

Pneumoperitoneum – Update 2006

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Introduction

The European Association for Endoscopic Surgery (EAES) published guidelines concerning pneumoperitoneum for laparoscopic surgery in 2002 [14]. This extensive documentation concerns evidence-based clinical practice guidelines focussing on the pathophysiological basis for clinical indications, establishing pneumoperitoneum and perioperative aspects. Technique-specific complications are of great concern and most of these are related to the access of the abdominal cavity and the creation of pneumoperitoneum in laparoscopic surgery.

Under the mandate of the EAES Scientific Committee, an update concerning the access technique, insufflation pressure and warming of the insufflation gas has been performed. The pathophysiological bases for the clinical indications and perioperative aspects are not discussed in this update.

Methods

For this update a systematic review was performed by searches (as of March 2006) in Medline, the Cochrane Library and reference lists. The update includes studies published between 1999 and 2006 that have not been referred to in the previous guidelines. The medical subject headings used were laparoscopy, pneumoperitoneum in combination with access, Veress, open, insufflation, warming, humidified and randomised. The primary intention was to identify clinically relevant randomised controlled trials (RCTs). Systematic reviews and large individual cohort studies were also included. No animal studies were included. Only studies written in English were considered. All studies were graded according to the scientific-evidence level described by Sackett et al. [16] also used in the previous EAES guidelines.

The tables of RCTs have been updated from the previous guidelines and summarised in three settings: clinical trials of different access techniques, low- and high-pressure pneumoperitoneum, and hypothermia.

Access Techniques

Consensus 2002: For severe complications (e.g. vessel perforation) it is impossible to show a difference between closed- and open-access techniques in RCTs; therefore, large-outcome studies should be considered. In the RCTs, the rate of major and minor complications is surprisingly high, which may be due to the surgical learning curve or to how “complication” is defined. Insertion of the first trocar with the open technique is faster compared with that of the Veress needle (grade A). The RCTs comparing closed (Veress/trocar) versus open approaches have sample sizes that are not sufficient to show any difference in major complications. In large-outcome studies there were fewer complications in the closed group (grade B). The committee analysing the RCTs found the open approach faster and it was associated with a lower incidence of minor complications (grade A). The committee could not favour the use of either access technique. However, the use of either technique may have advantages in specific patient subgroups (grade B).

Update 2006: Meta-analysis of nonrandomised studies comparing open versus closed (Veress/trocar) access concluded a trend towards a reduced risk of major complications, access-site herniation and minor complications in nonobese patients during open access (grade B). Data regarding different closed techniques; direct trocar insertion, Veress/trocar and Veress/radially expanding access (REA) has been added. Major complications in studies of direct trocar versus Veress/trocar were inconclusive (grade B). Minor complications in RCTs were fewer with direct trocar insertion compared with Veress/trocar (grade A). REA versus conventional cutting-tip trocar (second trocar) in a RCT causes less postoperative pain, better patient satisfaction and fewer local wound events (grade A). There is no RTC large enough to address serious complications.

There are four basic techniques used to create pneumoperitoneum: open access technique, blind Veress followed by either a conventional cutting-tip trocar or a REA device, direct trocar insertion with elevation of the rectus sheet and optical trocar insertion.

The true incidence of visceral and vascular injuries of the aforementioned techniques is still unknown but is believed to be less than 1%. Differences that occur by chance would be difficult to discern without exceptionally large sample sizes.

Five randomised clinical trials of different access techniques are described in Table 3.1. Two of these studies included more than 500 patients and both compare direct trocar insertion to Veress/trocar access. It is concluded that the Veress/trocar causes an unacceptably high number of complications, but mostly are minor. The direct trocar insertion is easy and effective (grade A) [1, 8]. The use of the open balloon blunt-tip trocar is described as simple

Table 3.1. Randomised clinical trials of different access techniques

References/ years	No. of patients, and operations	Treatments	Methods	Results	Conclusion
Gunenc et al. [8]/ 2005	578 Randomised method not described, gynaecologic surgery	277-DTI 301-VN ^{a)}	Emphysema, entry failure and other complications	Emphysema: 0-DTI, 11-VN ($p < 0.05$) Entry failure: 2-DTI, 14-VN ($p < 0.05$) Other complications: 2-DTI, 8-VN (NS)	DTI is easy and effective
Agresta et al. [1]/ 2004	598 Single-blind general surgery	275-DTI 323-VN ^{a)}	Feasibility, complications in nonobese patients	Feasibility same Minor complications: 0-DTI, 18-VN ($p < 0.01$) Major complications: 0-DTI, 5-VN (NS)	VN unacceptable; high number of complications (7.4%)
Yim et al. [23]/2001	34 Double- masked ^{b)} adnexal surgery	34-REA 34-CCTT	Severity (VAS) and duration of pain, scar length, patient satisfaction and complications	Reduction in severity and duration of pain, shorter wound length, higher patient satisfaction in REA 4-epigastric bleeding in CCTT	REA had less postoperative pain and better patient satisfaction
Bernik et al. [3]/2001	180 Randomised method not described, chole- cystectomy	118-open BBTT 34-open Hasson 28-VN ^{a)}	Access time and gas leakage	BBTT faster; gas leakage inconclusive	BBTT simple and rapid
Bhojrul et al. [4]/ 2000	244 Double- blind general surgery	119-REA 125-VN ^{a)}	Complications, pain (VAS) and incisional hernias	Fewer port site complications in REA. Pain similar. No hernias	REA results in fewer local wound events

