

# Guideline on preventing entry-related gynaecological laparoscopic injuries: post-publication reflections of the senior author

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**Abstract** A few months ago, the Royal College of Obstetricians and Gynaecologists of the UK published the latest clinical guideline relevant to gynaecological surgery entitled “Preventing entry-related gynaecological laparoscopic injuries”, which is freely available for all to read on the college website. The preparation of this document not only took a long time, requiring a considerable amount of literature research, but also very arduous because we were required to make constant changes to the manuscript as a result of the comments and criticisms from the three lead reviewers of the Guidelines and Audit Committee but mainly from having to satisfy the objections of no less than 20 separate peer reviewers. By and large, the document has been well received by our colleagues, but this article intends to highlight some of the difficulties and problems encountered during production and to answer some of the criticisms we have received since publication.

**Keywords** Laparoscopic injury · Laparoscopic entry · Laparoscopic complications · Closed laparoscopy · Veress needle · Hasson technique · Open laparoscopy · Direct entry laparoscopy and clinical guidelines

## Introduction

For a number of years now, the Royal College of Obstetricians and Gynaecologists (RCOG) of the UK have produced guidelines as an educational aid to good clinical practice. Because they were produced in hard copy with a green line running across the top of the first page, they were colloquially referred to as green-top guidelines, but they are no longer produced in hard copy but can be downloaded from the RCOG website: <http://www.rcog.org.uk/index.asp?pageID=2426>.

These guidelines present recognised methods and techniques of clinical practice based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The recommendations are based on evidence-based medicine, as described below, and because they represent the views of the highest authority in our speciality in the UK, with additional input from international experts, and because they are extensively peer reviewed, they become the equivalent of “tablets of stone” particularly as far as the legal profession and hospital administrators are concerned, which is unfortunate.

The RCOG further makes the point that these recommendations are not intended to dictate an exclusive course of management or treatment, but they must be evaluated with reference to individual patient needs, local resources and limitations unique to the institution, bearing in mind that there will always be variations in local populations. Where there are areas of clinical uncertainty, they suggest that further research may be indicated and usually a date is set in the future when the guideline will be reviewed to take into consideration changes in medical or surgical practice that have occurred since the guideline was produced.

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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 as shown in the Appendix.

The past 50 years has witnessed a revolution in surgery with the introduction of minimal access surgery, which is now being used for an increasing number of gynaecological operations, replacing the large abdominal scars with multiple smaller incisions allowing the patient to recover with less pain and a quicker return to full activity. Although the advantages of this kind of surgery are obvious, the introduction of these techniques have unfortunately been associated with a worrying increase in litigation to the extent that virtually any injury or accident occurring during a minimal access procedure is likely to result in litigation, whereas similar injuries during open surgery can often be recognised and repaired during the original operation and not involving any increased length of hospital stay or delayed recovery.

Although there have been vast improvements in surgical proficiency and expertise combined with extraordinary advances in technology in terms of electronic and optical equipment, which have allowed properly trained and skilled surgeons to perform most gynaecological operations laparoscopically, there remains a major difference in the need to insert needles, trocars and cannulae in order to obtain access to the pelvic and abdominal organs.

In October 2006, I was approached by the Chairman of the Guidelines and Audit Committee of the RCOG and the Council of the British Society for Gynaecological Endoscopy (BSGE) to produce a guideline on their behalf, and I was ably assisted from the outset by Mr. Kevin Philips, who is a Consultant Obstetrician and Gynaecologist from Cottingham Hospital in Hull, North Yorkshire and former Honorary Secretary of the BSGE who had published several papers on different aspects of laparoscopic surgery. We had become aware of the wide variation of the techniques used by different surgeons and soon realised that it would be impossible in a small guideline to deal with all complications of laparoscopic surgery involving all the different operations performed. We also realised that the unique feature distinguishing laparoscopic surgery from open laparotomy or vaginal surgery is the first entry into the abdomen, which is common to all laparoscopic procedures, which may cause bowel or vascular injury. We decided therefore to concentrate the guideline on evaluating the evidence related to different entry techniques.

