Establishing Pneumoperitoneum: What Is the Safest Technique for Pneumoperitoneum?

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13.1 How to Access the Peritoneal Cavity and How to Create the Pneumoperitoneum

The emergence of laparoscopy, which is currently widespread throughout the world as the technique of choice for many surgical procedures, was closely associated to the issues of pneumoperitoneum establishment and first access to the abdomen whereby the camera should be inserted. This step is a must for any laparoscopic surgery, and all surgeons who have dedicated themselves to the development of minimally invasive culture and procedures have devoted much effort and attention to the detection of a technique for pneumoperitoneum joining together speed, simplicity, safety, and low complication rate.

The techniques for optical trocar insertion can be divided into open and closed techniques; the latter in turn are divided into techniques with and without preliminary creation of pneumoperitoneum. Numerous variants, characterized by minute

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detail, have been provided. In this chapter, the SILS has not been analyzed: owing to the size of the door and to the peculiarities related to instrument management, this technique deserves a separate discussion.

13.1.1 Open Laparoscopy (OL) or "Minilaparotomy"

This is the technique originally described in 1971 by Hasson [1] and foresees the insertion of the camera trocar upon visual recognition of the intraperitoneal structures through a small laparotomy, eventually thanks to an S-shaped retractor. The visualization of the abdominal contents is considered a fundamental step in this technique. The access is usually umbilical and envisages the sequential opening of skin, subcutaneous tissue, linea alba, and peritoneum and the digital inspection of the inner surface of the peritoneal cavity.

The main advantage of this technique is that it minimizes the risk of preperitoneal insufflation and then gas embolism; other advantages include a high likelihood of success and a reduced probability of causing vascular and visceral lesions, even if this is not totally set at zero (two cases of aortic injury and multiple cases of small bowel injury [2, 3] have been reported); moreover, by OL it is easy to close the access site plan by plan, which could theoretically reduce the incidence of incisional hernia. The disadvantages are mainly related to the need to carry out an incision larger than in other techniques, with consequences on aesthetic and postoperative symptoms, and a greater chance of suffering from gas leakage during surgery. From a theoretical point of view, the greater size of the access and most trephination of tissues may lead to a higher rate of parietal infection.

Hasson himself in 2000 published a historical series of 5,284 patients over 29 years, bringing a total of 27 (0.5 %) complications related to the first access (comprising for the most part minor wound infections and minor hematomas [4]). In the following years, some small technical variations have been proposed, not altering the substance of the foregoing [5, 6].

13.1.2 Veress Needle Laparoscopy (VN) or Closed Laparoscopy After Creation of Pneumoperitoneum

The classical alternative to the open technique provides for the blindly creation of pneumoperitoneum through abdominal puncture with a Veress needle (an approximately 2 mm hollow needle with an obturator that retracts when it engages firm tissue such as fascia [7]) and subsequent, still blind, insertion of the first trocar for the camera, counting on the fact that the pneumoperitoneum has distanced the vascular and visceral contents of the abdomen from the abdominal wall. Many surgeons prefer still using Veress needle in the left upper quadrant instead of the umbilical scar, and in any case this is the place indicated in the presence of previous midline laparotomy. Many tricks have been reported in the literature, with the aim

to reduce injuries by VN [8, 9]: the use of a sharp Veress needle, patient lying level and in flat position, timing of trocar placement based on pressure rather than gas volume, and very high-pressure pneumoperitoneum, up to 25 mmHg.

This method has been classically used, especially in the gynecological field, more than the open laparoscopy, since it is considered less traumatic and more respectful of the principles of minimal invasiveness. However, disadvantages are well known, even from a theoretical point of view, as not only does this technique entail an increased risk of serious vascular and visceral injury but also the same can remain unrecognized. In an outdated French study, focused on vascular lesions, it was shown that more than ¾ of them had been caused by the VN [10].

