



Principles of safe laparoscopic entry



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Introduction

Laparoscopy is now the preferred approach for performing diagnostic procedures and therapeutic interventions in gynaecology. Minimally invasive surgery is less disabling, reduced hospital stay and more cost effective to health care systems, when compared with conventional open operations [1–6]. Although the risk of major complications does not significantly differ between benign gynaecological laparoscopic and conventional open procedures, laparotomy has been associated with a 40% higher risk of minor complications [6]. Most often the risk of complications during laparoscopy occurs during initial entry into the abdominal cavity. The rates of life-threatening complications at the time of abdominal entry are low – 0.4 gastrointestinal iatrogenic injuries and 0.2 major blood vessel injuries per 1000 laparoscopies [7]. However these represent approximately 50% of all serious laparoscopic complications [8] and laparoscopic medico-legal litigations (http://www.piaa.us/LaparoscopicInjuryStudy/pdf/PIAA_2000). Minor complications include extra-peritoneal insufflation, which also occurs prior to the initiation of the intended surgical procedure, and postoperative wound infection.

On reviewing the published literature (gynaecology, urology, general surgery), it appears that most practitioners use one of three blind primary entry methods to access the peritoneal cavity during laparoscopic surgery: (1) the closed (classic or Veress needle) technique, (2) the open (Hasson) technique, and (3) the direct trocar insertion described by Dingfelder in 1978 [9,10]. Variations of these three techniques such as visual entry systems and radially expanding trocars are less frequently utilized. Evidence based risk management methods can be applied to deconstruct the primary abdominal entry into its three distinctly separate, interdependent and salient components; entry methods, entry instruments and entry sites [11]. Based on currently available data, no one abdominal entry method appears to be generally considered superior over another and recommended as the technique of choice [2,12–14]. However, in the large majority of trials, there is a type II error to detect complications. Since the complication rates are low, most trials are inadequately powered to detect statistically significant differences between the comparison techniques. For example, to show a difference in bowel injury rate of say 50%, *i.e.*

from 0.04% to 0.02%, a study population in excess of 800,000 patients is required [15]. Thus, surgeons should interpret with caution published data attempting to demonstrate a potential difference in rare complications, but also, erroneous belief that all entry techniques are equally safe should be rejected [12].

The U.S. Food and Drug Administration (FDA), the Center for Devices and Radiological Health (CDRH) and Systematic Technology Assessment of Medical Products (STAMP) published a Laparoscopic Trocar Injury report, where several important recommendations and important observations are made (<http://www.fda.gov/cdrh/medicaldevicesafety/stamp/trocar.html>) [16]. Moreover, clinical practice and research performed over the last few decades have provided evidence that allows the establishment of safety-promoting criteria regarding the execution of common alternatives for laparoscopic abdominal entry. In the present guideline, we have reviewed data through analysis of pertinent original works, previous reviews, available international and national guidelines and consensus expert opinion to present practical guidelines on principles of safe laparoscopic entry.

Methods

The working group initially defined relevant topics and formulated a list of key clinical questions for each laparoscopic entry technique (Table 1). A search from Medline/PubMed and the Cochrane Database, written in English and published up to September 15, 2015 was carried out using keywords: laparoscopic/abdominal entry/access, laparoscopic complications, Veress needle, pneumo-peritoneum, open (Hasson), visual entry, direct trocar, shielded trocar, and radially expanded trocar. The group selected and analyzed relevant publications, both original works and previous reviews, in which bibliographies were also checked to identify additional references.

In addition, international and national guidelines focused on laparoscopic entry were identified by searching the Web sites of the American Association of Gynecologic Laparoscopists (AAGL), American College of Obstetricians and Gynecologists (ACOG), Asia-Pacific Association for Gynecologic Endoscopy and Minimally Invasive Therapy (APAGE), British Society of Gynaecological Endoscopy (BSGE), European Association for Endoscopic Surgery (EAES), European Society of Gynaecological Endoscopy (ESGE), International Society for Gynecologic Endoscopy (ISGE), Nederlandse Vereniging voor Obstetrie en Gynaecologie (NVOG), Royal

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Table 1
Laparoscopic entry – topics and key clinical questions.

Topic	Questions
1. Safe surgical techniques and training	Which entry technique is associated with the lowest rate of failed entry and the lowest risk of complications (closed or open technique)? How should the surgeons be trained in safe laparoscopy?
2. Closed (Veress needle) entry technique	How should the closed entry technique be performed? - Skin incision - Veress needle placement sites - Angle of Veress needle insertion - Elevation of the anterior abdominal wall - Number of Veress needle placement attempts - Appropriate intra-abdominal pressure before the primary trocar insertion - Insertion of the primary trocar - Adequate intra-abdominal pressure - Extra-peritoneal insufflation - Secondary ports
3. Open (Hasson) entry technique	How should the open entry technique be performed? How should the trocars be removed (any technique)? What are the proven advantages and disadvantages of the open entry technique?
4. Alternative entry techniques	What alternative entry techniques are available? - Direct trocar insertion - Radially expanding access systems - Visual entry systems
5. High-risk patients	What specific measures are required for laparoscopic entry in very thin women and extremely obese women? Can laparoscopy be safely performed during any trimester of pregnancy and what specific measures are required?

Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Royal College of Obstetricians and Gynaecologists (RCOG), Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), Society of Laparoendoscopic Surgeons (SLS), Society of Obstetricians and Gynaecologists of Canada (SOGC), and Vlaamse Vereniging voor Obstetrie en Gynaecologie (VVOG). These guidelines were analyzed in parallel with the appraisal of supporting literature from which they derived their conclusions and recommendations.

For each topic (e.g., Veress needle technique) and each key question (e.g., creation of pneumo-peritoneum) the identified information was graded by the level of evidence (Table 2). The recommendations are formulated in accordance with the evidence quality rates, and validated through multiple cycles of literature consultation.

No Ethical Committee approval was required for this work.

Literature review, considerations and recommendations

Closed entry technique

The closed technique, also known as the classic or the Veress needle technique, consists of the following sequence: skin incision – Veress needle introduction – pneumo-peritoneum creation – primary trocar insertion. A pneumo-peritoneum using CO₂ was established to promote the safe insertion of sharp trocar/cannula system. This method was initially popularized by Raoul Palmer (France), in late 1940s [17], and became a widely accepted practice by a majority of gynaecologists [8,13,18,19]. Based on the 2008 Cochrane Review and its updates from 2012 and 2015, the risk of failed abdominal entry (8.5–11.6% and 2.6–3.0% on the

Table 2

Evidence quality grading and classification of recommendations (in accordance with the system adopted by the U.S. Preventive Services Task Force).

Quality of evidence	Strength of recommendations
I: Evidence obtained from at least one properly randomized controlled trial	A. There is good evidence to recommend the clinical action
II-1: Evidence obtained from well-designed controlled trials without randomization	B. There is fair evidence to recommend the clinical action
II-2: Evidence obtained from well-designed cohort or case-control studies, preferably from more than one centre or research group	C. The existing evidence is conflicting and does not allow to make a recommendation for or against the clinical action; other factors may influence decision-making
II-3: Evidence obtained from multiple time or place series, with or without the intervention. Dramatic results in uncontrolled trial could also be included in this category	D. There is fair evidence to recommend against the clinical action
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	E. There is good evidence to recommend against the clinical action I. There is insufficient evidence, in quantity or quality, to make a recommendation; other factors may influence decision-making

first and second attempt, respectively), extra-peritoneal insufflation (~2%) and omental injury (~2%) is substantial when the closed approach is chosen [12,13,20,21].

Clinical question: how should the closed entry technique be performed?

All equipment should be checked, correct connections confirmed and laparotomy instruments available in case of conversion. Urinary catheter and/or nasogastric tube are placed before laparoscopy since a filled bladder or stomach increases the risk of iatrogenic injuries [14]. To avoid displacement of the “pelvic” bowel in a cephalad direction and reduce the risk of damage to retroperitoneal structures by misdirection of the Veress needle or the primary trocar, the patients should be horizontal at the time of laparoscopic entry [22], although reliable studies on appropriate patient positioning are missing.

Skin incision

The skin incision should be at the deepest point of the umbilical pit as this is the point where all the abdominal wall layers (skin, subcutaneous layer, fascia and parietal peritoneum) merge and fuse, and there is an absence of muscles and subcutaneous fat. This is the thinnest entry point to the abdomen independent of patient's body mass index (BMI) (Fig. 1). At this point, the incision is performed with a No. 15 or a No. 12 curved scalpel blade, as the cutting edge of these blades only penetrates the skin whilst. Other pointed blades (such as a No. 11 blade), when used in a stabbing direction may penetrate through the entire abdominal wall and inadvertently injure underlying structures (expert opinion). This is especially important in thin women and paediatric patients [14,19]. The direction of the skin cut should always be aimed upwards, up to the level of the umbilical rim, resulting in an incision length of between 9 and 10 mm [7]. Injuries with the Veress needle or trocars may occur when the skin incision is not large enough to accommodate the cannula's diameter. With the CO₂ connected and flowing, check the Veress needle for proper spring action, opening of its tip, and unimpeded CO₂ flow [14].