Complications of laparoscopic surgery can lead to considerable suffering for patients, their relatives and their doctors as well as increased financial costs in performing reparative surgery, and with any laparoscopic accident, there is increasingly a likelihood of progression to legal proceedings with all the financial costs entailed

therein. The main problem with bowel damage associated with laparoscopic surgery is the likelihood that such damage may not be immediately recognised and could present some time later, unfortunately, often after discharge from hospital. In a review of surveys of bowel injuries in the decade up to 2000, Brosens and Gordon found that 15% of bowel injuries were not diagnosed during laparoscopy and one in five cases of delayed diagnosis resulted in death [1]. It is essential therefore that patients and attending staff understand that the recovery from laparoscopic surgery is usually rapid, and where this is not the case that early diagnosis and treatment are essential, and senior medical staff should be involved. A potentially serious complication may require difficult reparative surgery often involving a disfiguring scar and, sometimes, a temporary colostomy.

As the relative infrequency of these accidents prevents any individual laparoscopic surgeon from gaining a true appreciation of their importance or frequency, it is necessary to resort to meta-analyses of a large series of published papers to assess the evidence.

### **Incidence of complications**

A review of the literature shows a dearth of comprehensive studies on complications, and we relied for the most accurate data on two national complication enquiries; a retrospective study from all hospitals in Finland and a prospective survey of selected hospitals in The Netherlands.

In Finland, 256 complications were reported to the National Patient Insurance Association following 70,607 laparoscopic procedures (3.6 per 1,000). Finland, like New Zealand, is one of the few countries in the world that operates a “no fault compensation scheme” for all medical injuries. Thus, it is likely to be a true representation of all the injuries sustained by patients throughout the country; otherwise, they would not receive the financial compensation to which they were entitled by law. The rate of major complications was 1.4 per 1,000 procedures comprising intestinal injuries (0.6 per 1,000), urological injuries (0.3 per 1,000) and vascular injuries (0.1 per 1,000) [2].

Jansen et al. reported the results of a prospective multi-centre study of 72 hospitals in The Netherlands in which there were 145 complications from 25,764 laparoscopies (5.7 per 1,000) [3]. There were two fatalities, and 84 women (3.3 per 1,000) required a laparotomy because of complications. There were 29 cases of gastrointestinal damage (1.13 per 1,000) and 27 lesions of intra-abdominal vessels (1.05 per 1,000); 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 per 1,000 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]. Evidence level III

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 per 1,000) [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 per 1,000) [8]. The bowel injuries in these studies occurred during simple procedures for diagnostic or sterilisation purposes where the pressure method, insufflating to 20–25 mmHg before inserting the primary trocar recommended for safe entry, in the Middlesbrough Consensus, was not employed [9]. Evidence level III

### 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 sub-headings, and this was combined with a keywords 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 BSGE, and our suggestions were critically appraised at a 1-day study meeting entitled “Avoiding complications of laparoscopic surgery” held on July 7th 2006 at the University of Surrey Postgraduate Medical School, with national and international speakers and colo-rectal, general and urological surgeons.

For the purposes of this article, the main recommendations of the Green-top Guideline are in italic type, and my observations as to the controversies and difficulties we had with each section are in regular type.

### Assessment, counselling and consent

We listed as a good practice point (GPP) the following section.

*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.*

During the preparation of the Guideline, there were some debates about the latter, but I am firmly of the belief that if the fascia is correctly sutured for all incisions more than 7 mm, then hernia formation should be almost impossible. Nevertheless, it was pointed out by peer reviewers that they had seen omental herniation through an umbilical port as small as 5 mm, so it was included in the recommendations.

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

This advice is not based on randomised controlled trials but on evidence obtained from expert committee reports or opinions and clinical experience of respected authorities and is therefore graded as evidence level IV (grade C).

It is important to bear in mind that most laparoscopic procedures in our specialty are performed electively and almost always for benign conditions. In an interesting paper by Beresford et al. reflecting on what patients wished to know about the risks of elective cardiac surgery, they concluded that 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]. In another survey on women’s views about the risks of laparoscopy, Kennedy and his group from Oxford University presented evidence from women undergoing diagnostic laparoscopy for pelvic pain suggested that they do want to know all the possible complications [11]. Potential complications should therefore be discussed according to the principles of counselling described in the excellent pamphlet published by the RCOG Clinical Governance Advice No. 6 “Obtaining valid consent”, which can be downloaded from the RCOG website.