Even the VN technique has recently received some proposals for amendments, with the aim to reduce the risk of vascular and visceral lesions while maintaining the highest minimal invasiveness; the most reported modification of the VN technique is represented by the STEP system (Inner Dyne, Sunnyvale, California, USA): after introduction of the classical VN, the needle is removed, and the outer sleeve, which remained in place, is used as a guide for a series of dilations through which a port up to 12 mm diameter may be obtained [11].

13.1.3 Direct Trocar Insertion (DTI), Direct Entry Technique, or Closed Laparoscopy Without Creation of Pneumoperitoneum

An alternative to the two classical techniques above described, called DTI, has developed in recent years and has taken more and more space among the surgeons dealing with laparoscopy [12]. This technique provides, with many variations, a small skin incision and the insertion of the first trocar without having preliminarily induced pneumoperitoneum. Some authors suggest lifting the skin at the time of the introduction of the trocar [13] and others to lift the fascia, and many surgeons use this technique with a disposable shielded trocar. After visual check that the tip of the trocar has crossed the peritoneum, gas insufflation may start. After the procedure, it is generally not necessary to close the parietal defect.

The advantages of this technique are a smaller incision and a rate of gas leakage lower than the OL, while the time of obtaining pneumoperitoneum and the probability of gas insufflation in the abdominal wall are lower compared to VN. The disadvantages are a success rate lower than the OL and a risk of vascular and visceral injury greater than the OL (but less than the VN). The rate of parietal infection may be less than in OL and similar to VN. Obviously, for the fact of being a closed technique, the DTI is not ideal in patients with a history of peritonitis or with scars from previous abdominal operations.

Recent developments in medical technology have focused more on the DTI than on the other techniques; in particular, trocars shaped to apply a radial force and trocar housing the camera at the same time of the entrance through the abdominal wall (the so-called optical trocar) have been developed.

13.2 Complications in Establishing Pneumoperitoneum: Classification and Definition of Outcomes

Possible complications of the first access for laparoscopy can be classified into major and minor and intraoperative and postoperative (early and late). There is no unanimous agreement on this classification, particularly with regard to the judgment about the severity of a complication. Strictly speaking, a complication should be considered major if it leads to a change in normal operative and postoperative procedure (i.e., significant lengthening of the intervention time, blood transfusions, conversion to laparotomy, longer length of stay, ICU course, and mortality). Cochrane review classifies the complications as follows: major complications are mortality, vascular injury, visceral injury, gas embolism, solid organ injury, and failed entry (unable to access the peritoneal cavity); minor complications are extraperitoneal insufflation and trocar site bleeding [14].

In more detail:

1. The major vascular complications consist in damage of the great retroperitoneal vessels. Unfortunately, some cases were recorded, although anecdotal, of patients who died of VN accidental injuries of the iliac and cava veins, because the time between the placement of the needle and the introduction of the camera is sometimes more than a few minutes and in this time a significant amount of blood may leak from this kind of vascular tear.
2. The major visceral complications consist in the creation of a full-thickness tear in the wall of an intestinal loop, stomach, or colon. The puncture with VN rarely entails severe damage; it has been shown that a visceral hole made from a needle, although large, can repair itself after needle extraction, due to the overlapping of different layers by which the visceral wall is composed; the injury to a viscus done by the first trocar inserted with closed technique is more serious, owing to the size of the trocar itself. Visceral lesions made by OL have normally less consequences, as they are caused by failure in recognizing the structure that is going to be opened, which is exchanged for the parietal peritoneum and is instead the bowel serosa. Indeed, the most important aspect of the gastroenteric damage is the timing of recognition, which is usually immediate with OL and DTI coupled with optical trocar, while by classical DTI and VN it cannot be recognized. The rare cases of death due to abdominal sepsis from iatrogenic fistula were due to lack of intraoperative recognition of the lesion and then to the delayed treatment of peritonitis, especially when at the end of the procedure an abdominal drain is not left in place.
3. Another organ that can be damaged during the first access for laparoscopy is the bladder; obviously, the lack of bladder catheter and very low incision are risk factors for this eventuality. Sometimes the bladder is completely passed away, so even intraoperatively the lesion cannot be recognized. The late consequences are less severe than those mentioned above; the simple and often prolonged maintenance of the bladder catheter allows for the bladder healing.
4. Injury of solid organs (liver, spleen, kidney) and of the omentum is reported less frequently and is almost always quickly recognized for bleeding; their

intraoperative treatment, though it may sometimes require laparotomy, is normally easy.