BBTT balloon blunt-tip trocar, *CCTT* conventional cutting tip trocar, *DTI* direct trocar insertion, *NS* not significant, *REA* radially expanding access, *VAS* visual analogue scale, *VN* Veress needle.

a) Veress needle followed by conventional cutting-tip trocar.

b) Self-controlled study not including primary trocar entrance

and rapid (grade A) [3]. The REA is compared with Veress/trocar in two randomised studies and both conclude that the use of REA is associated with fewer local wound events, better patient satisfaction and less pain (grade A) [4, 23].

Inclusion criteria were met in 40 studies in a meta-analysis that summarised complications according to open access, Veress/trocar and direct trocar insertion. Fifty-six percent of all major complications were visceral injuries. It was concluded in prospective nonrandomised studies comparing open and closed (Veress/trocar) access that there is a trend in open access towards a reduced risk of major complications, access site herniation and in nonobese patients a reduced risk of minor complications. In prospective nonrandomised studies comparing direct trocar and Veress/trocar access major complications were inconclusive. There were fewer minor complications with direct trocar insertion, predominantly owing to a reduction in extraperitoneal insufflation. Three access-related deaths have been reported (grade B) [10].

Another meta-analysis, including 61 studies, described the overall frequency of bowel injuries of 0.7/1,000 and major vascular injuries in 0.4/1,000 patients. The overall incidence of major injuries at the time of entry was 1.1/1,000. Direct trocar insertion is associated with a significantly reduced major injury incidence of 0.5/1,000, when compared with both open and Veress/trocar entry. In older studies the open entry was often used in high-risk patients, which might be the explanation for the increased incidence of bowel injuries in this group. Open entry appears to minimise vascular injury at the time of entry (grade B) [13].

In a large database study including 14,000 patients, different access techniques were used and the incidence of visceral injuries was 0.13%, major vascular injuries 0.007% and mortality 0.007% (grade B) [19]. In a database analysis of 4,600 patients comparing open versus Veress/trocar access in two different consecutive time cohorts, no cases of major vascular injuries were seen in either group. Visceral injuries were seen in 0.17% of patients in the Veress group and in 0.05% of patients in the open group (not significant) (grade B) [12]. In a consecutive series comparing direct trocar insertion versus Veress/trocar there was a significantly higher overall complication rate in the Veress/trocar group, 14 versus 0.9% ($p < 0.01$). Two major complications, one visceral and one vascular, were seen in the Veress group (grade B) [22]. The REA device is compared to an ordinary cutting-tip trocar used as the secondary port regarding abdominal wall events. REA is free of abdominal wall complications in 99.8% of cases. Cutting-tip trocars have demonstrated increased complication rates for the abdominal wall in terms of bleeding and larger fascia defects that would potentially increase the risk of port site hernias (grade B) [7]. Optical trocar insertion was reported in one retrospective study including 650 patients. The time for entrance was short and a total of 0.3% of bowel injuries were described and no major vascular injuries were reported (grade B) [20].

Insufflation Pressure

Consensus 2002: The committee recommends use of the lowest intraabdominal pressure (IAP) allowing adequate exposure of the operative field rather than using a routine pressure (grade B). An IAP lower than 14 mmHg is considered safe in a healthy patient (grade A).

Update 2006: The previous recommendations are still valid and are further supported by less pain and higher quality of life postoperatively using a low insufflation pressure (grade A).

In this update another three RCTs, including a total of 288 patients, were analysed (grade A) [2, 11, 17]. All three studies focussed on postoperative discomfort regarding pain, shoulder-tip pain, analgesia consumption or quality of life (Table 3.2). All three compare low-pressure versus high-pressure pneumoperitoneum. The definition of normal and low laparoscopic insufflation pressure was previously defined in the EAES guidelines as 12–15 and 5–7 mmHg, respectively. These definitions are not in accordance with the definitions used in two of the studies [11, 17]. The largest study of 148 cases used the recommended pressure levels of the two groups mentioned before and demonstrated significantly less pain postoperatively for the first 5 days, less analgesia consumption for the first 4 days and better quality of life concerning physical activity 7 days postoperatively [2]. There was less frequency and intensity of shoulder-tip pain together with less analgesia consumption in another study comparing 9 versus 13 mmHg [17]. The last study compared 10 versus 15 mmHg and does not show any difference between the groups concerning pain or quality of life [11].