### Safe surgical techniques and training

How should surgeons be trained in safe laparoscopic techniques?

In this section of the Green-top Guideline, there was again no evidence from randomised controlled trials, and

the advice given was merely a GPP and essentially common sense.

1. *Surgeons intending to perform laparoscopic surgery should have appropriate training, supervision and experience. GPP*
2. *Surgeons undertaking laparoscopic surgery should be familiar with the equipment, instrumentation and energy sources they intend to use. GPP*
3. *Surgeons undertaking laparoscopic surgery should ensure that nursing staff and surgical assistants are appropriately trained for the roles they will undertake during the procedure. GPP*

At the Minimal Access Therapy Training Unit in Guildford, we particularly stress to the trainees that they should rehearse at their simulators or work stations their reaction to emergency situations, which can arise with frightening speed during laparoscopic surgery and also to be absolutely certain that, in the operating rooms at their own hospitals, all equipment that could conceivably be needed for emergency reparative surgery should be instantly available. This particularly applies to vascular clamps and the equipment needed for the repair of major blood vessels and bowel.

The safe practice of any surgical technique lies in effective structured training and supervised practice. Clearly, for those surgeons intending to undertake even more complex laparoscopic procedures, this training will need to be supplemented by a process of mentorship, the trainee acting as an apprentice, performing surgery of increasing complexity with the support of an experienced laparoscopic surgeon for a minimal period of 1 year.

### Laparoscopic entry techniques

The most difficult and controversial aspect of preparing this Green-top Guideline was trying to get agreement over the safest laparoscopic entry technique. The document was extensively peer reviewed, not only by many very eminent gynaecologists from the UK but also from international experts, including Professor Ray Garry from the University of Western Australia who had convened the original Middlesborough Consensus meeting in 1999. We were honoured to have input from Peter Maher from Melbourne, the current President of the International Society for Gynecologic Endoscopy, and Tony Smith representing the British Society of Urogynaecology. We were particularly grateful for the advice of Mr. Bernie Ribeiro, the then President of the Royal College of Surgeons of England, although he would not countenance the idea that Veress needle entry is as safe as the open Hasson method, which is recommended by his

college for their trainees. We therefore felt it appropriate to describe in detail the two most popular techniques of entry and to try to discover what evidence, if any, favoured one over the other.

*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 to achieve this. Gynaecologists have tended to favour the closed or Veress needle entry technique whereby the abdominal cavity is insufflated with carbon dioxide gas prior to the introduction of the primary trocar and cannula. The Royal College of Surgeons of England recommend 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 (Veress needle) laparoscopic procedures, the risk of bowel damage was 0.4 per 1,000 and of major vessel injuries was 0.2 per 1,000 [13]. Evidence level IIa–III*

For the gynaecological fraternity, this was a particularly interesting study because the Australian College of Surgeons had quite deliberately set out to prove, once and for all time, that the Hasson open entry technique should be universally adopted, but when the results were analysed, they had, to put it colloquially, “shot themselves in the foot” and found that this assertion was unproven [14–17]. Additionally, we found two well-conducted, but relatively small, randomized controlled trials that found no evidence to suggest that one technique was clearly superior to another

*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 1a*

This dispute will probably never be entirely resolved to the satisfaction of those who insist on evidence-based medicine because the level of injury is so low that a simple power calculation suggests that to organise a clinical trial to prove a statistically significant difference in the safety of the two methods would require about 150,000 patients in each arm of the study.

### 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. Grade 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. Grade 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 the position of the aorta before insertion of the Veress needle. Grade 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. Grade C.*

It was for this reason that the Middlesborough Consensus recommended that a disposable Veress needle should be used in order to reliably hear these important clicks, which signify that these two layers have been penetrated, whereas for all other ports, reusable equipment could be justified on the grounds of economy.