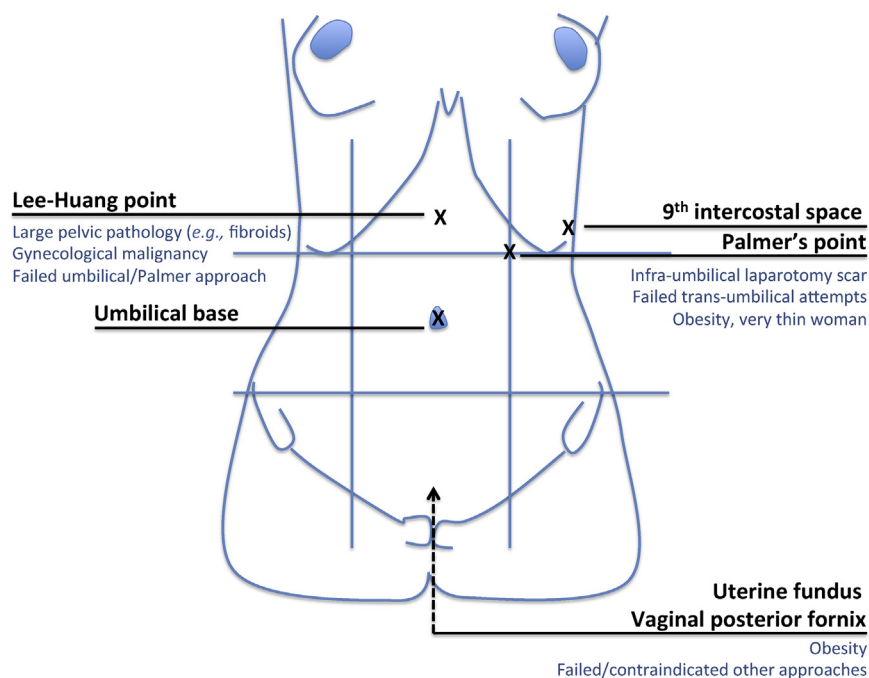


Fig. 1. Umbilical and alternative Veress needle insertion sites with respective indications.

A disposable single-use Veress needle may be required if a reusable one, fulfilling the safety criteria, is not available [23].

Veress needle placement sites

The base of the umbilicus or trans-umbilical insertion is contraindicated in patients with known or suspected umbilical pathology (e.g., adhesions, herniation) [24] or after three failed attempts to insert the Veress needle [25,26]. Varma and Gupta also advise Palmer's point (see below) when prominent aortic pulsations are palpated in close proximity to the umbilicus [7].

Left upper quadrant (LUQ), also referred as **Palmer's point**, is located 3 cm below the left subcostal border in the mid-clavicular line (Fig. 1) [17,23]. LUQ has been advocated in patients with longitudinal peri/intra-umbilical laparotomy scars, obesity [8,19,23,27], very thin women with android pelvis and prominent sacral promontory in whom large vessels lie within 2 cm of the umbilicus [28]. The LUQ entry should be also considered after three failed trans-umbilical attempts [7]. The Palmer's point serves for both Veress needle and primary trocar insertion after abdominal insufflation [23,29–33]. Gastric decompression is recommended especially in cases where difficult endotracheal intubation was encountered. Contraindications for this approach include splenomegaly, hepatomegaly, portal hypertension, gastric or pancreatic masses, history of a splenic or gastric surgery and presence or suspicion of left upper quadrant adhesions [34].

The **9th intercostal space (ICS)** at the anterior axillary line (Fig. 1) [23,33,35] is where the Veress needle is placed directly above the lower rib, to avoid neurovascular injury. Once pneumoperitoneum is established, the primary trocar and 5–10 mm laparoscope are introduced at the same point. Surgery may be performed using the LUQ point as the primary port. In 918 patients, included in a retrospective study on 9th ICS entry, a single case of iatrogenic pneumothorax and one case of stomach perforation were encountered [33].

Other reported Veress needle insertion sites for pneumoperitoneum include the **Lee-Huang point** (positioned in the midline between the umbilicus and sternal xiphoid process [36]), the **uterine fundus** [19,37] and **posterior vaginal fornix**

[18,19,38–40]. The last two approaches may be helpful in obese women [18,19,37–39], while the Veress needle and primary port placement through the Lee-Huang point have been found safe and useful in patients with large pelvic masses (e.g., fibroids) or malignancy [36,41,42]. The Lee-Huang point should be avoided in patients with previous supra-umbilical surgery.

Trans-umbilical Veress needle insertion: abdominal wall elevation and needle angulation

Some experts recommend the elevation of the lower anterior abdominal wall by hand or by the use of forceps/towel clips at the time of Veress and primary trocar placement [14,43]. According to the 2012 Cochrane review, there is no difference between lifting or not lifting the abdominal wall in reducing the risk of vascular or visceral injuries but elevation was found to be associated with a significantly higher rate of failed entry [20]. Thus, it cannot be recommended as a step of a routine procedure.

Some experts recommend displacement of the umbilicus caudally by the assistant's hands grasping and pulling the skin and subcutaneous layer of the lower abdominal wall caudally. This manoeuvre displaces the umbilicus by an average of 6 cm (range 2–9 cm) caudally minimizing the risk of injury to retroperitoneal structures [44].

A needle of appropriate length should be chosen to reach the abdominal cavity, especially in obese women when the LUQ site is used. Patient's body habitus is also decisive for the selection of the Veress needle insertion angle. Using CT scan measurements, the average distance between the umbilicus and the position of the aortic bifurcation is 0.4 cm, 2.4 cm and 2.9 cm in women with body mass index (BMI) <25 kg/m², 25–30 kg/m² and >30 kg/m², respectively [19,27,28]. Thus, the insertion angle of the Veress needle should vary between 45° in non-obese women, and 90° in morbidly obese women [14,19]. Applying a constant, but gentle pressure, the Veress needle is introduced with appropriate angulation in the mid-sagittal plane. Two clicks may be heard/felt, corresponding to the penetration of the abdominal fascia and parietal peritoneum, respectively. The insertion should be ceased as soon as the abdominal entry is achieved. Lateral movements of

the introduced needle must be avoided, since these may enlarge a puncture visceral/vascular injury of 1.6 mm to an injury of up to 1 or more cm [19].

