within the peritoneal cavity by the laparoscope and the entry point of the port is away from these vessels. The deep epigastric arteries and the venae comitantes running beside them can be visualised just lateral to the lateral umbilical ligaments (the obliterated hypogastric arteries) in all but the most obese patient. In the woman who is obese, the incision should be made well lateral to the edge of the rectus sheath, taking care to avoid injury to vessels on the pelvic side wall.

It is recommended that removal of the ports is also under direct vision in order that any haemorrhage can be observed and treated if present. Any non-midline port over 7 mm and any midline port greater than 10 mm requires formal deep sheath closure to avoid the occurrence of port site hernia.

Evidence level IV

10. The woman who is obese

What specific measures are required for laparoscopic surgery in the obese woman?

The open (Hasson) technique or entry at Palmer's point are recommended for the primary entry in women with morbid obesity. If the Veress needle approach is used, particular care must be taken to ensure that the incision is made right at the base of the umbilicus and the needle inserted vertically into the peritoneum.

C

Women who are grossly obese are at a significantly greater risk of complications when undergoing laparotomy. Laparoscopic surgery may therefore be of particular benefit to these individuals. It is generally recommended that an open (Hasson) technique should be performed for primary entry in women who are morbidly obese, although even this technique may be difficult. If a Veress needle approach is used in the woman who is morbidly obese, it is important to make the vertical incision as deep as possible in the base of the umbilicus, since this is the area where skin, deep fascia and parietal peritoneum of the anterior abdominal wall will meet. In this area, there is little opportunity for the parietal peritoneum to tent away from the Veress needle and allow preperitoneal insufflation and surgical emphysema. If the needle is inserted vertically, the mean distance from the lower margin of the umbilicus to the peritoneum is 6 cm (\pm 3 cm). This allows placement of a standard length needle even in extremely obese women.³⁸ Insertion at 45 degrees, even from within the umbilicus, means that the needle has to traverse distances of 11–16 cm, which is too long for a standard Veress needle.³⁹

Evidence level IV

11. The woman who is very thin

What specific measures are required for laparoscopic surgery in the woman who is very thin?

The Hasson technique or insertion at Palmer's point is recommended for the primary entry in women who are very thin.

C

Women at highest risk of vascular injury are the young, thin, nulliparous women with well-developed abdominal musculature; patients with severe anorexia are at particular risk. The aorta

Evidence level IV

may lie less than 2.5 cm below the skin in these women.⁴⁰ Great care, therefore, must be taken when performing first entry and a Hasson approach or insertion at Palmer's point is preferable in this situation.

12. Auditable standards

1. Documentation of appropriate counselling.
2. Clinical incident reporting of all adverse events or complications.

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APPENDIX

Clinical guidelines are: 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: *Guidance for the Development of RCOG Green-top Guidelines* (available on the RCOG website at www.rcog.org.uk/clingov1). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels	Grades of recommendations
Ia Evidence obtained from meta-analysis of randomised controlled trials.	A Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
Ib Evidence obtained from at least one randomised controlled trial.	B Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)
IIa Evidence obtained from at least one well-designed controlled study without randomisation.	C Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)
IIb Evidence obtained from at least one other type of well-designed quasi-experimental study.	Good practice point
III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.	<input checked="" type="checkbox"/> Recommended best practice based on the clinical experience of the guideline development group.
IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.	

DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available.

This means that RCOG Guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.

The Guidelines review process will commence in May 2011 unless otherwise indicated