*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. Grade C*

*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 Palmers 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]. Evidence level 1b*

#### Tests for correct placement of the Veress Needle

*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 (<8 mmHg) and the gas is flowing freely [22]. Evidence level 1b*

There has been a disturbing tendency among lawyers in recent years to enquire if these so-called safety tests have been carried out, implying that, if they have not, it suggests sub-standard care. This is therefore an important reference, but it is nevertheless suggested that it is good clinical practice to record on the operation record the initial and final pressure and volume of gas used and note if there were any entry complications.

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. Grade B*

*The distention 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. Grade B*

It is necessary to achieve a pressure of between 20 and 25 mmHg before inserting the trocar, as this results in increased splinting of the abdominal wall 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 should have been theoretically 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 was only 0.6 cm. When the same force was applied to an abdomen distended to 25 mmHg, the depth was 5.6 cm (range, 4–8 cm). The mean volume of CO<sub>2</sub> required to reach this pressure was 5.58 l [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 use the pressure technique, insufflating the abdomen to 20–25 mmHg before inserting the primary trocar. Evidence level IIb

This was the single most important recommendation of the Middlesborough Consensus Meeting held in 1999, but because it was only published in a specialist journal, *Gynaecological Endoscopy*, it was only read by relatively few surgeons whose main interest was laparoscopic gynaecological surgery.

Where should the primary trocar be inserted?

*The primary trocar should be inserted in a controlled manner at 90° 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. Grade C*

*Once the laparoscope has been introduced through the primary cannula, it should be rotated through 360° to check visually for any adherent bowel, and if this is present, it should be closely inspected for any evidence of haemorrhage, damage or retroperitoneal haematoma. Grade 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 inserted at Palmer's Point in the left hypochondrium. Grade 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. Grade C*

### **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. Grade C*

The Hasson technique of open laparoscopic entry is an alternative to closed laparoscopy, which 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

### **Alternative entry techniques**

What alternative entry techniques are available?

*Direct trocar insertion*

Direct trocar insertion is an acceptable alternative trocar insertion method. Grade 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 entry in terms of major complications; there may be an advantage when considering minor complications [20]. Evidence level Ia

Unfortunately, from my own point of view, as senior author of this Guideline, this was a recommendation that I was very unhappy about. I have little doubt that, in the hands of extremely experienced laparoscopic surgeons operating on very low risk patients, it is an acceptable entry technique and we certainly did not have the evidence base to prevent it being inserted into the Guideline. Nevertheless, I feel certain that, if used by less-experienced surgeons, it will result in injury and quite clearly lacks the built-in safety mechanisms of the more generally accepted entry techniques described above. It will be interesting to see if future complication audit studies support my misgivings.

### **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]. Visiport™ Covidien, Mansfield, MA, USA, radially expanding trocars [32], Step™ Innerdyne Inc., Sunnyvale, Ca, USA, Second Generation Endotip systems, EndoTIP™, Karl Storz, Tuttingen, GDR. 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*

### **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. Grade B*

The rate of adhesion formation at the umbilicus may be up to 50% following midline laparotomy and 23% following low transverse incision [37]. Therefore, the umbilicus may not 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. CO<sub>2</sub> is then instilled to 25 mmHg pressure, and a 2–5-mm endoscope is used to inspect the under surface 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 a lot of 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 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 pre-peritoneal 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 this entry site 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. Evidence Level III

## Secondary ports

How should secondary ports be inserted?

*Secondary ports must be inserted under direct vision perpendicular to the skin, whilst maintaining the pneumoperitoneum at 20–25 mmHg. Grade C*

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

*During the 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. Grade C*

*Secondary ports must be removed under direct vision to ensure any haemorrhage can be observed and treated if present. Grade 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 their 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 women. In obese women, 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 when the sharp trocar is introduced. The index finger of the operator's hand should be used to guard against accidental slippage of the trocar.