Verification of correct Veress needle placement and the number of placement attempts

Various tests have been proposed and described to verify correct intraperitoneal placement of the Veress needle's tip. These include the double-click, saline hanging-drop, "hiss" sound and the aspiration/syringe test [45–47]. As these tests have not been found to be completely fool-proof, some experts do not consider performing these tests necessary [47]. By contrast several prospective studies have demonstrated that the initial intra-abdominal pressure (IAP) ≤ 8 mmHg provides a reliable confirmation of appropriate Veress needle tip placement through the umbilicus or Palmer's point [48–50]. In obese women IAP may be higher than in non-obese women, and can be up to 10 mmHg when the Veress needle is correctly inserted.

The rate of injuries associated with the Veress needle insertion dramatically increases with the number of placement attempts (0.8–16.3% for one, 16.3–37.5% for two, 44.4–64% for three and 84.6–100% for four or more attempts) [50]. If the Veress placement fails after 3 attempts, another insufflation-primary entry site, different entry instrument or alternate entry technique should be considered.

Adequate pneumo-peritoneum and primary trocar placement

Inadequate pneumo-peritoneum for primary trocar insertion is associated with a significantly increased injury risk. Therefore the use of insufflated CO₂ volume for this purpose must be avoided [19]. A Cochrane review compared low pressures (IAP < 12 mmHg) vs. standard pressures (IAP = 12–16 mmHg) in patients undergoing laparoscopic cholecystectomy [51]. The analysis, which included 15 RCTs (all of high risk of bias), demonstrated that low and standard pressure approaches do not differ in terms of iatrogenic morbidity, mortality and laparoscopy-to-laparotomy conversion rate. High-pressure insufflation has been also assessed [52–56]. With the increase of IAP, the free space under the umbilicus also increases and trocar penetration through the abdominal wall becomes easier and safer [14], but, simultaneously, a cardiovascular stress response is triggered [57,58]. In gynaecological patients, the use of high pressures (25–30 mmHg) instead of the standard IAP have been found to provoke slight changes in cardiac rate and arterial blood pressure and a significant decrease of approximately 20% in pulmonary compliance [56]. However, all of these hemodynamic changes did not produce adverse clinical effects [56]. Currently, there is no reliable evidence regarding the effects/safety of the high-pressure entry in patients with compromised cardiopulmonary function. However, it is important to remember that the acute Trendelenburg position (such as during robotic laparoscopic procedures) will have a far greater hemodynamic effect. Taking all together, IAP for primary trocar introduction should be 25 mmHg in healthy women with immediate IAP reduction to 12–16 mmHg after all trocars have been inserted. This pressure achieves three things: (1) creates a tense splinting effect of the abdominal wall that does not indent when linear penetration force is applied during trocar insertion, (2) creates approximately 6 cm distance between the anterior abdominal wall and the underlying intra/retroperitoneal organs/structures and (3) does not compromise venous return [22].

Primary trocar should be inserted in the same direction as the Veress needle, in a controlled, two-handed manner [7]. It is advised to keep the trocar valve open to be able to hear the gas flow,

indicating that the trocar tip is located in the abdominal cavity [14]. The laparoscope is then introduced and a 360° visual inspection is carried out to confirm the trocar position and identify any inadvertent injury and observe intraperitoneal anatomy and pathology.

Secondary ports

It is advisable to insert secondary (ancillary) trocars under direct vision, at a 90° angle (perpendicular) to the skin/abdominal wall, in a controlled, screwing manner. Direct visualization and skin trans-illumination may identify the epigastric vessels especially in thin patients [59–61]. A safe and useful site for secondary trocar placement is located on an imaginary line connecting the umbilicus and the anterior superior iliac crest, approximately 2 cm from the iliac crest [7].

Panel 1. Summary of recommendations for closed entry technique

Veress needle placement sites: *Umbilical base; LUQ*, if trans-umbilical entry fails after 3 unsuccessful attempts or there are umbilical abnormalities such as a hernia or suspected/known adhesions that contraindicate trans-umbilical entry (II-2/A); *alternative sites (e.g., Lee-Huang point, trans-uterine insertion)*, if both umbilical and LUQ insertion fail (I/A).

Elevation of the lower anterior abdominal wall during the Veress needle trans-umbilical insertion: *Not recommended as a routine practice* – abdominal wall lifting does not reduce the risk of iatrogenic injuries and increases the failed entry rate (II-2/B).

The angle of the Veress needle during the trans-umbilical insertion: *Adjusted to the patient's BMI*, from 45° in women with normal weight to 90° in obese patients (II-2/B).

