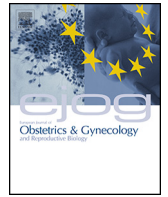




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Principles of safe laparoscopic entry



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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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