It is recommended that removal of the ports is also performed under direct vision in order that any haemorrhage can be observed and treated if present. Any non-midline port over 7 mm and a 5-mm port that has been used for repeated passages of trocars for the removal of tissue or change of instruments and any midline port greater than 10 mm require formal deep sheath closure to avoid the occurrence of port site hernia. Evidence level IV

## The obese woman

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

*The open (Hasson) technique or entry at Palmer's point is recommended for the primary entry in morbidly obese women. 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. Grade C*

Grossly obese women 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 to perform an open (Hasson) technique for primary entry in morbidly obese women, though even this technique may be difficult with a grossly thickened abdominal wall. If a Veress needle approach is used for morbidly obese women, 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 when the umbilical cord sloughs away soon after birth. In this area, there is little opportunity for the parietal peritoneum to tent away from the Veress needle and allow pre-peritoneal 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±3 cm. This allows placement of a standard length needle even in extremely obese women [38]. Insertion at 45°, 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, 40].

The endoscopic threaded imaging port (EndoTIP™ Storz, Tutlingen, GDR) is probably the instrument of

choice in very large women because the abdominal wall is elevated under laparoscopic vision during the entry process. The upward force and clockwise rotational movement allows all the layers of the abdominal wall to be seen, as they are picked up by the outer threads of the trocar and spread radially as the muscle and fascia are penetrated until a clear view appears of the peritoneum where a site of final penetration can be selected [41]. Evidence Level IV

### The very thin woman

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

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

Women at highest risk of vascular injury are the young, thin, nulliparous women with well-developed abdominal musculature, and patients with severe anorexia are at an even greater risk. The aorta may lie less than 2.5 cm below the skin in these women [41]. Great care, therefore, must be taken when performing first entry, and a Hasson approach or insertion at Palmer's point is preferable for these women. Alternatively, this would seem an indication par excellence for the Endotip™ (Storz, Tutlingen, GDR), since the threaded trocar is elevated during insertion under optical control and there is no downward pressure that could damage the great vessels, which are perilously close to the anterior abdominal wall underneath the umbilicus. For similar reasons, it is, in my opinion, the entry method of choice in morbidly obese patients. Evidence level IV.

### Conclusion

Several months have now elapsed since the publication of this Green-top Guideline, and the document has been well received with very little adverse criticism. It was followed by the Cochrane Collaboration publication on the same subject [42], which was drawn from the same evidence base and was virtually identical in its findings and recommendations, although they missed out several important meta-analyses.

The Middlesborough Consensus Document on safe laparoscopic entry followed an international meeting of gynaecologists and general surgeons with a special interest in laparoscopic surgery convened by Professor Ray Garry to critically evaluate the available published evidence on entry techniques [9]. I was pleasantly surprised to find that these recommendations had withstood the test of time since

they were produced in 1999, and we were really not able to improve on them in any significant way.

In a postal survey of all specialist gynaecologists in the UK and Ireland carried out in 2005, only 26% of the respondents were aware of these recommendations and only 34% had changed their technique in the previous 5 years. Only 16% insufflated to 25 mmHg, and fully, a third (32%) admitted to insufflating to only 15 mmHg or less. Sadly, only 39% had the patient in the supine position before inserting the Veress needle, only 44% inserted the needle beneath the umbilicus, 43% used a transverse incision and incredibly 56% did not check that the needle was correctly positioned [43].

Looking back, it was really a shame that the Middlesborough Consensus Document had not been published in a journal with a wider readership than *Gynaecological Endoscopy*, which was only read by those of us with a special interest in the development of laparoscopic surgery. We are hopeful that by publishing this Green-top Guideline online and in this more popular journal, it will be read by a wider audience and help to reduce the number of laparoscopic accidents and provide less opportunities for unpleasant litigation.

### Appendix

#### Classification of evidence levels

- Ia Evidence obtained from meta-analysis of randomised controlled trials
- Ib Evidence obtained from at least one randomised controlled trial
- IIa Evidence obtained from at least one well-designed controlled study without randomisation
- IIb Evidence obtained from at least one other type of well-designed quasi-experimental study
- III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
- IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

#### Grades of recommendations

- 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 and Ib)
- B. Requires the availability of well-controlled clinical studies but no randomised clinical trials on the topic of recommendations (Evidence levels IIa, IIb, and III)
- 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 I)

#### Good practice point (GPP)

Recommended best practice based on the clinical experience of the guideline development group.