Confirmation of correct Veress needle placement: *Veress Intraoperative Pressure (VIP ≤ 8 mmHg) is the only one reliable indicator of correct Veress needle placement. Other Veress placement tests are not necessary while swinging needle test must be avoided (II-1/A).*

Adequate pneumo-peritoneum: *Transient High Intraoperative Pressure Entry (HIP = 25 mmHg) in healthy women with immediate IAP reduction to 12–16 mmHg upon completion of all trocar insertions (II-1/A).*

Open entry technique

Open laparoscopic entry is a mini-laparotomy performed at the umbilical level, permitting the placement of a cannula followed by CO₂ insufflation and a laparoscope in a direct manner. The technique, initially described by Harrith Hasson in 1971 [62], and its variants were introduced to allow abdominal access without the use of sharp instruments other than using a scalpel blade and a Snap-Hemostat or Kelly clamp used to blindly perforate the parietal peritoneal membrane. The trocar/cannula systems engaged in this approach are blunt and the cannula can be secured in place by stay sutures to the anterior rectus fascia. In comparison with the Veress needle technique, the open entry has not gained such popularity by gynaecologists compared to general surgeons [19], probably due to differences in training, bias and patient subpopulations. The open laparoscopic entry is

widely considered to be the preferred method for patients with a history of previous surgeries (*i.e.*, suspected intra-abdominal adhesions) or after other entry techniques fail [20]. The open technique has also been used in pregnant women, as well as in very thin patients and children who have short anterior–posterior abdominal diameters [63].

Clinical question: how should the open entry technique be performed?

The umbilical skin is being incised transversely or longitudinally [19]. The length of the incision should permit subcutaneous tissue dissection, fascia incision and entry to the cavity under direct vision of each abdominal wall layer [62]. Parietal peritoneum can be opened either bluntly or sharply, and the cavity should be verified by palpation with a finger [14]. The cannula is then introduced with the blunt obturator in place. Royal College of Obstetricians and Gynaecologists (UK) states: “the fascial edges 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 (evidence level IV)” (<http://bsge.org.uk/userfiles/file/GtC%20no%2049%20Laparoscopic%20Injury%202008.pdf>) [64]. Currently, blunt-tip trocars with an inflatable balloon are frequently engaged to ensure airtight fixation [14]. After the primary trocar insertion, CO₂ is inflated to create the pneumo-peritoneum. The laparoscope is subsequently introduced and the cavity is inspected. Additional ports are established as described for the Veress needle technique, under direct visual control. At the end of the surgical procedure, both the fascial defect and the skin are sutured.

Clinical question: what are the proven advantages and disadvantages of the open entry technique?

Prevention of extra-peritoneal insufflation and gas embolism, and reduced incidence of vascular and intestinal iatrogenic injuries have been proposed as the main advantages of the open entry technique [62]. Several studies and reviews on the benefits and complications of the open vs. other laparoscopic entry techniques in gynaecology and other disciplines have been published [9,13,63,65–70], but there is no superiority of the open method or any other primary abdominal entry technique. The most recent Cochrane Review evaluated 13 laparoscopic entry techniques by analysing 46 RCTs (7389 participants), including three multi-arm trials [13]. Although the evidence was generally of very low quality, mainly due to imprecision and poor reporting of study methods, the authors concluded that the open technique is associated with a reduction in failed entry in comparison with the closed technique (Peto OR 0.16, 95% CI 0.04–0.63, $n = 665$, two RCTs, $I^2 = 0\%$). Assuming a risk of failed entry of 31 per 1000 patients when using the closed technique, the evidence indicates that between 1 and 20 patients will experience a failed entry with the open technique. In addition there is no significant difference in the incidence of accidental injury, vascular (Peto OR 0.14, 95% CI 0.00–6.82, three RCTs, $n = 795$, $I^2 = n/a$) or visceral injury (Peto OR 0.61, 95% CI 0.06–6.08, three RCTs, $n = 795$, $I^2 = 0\%$), while mortality, gas embolism or solid organ injury were not reported in any of the studies.

The European Association for Endoscopic Surgery guideline reported that, “insertion of the first trocar with the open technique is faster as compared to the Veress needle (grade A)” [19]. Nevertheless, there are studies indicating that there is no benefit in time [66,71]. For any entry technique, the reduction in the execution time and the decrease of the complication rate can be expected to follow the surgeon’s learning curve. Other suggested advantages of the open laparoscopic approach are facilitated retrieval of surgical specimens through the larger umbilicus incision and correct, anatomical, repair of the anterior abdominal wall defect.

Factors that may limit the use of the open entry include relative complexity of the technique, patient obesity and the difficulty of maintaining pneumo-peritoneum [66]. Despite the modifications of Hasson trocars, port site gas leakage remains a substantial and a bothersome problem. In the case of CO₂ leakage, many surgeons use towel clamps around the trocar or suture the incision.

Panel 2. Summary recommendation for open entry technique

The open (Hasson) technique may be considered as an alternative to the closed technique, being associated with a reduced rate of failed abdominal entry, without a significant difference in visceral or vascular injury rates (II-2/C).

Alternative approaches

Clinical question: what alternative techniques are available for laparoscopic entry?