5. Minor vascular complications consist of parietal vessel lesion, the most frequent of which are represented by the injury to the epigastric vessels and, more laterally, to circumflex iliac vessels. Often during surgery, trocar buffers bleeding, which, however, continues after the trocar avulsion; bleeding in the abdomen in the postoperative period is a rather frequent event, which may require blood transfusions, angiographic treatment, or reintervention .
6. If the Veress needle is not positioned correctly beyond the parietal peritoneum, the insufflation of gas in the preperitoneal space can lead to troublesome subcutaneous emphysema and in rare cases even to gas embolism, of which some fatal cases were reported. Both the DTI and OL techniques virtually set at zero the risk of this complication.
7. The Veress needle may otherwise be located within the omentum, and inflation may continue in this structure, resulting in the creation of intra-abdominal air collections that can partially hinder the operation. The same can happen, even with DTI and OL, with the round ligament, which is a frequent site of pneumatosis by insufflation.
8. The unsuccessful establishment of pneumoperitoneum is a classical and frequent complication of the VN, which is significantly lowered by DTI and virtually cleared by OL.
9. The most frequent early postoperative complication is represented by the infection and the hematoma at the entry point of the port. Some risk factors related to the patient (diabetes, obesity, immunosuppression) and to the technique (OL brings a greater risk than DTI and VN; multiple repositioning of the trocar carries a higher risk) have been identified; obviously, the main risk factor is constituted by the presence of an intraperitoneal contamination, associated to a not protected extraction of the surgical specimen from the wall.
10. A dreaded late complication is the port-site incisional hernia, which entails the need for a second operation, in most cases with placement of a mesh. This occurrence is more frequent with port placed by OL through large fascial incisions and for cases in which the parietal defect is not sutured at the end of the intervention.

Overall, the incidence of complications related to the placement of the first trocar and the induction of pneumoperitoneum is extremely low, but many authors have pointed out that even an incidence proportionally negligible, compared to the extremely high number of procedures performed every day throughout the world, assumes an epidemiological importance; for instance, more than 250 major injuries/year would be expected in the UK alone [8]. Obviously, this considerably limits the possibility of addressing this topic with the principles of evidence-based medicine: in a study by Garry, it was estimated that to reduce the incidence of intestinal injury from 0.3 to 0.2 %, it would have been required 828,204 patients [15].

The incidence of injury to the great vessels is about 0.09 % and injury to the bowel is about 0.18 % [14]. However, in other studies, the relationship between these two events seems reversed: out of the 629 lesions described in the Medical

Device Reports to the FDA between 1993 and 1996, 65 % were vascular and 29 % visceral lesions [16]. Other series reported an incidence of vascular lesions varying from 0.04 % [17] to 0.14 % [18] and 0.18 % [19] in retrospective evaluations of 103,852, 2,201, and 14,243 laparoscopic procedures, respectively; visceral lesions in the same series ranged from 0.06 to 0.4 %.

The incidence of minor parietal complications is rather higher, although data are significantly different in published series, probably in relation to a different definition of these complication: Lal, for example, in 2004 reported 6.49 % of minor umbilical sepsis and 2.91 % of periumbilical hematoma in 755 laparoscopies performed with OL [20], but then in a later paper by the same group, including 6,000 cases, wound infections had fallen to 0.9 %; the port-site hernia rate in this second series was 0.4 % [21].