## References

- Brosens I, Gordon A, Campo R, Gordts S (2003) Bowel injury in gynaecologic laparoscopy. *J Am Assoc Gynecol Laparosc* 10 (1):9–13
- Harkki-Siren P, Kurki T (1997) A nationwide analysis of laparoscopic complications. *Obstet Gynecol* 89:108–12
- Jansen FW, Kapiteyn K, Trimbos-Kemper T, Hermens J, Trimbos JB (1997) Complications of laparoscopy: a prospective multi-centre observational study. *Br J Obstet Gynaecol* 104:595–600
- Pierre F, Chapron C, de Poncherville L, Harchaui Y, Dognon L. French survey on gynaecological major laparoscopic surgery complications in unselected population of operators. ISGE Meeting, Birmingham, UK 8–10 December 1997
- Querleu D, Chevallier L, Chapron C, Bruhat MA (1993) Complications of gynaecological laparoscopic surgery—A French Collaborative Study. *N Eng J Med* 328:1355
- Chamberlain GVP, Brown JC (1978) Gynaecological laparoscopy—the report of the Working Party of the Confidential Inquiry into Gynaecological Laparoscopy. Royal College of Obstetricians and Gynaecologists, London
- Richardson RE, Sutton CJG (1999) Complications of first entry. A prospective laparoscopy audit. *Gynaecol Endosc* 8:327–334
- Jones KD, Fan A, Sutton CJG (2002) Safe entry during laparoscopy: a prospective audit in a district general hospital. *Gynaecol Endosc* 11:85–89
- A consensus document concerning laparoscopic entry techniques: Middlesborough, March 19–20 1999 (1999) *Gynaecol Endosc* 8:403–406
- Beresford N, Seymour L, Vincent C, Moat N (2001) Risks of elective cardiac surgery: what do patients want to know? *Heart* 86:626–631
- Moore J, Ziebold S, Kennedy S (2002) ‘People sometimes react funny if they’re not told enough’: women’s views about the risks of diagnostic laparoscopy. *Health Expect* 5:302–309
- Thomas WGE (1996) Minimal access surgery. The Intercollegiate basic surgical skills course: participant handbook. Royal College of Surgeons of England, London, pp 43–13
- Garry R (1999) Towards evidence-based laparoscopic entry techniques: clinical problems and dilemmas. *Gynaecol Endosc* 8:315–326
- Penfield AJ (1985) How to prevent complications of open laparoscopy. *J Reprod Med* 30:660–663
- Hasson HM (1999) Open laparoscopy as a method of access in laparoscopic surgery. *Gynaecol Endosc* 8:353–362
- Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIP-S) (2001) A systematic review of the methods used to establish laparoscopic pneumoperitoneum. ASERNIP-S Report No. 13, ASERNIP-S, Adelaide, South Aus
- Garry R (2006) Laparoscopic surgery. *Best Pract Res Clin Obstet Gynaecol* 20:89–104
- Cogliandolo A, Manganaro T, Saitta FP, Micali B (1998) Blind versus open approach to laparoscopic cholecystectomy: a randomised study. *Surg Laparosc Endosc* 8:353–5
- Bemelman WA, Dunker MS, Busch OR, Den Boer KT, de Wit LT, Gouma DJ (2000) Efficacy of establishment of pneumoperitoneum with Veress needle, Hasson Trocar, and modified blunt trocar (TrocDoc): a randomized study. *J Laparoendosc Adv Surg Tech A* 10:325–30
- Ahmad G, Duffy JMN, Phillips K, Watson A (2007) Laparoscopic entry techniques (protocol). *Cochrane Database of Syst Rev* (3): CD006583. doi:10.1002/14651858.CD006583.
- Briel JW, Plaisier PW, Meijer WS, Lange JF (2000) Is it necessary to lift the abdominal wall when preparing a pneumoperitoneum? A randomised study. *Surg Endosc* 14:862–864
- Teoh B, Sen R, Abbot J (2005) An evaluation of 4 tests used to ascertain Veres needle placement at closed laparoscopy. *J Minim Invasive Gynecol* 12:153–8