Direct trocar insertion technique

In 1978, Dingfelder first published the description of the direct laparoscopic trocar insertion (DTI) a single blind step without prior pneumo-peritoneum as an alternative to the Veress needle technique [72]. The advantage of this method was thought to be avoidance of the complications related to Veress needle use, including extra-peritoneal insufflation, omental/intestinal insufflation and CO₂ embolism as well as failed pneumo-peritoneum [73–76]. Use of the direct trocar entry technique has been mainly reported in virginal abdomens and non-obese individuals [77–83]. Altun et al. described the direct abdominal entry in 155 morbidly obese patients as a safe and quick approach for laparoscopic bariatric surgery [84]. Direct trocar insertion is the fastest abdominal entry technique [19]. Upon muscular relaxation, bladder drainage and an intra-umbilical skin incision, the anterior abdominal wall is elevated by two towel clips or manually, and a sharp trocar/cannula is directly introduced aiming towards the hollow of the pelvis [80,84]. On removal of the trocar, the laparoscope is inserted to confirm appropriate placement of the cannula [45]. Then CO₂ is insufflated for secondary trocar insertion under direct visual control. The recommended trocars for direct peritoneal entry are to be sharp and pointed to minimize penetration force [16,85]. The use of both bladeless and bladed optical trocars have been also reported [86–91], although the manufacturers generally recommend the insertion of bladed optical trocars only after pneumo-peritoneum is established.

In comparison with the Veress needle technique, a lower risk of vascular injury has been associated with the direct trocar entry (Peto OR 0.13, 95% CI 0.03–0.66, five RCTs, $n = 1522$, $I^2 = 0\%$; low quality evidence) [13]. The direct trocar placement has been also found to reduce the risk of failed entry (Peto OR 0.21, 95% CI 0.14–0.30, seven RCTs, $n = 3104$; $I^2 = 0\%$; moderate quality evidence) [13]. Assuming a risk of iatrogenic vascular injury of 8 per 1000 patients when using the Veress needle, the evidence indicates that between 0 and 5 patients will experience a vascular injury with the direct insertion. For every 1000 laparoscopic interventions, 64 patients will experience failed entry with the closed technique vs. 10–20 patients with the direct insertion. Nevertheless the vascular injury significance obtained in this analysis may be unreliable since it was sensitive to the choice of the statistical tool used. On the other hand, 4 RCTs with very low quality evidence

did not demonstrate the existence of a statistically significant difference between the direct trocar and Veress needle entry for visceral injuries (Peto OR 1.02, 95% CI 0.06–16.24, $n = 1438$, $I^2 = 49\%$;) while 2 RCTs, also with very low quality evidence, did not find a significant difference between these two techniques regarding solid organ injuries (Peto OR 0.16, 95% CI 0.01–2.53, $n = 998$, $I^2 = n/a$) [13]. No events were recorded for gas embolism or mortality.

Based on the available evidence derived from 7 RCTs, surgeons erroneously believe that the direct primary trocar insertion technique is as safe as the other methods, although all reviews clearly state that none of the RCTs are powered to detect differences in major complications. Any recommendations from published studies attempting to show a potential difference in rare complications should be interpreted with extreme caution as they are severely underpowered [12]. Other issues associated with DTI may be that injuries to bowel and major blood vessels are more catastrophic which may lead to higher litigation, under reporting and difficulty defending unintended injuries. The catastrophic nature of DTI injuries is invariably related to the size of the hole created by the sharp trocar. For example, a <2 mm bowel injury from a Veress needle is likely to be self-limiting and require no treatment compared to larger trocar injuries [92].

Direct trocar injuries seem to have higher medico-legal litigation rates and may be more difficult to defend. Since cases of known or suspected adhesions from previous surgery should be excluded from direct trocar insertion, when injuries occur in absence of abnormal anatomy and/or malfunctioning of the trocar, then patient injury is usually ascribed to operator error (loss of controlled entry). Consequently they may not be defensible in a court of law. The evidentiary rule of *res ipsa loquitur* (the injury speaks for itself) may be applied when there is no other plausible explanation for the injury. In a case in United Kingdom, Palmer v Cardiff and Vale NHS Trust the judicial guidance accepted that in a patient without any apparent risk factors and a surgeon following a safe technique, the risk of injury is highly improbable. Thus the occurrence of any inadvertent injury under these circumstances would imply a negligent technique [93].

Taken together, further large studies are needed to fully evaluate the safety of the direct, gasless trocar insertion. Therefore, an evidence-based recommendation for practicing the direct abdominal entry cannot be currently established despite a number of reports supporting its safety even when performed by experienced surgeons.

Panel 3. Summary recommendation for direct trocar entry

The direct abdominal trocar entry provides a quick abdominal access and results in fewer extra-peritoneal insufflations and failed entries in comparison with the Veress needle entry (I/A), but its general use cannot be recommended until more reliable evidence is available.