13.3 Analysis of the Literature

The first laparoscopic access and the creation of the pneumoperitoneum are one of the surgical areas of investigation in which in recent years evidence-based medicine principles have been most frequently applied; however, while in the 1990s and 2000s several prospective studies were conducted, sometimes randomized and blinded, in recent times systematic reviews and meta-analysis have prevailed. The reason for this lies in the fact that the low incidence of complications necessitates the examination of an extremely large sample, the collection of which in a single center or in a single series is difficult.

13.3.1 Retrospective Studies

In the 1990s and 2000s, several authors have retrospectively revisited their experience; most of them finally suggest, based on clinical results and probably also on their own belief, that OL is safer than closed laparoscopy (EL 4) [22, 23].

13.3.2 RCT

A substantial amount of studies has compared OL with VN [24–28], concluding that OL is safer and faster (EL 2), with the exception of one study [28]; however, this series is focused only on the setting of polytrauma and shows that VN was faster (but not safer). Moreover, the average time for the creation of the pneumoperitoneum by OL in this paper was more than 7 min (while VN was 2.7 min), much higher than reported in most other series. Some studies provide evidence that OL reduces the rate of failed entry with respect to VN.

One study compared OL with DTI [25], however in a subgroup of patients (this was not the only comparison in this study), and another study [29] compared OL

with DTI with optical trocar (direct vision); none of these studies demonstrated a significant advantage of one of the two techniques (EL 2).

Several prospective studies have compared VN and DTI [25, 27, 30–33]; another paper compared VN and DTI with optical trocar [34]. Generally speaking, the majority of these studies pointed out that DTI allows a significantly lower incidence of failed entry (LoE 2), extraperitoneal insufflation (LoE 2), and omental injury (LoE 2), while no one could document a significant reduction in major adverse events neither of wound infections (LoE 2).

Finally, other randomized trials have compared standard trocars with radially expanding trocars (STEP), showing that the latter significantly reduce the incidence of bleeding from the port (LoE 2) [35], lifting and not lifting the abdominal wall before Veress needle insertion (LoE 2) [36], carbon dioxide gas insufflation with gasless laparoscopy (LoE 2) [37], a closed technique versus a parallel technique of Veress needle insertion (LoE 2) [38], and cutting versus blunt trocar (LoE 2) [39].

13.3.3 Multicentric Surveys and Systematic Reviews

Already in 1997, a first literature review, mainly based on retrospective series—in which the risk of underreporting is high—examined 489,335 cases of VN and 12,444 cases of OL: the rate of visceral injury was found to be 0.083 % with a mortality of 2.5 %, and the rate of vascular injury was 0.075 % with a mortality of 0.8 % in the VN group, while in the OL group the incidence of visceral injury was 0.048 % with no mortality, and there was no reported incidence of vascular injury [40]. The conclusion was that OL was the safer technique (LoE 3).

Another review mainly based on observational studies was published in 2002 [41]; even in this paper, it is hypothesized that, at least from the point of view of vascular complications, the OL would seem to be safer (LoE 3).

In 2003, a systematic review conducted by Merlin and Coll. [42], including prospective studies of open versus closed (VN + DTI) laparoscopy, indicated for OL a trend toward a reduced risk of major complications, of access-site herniation, of minor complications (by 57 %), and of conversions to laparotomy (LoE 3).

The meta-analysis published by Larobina and Coll in 2005 [43] included 760,890 cases of closed laparoscopy (336 major vascular injuries, a mean rate of 0.044 %, 1 injury per 2,272 cases) and 22,465 cases of OL (0 vascular injuries, $P = 0.003$). Visceral injuries occurred more frequently in closed laparoscopy (515 cases, mean rate 0.07) than in open laparoscopies (11 cases, mean rate 0.05; $P = 0{:}18$) (LoE 2).