- Phillips G, Gary R, Kumar C, Reich H (1999) How much gas is required for initial insufflation at laparoscopy? *Gynaecol Endosc* 8:369–374
- Tsaltas J, Pearce S, Lawrence A, Meads A, Mezzatesta J, Nicolson S (2004) Safer laparoscopic trocar entry: it is all about pressure. *Aust N Z J Obstet Gynaecol* 44:349–350
- Dingfelder JR (1978) Direct laparoscopic trocar insertion without prior pneumoperitoneum. *J Reprod Med* 21:45–47
- Agresta F, De Simone P, Ciardo LF, Bedin N (2004) Direct trocar insertion versus veress needle in non-obese patients undergoing laparoscopic procedures: a randomised prospective single centre study. *Surg Endosc* 18:1778–1781
- Borgatta L, Gruss L, Barad D, Kaali SG (1990) Direct trocar insertion vs. verres needle use for laparoscopic sterilisation. *J Reprod Med* 35:891
- Byron JW, Markenson G, Miyazawa K (1993) Randomized comparison of verres needle and direct trocar insertion for laparoscopy. *Surg Gynecol Obstet* 177:259
- Gunenc MZ, Yesilgedlar N, Bingöl B, Onalan G, Tabak S, Gökmen B (2005) The safety and efficacy of direct trocar insertion with elevation of the rectus sheath instead of the skin for pneumoperitoneum. *Surg Laparosc Endosc Percutan Tech* 15:80–1
- Tansatit T, Wisawasukmonchol W, Bunyavejchevin S (2006) A randomized, prospective study comparing the use of the missile trocar and the pyramidal trocar for laparoscopy. *J Med Assoc Thai* 89:941–7
- Mettler L, Schmit EH, Frank B, Semm K (1999) Optical trocar systems: laparoscopic entry and its complications. (a study of cases in Germany). *Gynaecol Endosc* 8:383–389
- Turner DJ (1999) Making the case for radially expanding access system. *Gynaecol Endosc* 8:391–395
- Bhoynul S, Payne J, Steffes B, Swanstrom L, Way W (2000) Randomized prospective study of radially expanding trocars in laparoscopic surgery. *J Gastrointest Surg* 4:392–397
- Feste JR, Bojahr B, Turner DJ (2000) Randomized trial comparing a radially expandable needle system with cutting trocars. *J Soc Laparoendosc Surg* 4:11–15
- Mettler L, Maher P (2000) Investigation of the effectiveness of the radially-expanding needle system, in contrast to the cutting trocar in enhancing patient recovery. *Minim Invasive Ther and Allied Technol* 9:397–402
- McGurgan P, O’Donovan P (1999) Optical Veress as an Entry Technique. *Gynaecol Endosc* 8:379–382
- Audebert AJ, Gomel V (2000) Role of microlaparoscopy in the diagnosis of peritoneal and visceral adhesions and in the prevention of bowel injury associated with blind trocar insertion. *Fertil Steril* 73:631–635
- Holtz G (1997) Insufflation of the obese patient. In: Diamond MP, Corfman RS, DeCherney AH (eds) *Complication of laparoscopy and hysteroscopy* 4, 2nd edn. Blackwell Science, Oxford, pp 22–25

39. Hurd WH, Bude RO, DeLancey JO, Gauvin JM, Aisen AM (1991) Abdominal wall characteristics with magnetic resonance imaging and computed tomography. The effect of obesity on the laparoscopic approach. *J Reprod Med* 36:473–476
40. Levy BS (1997) Perforation of large vascular structures. In: Diamond MP, Corfinan RS, DeCherney AH (eds) *Complications of laparoscopy and hysteroscopy* 5, 2nd edn. Blackwell Science, Oxford, pp 26–29
41. Ternamian AM, Deitel M (1999) Endoscopic threaded imaging port (EndoTIP) for laparoscopy: experience with different body weights. *Obes Surg* 9:44–47
42. Ahmad G, Duffy JMN, Phillips K, Watson A (2008) Laparoscopic entry techniques. *Cochrane Database Syst Rev* (2): CD006583
43. Lalchandani S, Phillips K (2005) A survey of practices of consultant gynaecologists. *Gynaecol Surg* 22:245–249