Radially expanding access system

Introduced in 1994, the radially expanding access system (STEP, Medtronic Covidien, Minneapolis, MN) consists of a 1.9 mm Veress needle and an expansible external polymeric sleeve surrounding the needle. This system was developed to eliminate the use of sharp trocars, to avoid radial force and the need of fascial defect suturing, as well as to promote cannula stability [19]. Following Veress needle insertion and abdominal cavity insufflation, the

inner Veress needle is removed and the outer sleeve, that remains in the Veress needle tract, is dilated up to 12 mm by insertion of a blunt obturator trocar by twisting and pushing movements [94]. A study performed in pigs demonstrated that the force required to place this trocar is 14.2 kg vs. 4–6 kg force needed for placement of a disposable trocar [95]. STEP trocars have been found to offer reduced rates of entry failure, trocar-site bleeding and extra-peritoneal insufflations [13,56,96,97]. However, there is no evidence of a significant difference between the radially expanding and non-expanding trocars regarding vascular iatrogenic injuries (Peto OR 0.24, 95% CI 0.05–1.21, two RCTs, $n = 331$, $I^2 = 0\%$; low quality evidence), visceral injuries (Peto OR 0.13, 95% CI 0.00–6.37, two RCTs, $n = 331$, $I^2 = n/a$; low quality evidence), or solid organ lesions (Peto OR 1.05, 95% CI 0.07–16.91, one RCT, $n = 244$; very low quality evidence) [13]. Thus, the STEP use cannot be recommended as a modality that improves patient's safety in comparison with the traditional trocars.

Panel 4. Summary recommendation for radially expanding access systems

The use of radially expanding access system cannot be recommended as a safer modality than the laparoscopic entry using traditional trocars (I/A).

Optical trocar and cannula access (direct vision) technique

In an attempt to improve primary peritoneal entry, and alternative to conventional blind primary trocar entry instruments and techniques, a single use optical trocar or reusable direct vision threaded visual cannula instrument and technique have been developed. Unlike all other primary peritoneal entry methods and instruments, the peritoneal cavity is approached under direct monitor view, with the following three specialized optical devices and methods: the reusable optical Veress needle [98–100], the single use optical trocar and cannula [86,101,102], and the reusable threaded visual cannula [9,18,103,104].

The reusable optical Veress needle sheaths a needle-scope optical catheter into a modified reusable Veress needle that permits peritoneal entry by applying linear penetration force, while conveying a cascade of entry images to the operating room monitors. Generally they are useful in ambulatory settings to perform minimally invasive diagnostic procedures, via a 3-mm skin incision [105]. Currently, there is no evidence for their superiority in comparison with application of the conventional Veress needle entry [14].

The single use optical trocars and cannulas apply conventional push-through peritoneal entry principals. The surgeon palms the single use optical trocar and cannula with the dominant hand and applies linear penetration force, while the 0° laparoscope is sheathed into the hollowed trocar, that sports a pointed, but not sharp, transparent tip, to convey real-time primary entry images.

The single-use optical trocar, with a 0° laparoscope in the hollowed trocar, is placed into the skin incision (0.5–1 cm), perpendicular to the abdominal wall [90,106]. Gentle linear pressure is applied while observing the progression of the device tip through each layer of the abdominal wall. After the abdominal cavity is reached, the hollowed trocar with the 0° laparoscope is withdrawn, then the 0° laparoscope reinserted through the cannula and the abdominal cavity is inspected to confirm correct placement of the device as well the absence of any unintended entry injury [106].

Retrospective studies with variable number of included patients have provided contrasting reports on the complication rates associated with the optical trocar use [89,90,107,108]. For example, Brown et al. described large bowel injuries in two consecutive patients from a series including 96 patients [108]. One RCT (194 patients) with very low quality evidence did not find a significant difference between the direct vision and Veress needle entry in the rates of visceral injury (Peto OR 0.15, 95% CI 0.01–2.34) while other primary outcomes were not reported [13]. Currently there is no evidence of a difference between the direct vision technique and open entry regarding the visceral injury rate (Peto OR 0.13, 95% CI 0.00–6.50, two RCTs, $n = 392$; low quality evidence), solid organ injury rate (Peto OR 6.16, 95% CI 0.12–316.67, one RCT, $n = 60$, $I^2 = n/a$; very low quality evidence), or failed entry rate (Peto OR 0.40, 95% CI 0.04–4.09, one RCT, $n = 60$; low quality evidence) [13]. More importantly, no vascular injuries have been reported to occur, considering that vessel-related accidents remain the second most common cause of death during laparoscopy, second to anaesthetic mortality.

In summary, the use of optical (direct vision) systems may be considered as an alternative for laparoscopic entry. However, there is no evidence supporting that their use improves patient safety in comparison with the traditional closed or open entry.

The reusable Ternamian EndoTIP – Endoscopic Threaded Imaging Port (Karl STORZ Endoscopy, Tuttlingen, Germany) instrument was designed to completely depart from the conventional push-through trocar [45,109]. As with all visual entry systems, knowledge of anatomy, appreciation of navigational cues (perceptual blindness), and correct recognition of displayed monitor images (situational awareness), are essential competencies for safe deployment [11,103].