In 2009, 2 important studies appeared: Azevedo [44] published his meta-analysis of 38 articles including overall 696,502 laparoscopies with VN, in which 1,575 injuries were reported (12.23 %), 126 (8 %) of which involved blood vessels or hollow viscera (0.018 % of all laparoscopies). Again in 2009, another meta-analysis was published [45], including 31 studies, in which OL was considered safest in 17 studies (54.84 %) and the closed approach safest in only 3 (9.68 %). Both papers concluded that OL is safer than VN (LoE 2).

13.3.4 Cochrane

The issue we are dealing with in this chapter has been the subject of a preliminary assessment by the Cochrane in 2008 [46] and of a revaluation in 2012 [14]. The latter is part of the editorial group, Cochrane Menstrual Disorders and Subfertility, and contains a comprehensive assessment of randomized trials comparing one technique with another until February 2011. In total, the authors selected 28 randomized controlled trials, which have as their object 4,860 patients; 14 types of comparisons have been reported in these studies. From an extremely thorough evaluation, it appears that none of the published studies were of high quality, for a series of bias, the most important of which was the lack of statistical power calculation. Several other methodological limitations characterize some of the papers: the absence of clear and homogenous exclusion criteria, the lack of information about the learning curve of the operators, the undefined preliminary outcomes, and the unclear method of randomization; moreover, intention to treat analysis was employed in only 3, and source of funding was declared in only two trials.

And indeed from this systematic review, no significant difference between the various techniques is revealed in the incidence of major complications (LoE 1). The failure to place the optical trocar into the peritoneal cavity was instead significantly less frequent with OL and DTI than with VN (OR 0.12, 95 % CI 0.02–0.92, and OR 0.21, 95 % Cl 0.14–0.31, respectively) (LoE 1). Extraperitoneal insufflation (OR 0.18, 95 % Cl 0.13–0.26) and omental injury (OR 0.28, 95 % CI 0.14–0.55) were less frequent with the DTI than with the VN (LoE 1).

13.4 Discussion and Final Remarks

From a historical perspective, considering with how fast and disruptive force laparoscopy has emerged as a standard approach for numerous surgical procedures, it was inevitable that the first step of this approach to the peritoneal cavity was one of those most subject to critical evaluation. All surgeons in their training phase have classically addressed the formative steps of access to the abdominal cavity by laparotomy; there is no doubt that, with the exception of the "hostile abdomen" due to the presence of multiple and diffuse entero-parietal adhesions, this procedure is easier to run than the creation of the pneumoperitoneum and the introduction of the camera. The complications of these technical steps, as far as rare, can be really dramatic, affecting the benefits that the mini-invasive technique certainly delivers.

For all these reasons, the scientific analysis of the best technique to start a laparoscopy is of considerable and widespread interest. And yet this is an area where there is reluctance by experienced surgeons to accept the dictates of evidence-based medicine: a 2007 survey between the English gynecologist experts in minimally invasive surgery [47] showed that more than one-third of them were unwilling to change practice (EL 3). The main reason for this lies in the fact that, as previously stated, there is no good-quality scientific evidence in favor of a technique or another.

However, some data appears reasonably clear. The ideal technique should be both effective, safe, and ultimately fast. Well, even if there are no data that identify any of the available techniques to be certainly superior to the other in these terms, it seems that what is logical and what was reported as statistically significant in the overall match at least does not belie.

What is logical:

1. That OL has a higher success rate than DTI and VN
2. That OL is safer (with regard to the major complications) than DTI and DTI is safer than VN
3. That DTI is faster than OL and VN

What emerges as significant from the available studies:

1. That OL and DTI have a higher success rate than VN
2. That OL and DTI are safer (with regard to major complications) than VN
3. That DTI is faster than OL and VN

The above would seem to point toward the use of DTI as the elective access for laparoscopy; however, safeguarding, as is obvious, the freedom of every surgeon to use the technique that is most convenient to him, that he knows best, and that in his own experience has created fewer problems for patients he operated.

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