Conventional push-through trocar and cannula systems have the risk of uncontrolled linear entry which can cause unintended injury irrespective of surgeon's skill and training [110]. Threaded trocars eliminate the use of sharp instruments, convert the uncontrolled excessive linear entry force to a rotational radial penetration force (torque) and allow a visual entry, as a 0° laparoscope is sheathed into the hollow threaded cannula in lieu of a trocar. Threaded ports also allow successive anterior abdominal wall tissue layers to be tented upwards along the cannula's outer threads, using Archimedes' principle, to lift and transpose successive anterior abdominal wall tissue layers onto the cannula's outer thread until the cannula enters the peritoneal cavity safely, under visual control [109,111]. They avoid or at the very least recognize inadvertent mishaps, allowing repair, before irreversible tissue injury occurs. Vessels encountered along the cannula's path gravitate radially and are not injured [112].

A long-term multicentre prospective study using this method in 4724 cases reported no vascular mishaps and only one inadvertent enterotomy, where the transverse colon was adherent across the umbilical region. The injury was immediately recognized and repaired. A considerable number of these patients had more than one previous laparoscopies and laparotomies and in several cases left upper quadrant entry was secured safely using the threaded visual cannula [113].

In summary, the use of optical (direct vision) systems may be considered as an alternative for laparoscopic entry. However, there is no evidence supporting that their use improves patient safety in comparison with the traditional closed or open entry.

It remains important not to equate the published optical trocar and cannula injury rates with the threaded visual cannula's record, as all published optical entry complications involve the single use optical trocars and not the trocar-less visual cannula system. There are fundamental design and application differences between the two different types [16,96,112,114–116].

Panel 5. Summary recommendation for optical (direct vision) entry

The optical trocar (direct vision) entry is not superior to the conventional open (Veress needle) or closed (Hasson) entry techniques regarding the risk of iatrogenic injuries (II-2/B). Based on available evidence, published data, expert opinion and FDA assertion, the threaded visual cannula entry system appears to be a safe entry method and instrument (II-2/B).

Laparoscopic entry in high-risk patients

Clinical question: what specific measures are required for laparoscopic entry in very thin and extremely obese women?

In extremely thin patients (BMI <18 kg/m²), the distance between the anterior abdominal wall and the great vessels is short, sometimes less than 2.5 cm [14,22]. Thus, very thin individuals are at particular risk for retroperitoneal vascular injury during Veress needle and primary trocar insertion. Although there is limited quantitative data comparing different entry techniques in low BMI patients, the open technique and the closed technique at Palmer's point are preferred by many experts [14]. If the transumbilical closed technique is chosen, great care has to be taken to ensure that the patient is flat to avoid injury to the aorta or inferior vena cava [22]. The Veress needle should be introduced in the vertical axis until the fascia is reached and then reoriented towards the mid pelvis at a 45° angle once the fascia is breached [20,22]. Other experts recommend displacement by manual pulling of the umbilicus caudally prior to Veress needle insertion.

Similar to very thin patients, limited data are available comparing the safety of different entry techniques in extremely obese patients (BMI >40 kg/m²) [117]. Both open and closed, and visual entry can be performed, but the closed technique is advocated by experts as the preferable option either through umbilicus (which has the thinnest part of the anterior abdominal wall independently of the BMI) or Palmer's point [14]. A Veress needle of appropriate length should be chosen. Its insertion at the umbilicus should be performed at the angle of 90°.

Alternative techniques are the uterine fundus and posterior vaginal fornix, which may be helpful for Veress needle insertion in the obese women [12,15,18,19,37–39].

Clinical question: can laparoscopy be safely performed during any trimester of pregnancy and what specific measures are required?

Approximately 1 in 500–635 pregnant women requires non-obstetrical abdominal surgery [118,119]. The indications for laparoscopy are the same in pregnant and non-pregnant women [120]. The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) guideline on laparoscopy in pregnancy suggest that laparoscopic interventions can be safely performed in any trimester of pregnancy [120]. Literature search did not identify sufficient data that could allow us to establish a recommendation other than an expert opinion on laparoscopic entry during pregnancy. The working group agrees with the SAGES, suggesting that the entry point in a 2nd or 3rd-trimester pregnant patient should be adapted to the height of the uterine fundus and previous incisions. Upon this adjustment, the Hasson method, classic Veress needle technique or optical trocar or visual threaded cannula entry could be effectively and safely performed [120]. If the closed entry

is chosen, we recommend the primary entry *via* the Palmer's point. Regarding the IAP, the gas insufflation of 10–15 mmHg can be used. The IAP of 15 mmHg has been found safe, with no increase of the adverse outcomes to the patient or the fetus [120–122].

Panel 6. Summary of recommendations for laparoscopic entry in high-risk patients

The open (Hasson) technique and the closed (Veress needle) entry *via* Palmer's point are preferred in *the patients with the BMI <18 kg/m² and pregnant women* while the closed (Veress needle) technique or visual entry with the threaded visual cannula *via* the umbilicus or Palmer's point is preferred in *the obese patients with the BMI >40 kg/m² (III/D)*.

Final remark

Safe and effective clinical practice for laparoscopic entry would be best served if the gynaecological surgeon would use one technique (open or closed), entry position (e.g., umbilicus) and type of instrumentation (e.g., reusable, disposable or EndoTIP) with which he/she feels most comfortable for the majority of procedures. In particular circumstances where this trusted technique poses a major risk of complications, he/she should be willing to use one alternative technique or position or instrument that he/she has been adequately trained to use.

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