The results from these studies further support low-pressure pneumoperitoneum being defined as 7 mmHg or lower. The ASA classification was not addressed separately in these studies. No systematic review or large individual cohort study addressing low-pressure versus high-pressure pneumoperitoneum has been identified.

Warming and Humidifying of Insufflation Gas

Consensus 2002: Warming and humidifying insufflation gas is intended to decrease heat loss; however, compared with external heating devices, the clinical effects of warmed, humidified insufflation gas are minor (grade B). Data on its influence on postoperative pain are contradictory (grade A).

Update 2006: Warming and humidifying insufflation gas compared with standard CO₂ is not associated with any clinically relevant increase in body temperature, especially when an external warming blanket is used in parallel (grade A). There is no clinically relevant effect on postoperative pain for the

Table 3.2. Randomised clinical trials comparing low- and high-pressure pneumoperitoneum. All studies were cholecystectomies

References/ years	No. of patients, operations and ASA classification	CO ₂ pressures compared	Method	Results	Conclusion
Koc et al. [11]/2005	50 Double-blind ASA I-III	10 vs 15 mmHg	Pain (VAS), analgesic consumption and QoL	No difference between the groups	Low-pressure PP does not reduce postoperative pain
Barczynski et al. [2]/ 2003	148 Single-blind ASA I-II	7 vs 12 mmHg	Pain (VAS), analgesic consumption and QoL	Less pain, analgesic consumption and better QoL (physical) for low pressure	Recommends low pressure PP if adequate exposure is obtained
Sarli et al. [17]/2000	90 Double-blind ASA I-II	9 vs 13 mmHg	Shoulder-tip pain (VAS) and analgesic consumption	Lower frequency and intensity of shoulder-tip pain and less analgesic consumption in low-pressure group	Low-pressure PP reduces the frequency and intensity of shoulder- tip pain

PP pneumoperitoneum, QoL quality of life

two methods (grade A). Warming and humidifying insufflation failed to reduce fogging (grade A).

A total of six RCTs included 279 patients (Table 3.3). A significant increase in body temperature was demonstrated using warmed and humidified CO₂ (grade A) [6, 9, 18, 21] and no differences were found in two studies [5, 15]. Pain, analgesic consumption, recovery and hospital stay failed to demonstrate any difference in four studies [5, 6, 15, 18]. Reduced analgesic consumption was demonstrated in one study [9] and increased pain was demonstrated in another study [21] in the warmed, humidified group. Failure to reduce fogging using warmed and humidified CO₂ was demonstrated in three studies [6, 9, 15].

No systematic review or large individual cohort study has been identified addressing the method of warming and humidifying the insufflation gas.

The application of an external warming device before and during anaesthesia is included as routine in most laparoscopic settings and the possible small effect of humidified and warmed insufflation gas is not justified. Spe-

Table 3.3. Pneumoperitoneum and hypothermia; randomised clinical trials

References/ years	No. of patients, and operations	Treatments and no. in groups	Temperature and measurement	Results	Conclusion
Davis et al. [5]/ 2006	44 Single-blind 4 groups Roux-en-Y	11–standard 11–heated (insufflator tube set) 11–humidified (Insuflow) 11–heated and humidified	Urine bladder	No difference in intra- abdominal humidity or temperature. Pain (VAS), recovery and hospital stay similar	Heating or humidifying of CO ₂ not justified
Savel et al. [18]/ 2005	30 Double-blind 2 groups Roux-en-Y	15–standard and 15–warmed and humidified (Insuflow)	Oesophageal probe	Temperature increased in warmed/ humidified group. Pain (VAS) and analgesic consumption similar	Warmed and humidified CO ₂ was not associated with any significant benefit with regards to postoperative pain
Hamza et al. [9]/ 2005	44 Double-blind 2 groups Roux-en-Y	21–standard 23–warmed and humidified (Insuflow)	Oesophageal probe Tympanic thermometer	Temperature increased and less analgesic consumption in warmed/ humidified group	Insuflow modestly reduced heat loss and analgesic consumption. It failed to reduce fogging of lens
Farley et al. [6]/ 2004	101 Double-blind 2 groups CCE	52–standard 49–warmed and humidified (Insuflow)	Oesophageal probe	Temperature increased in warmed/ humidified group. Pain, recovery and hospital stay similar	No major clinically relevant difference between the groups. Failed to reduce fogging
Nguyen et al. [15]/ 2002	20 Single-blind 2 groups Fundoplication	10–standard 10–heated (warming blanket and Insuflow)	Oesophageal probe Tympanic thermometer	No difference in temperature, pain (VAS), analgesic consumption, hemodynamics and lens fogging	Heated and humidified CO ₂ with additional external warming did not influence temperature or pain

Table 3.3 (continued)

References/ years	No. of patients, and operations	Treatments and no. in groups	Temperature and measurement	Results	Conclusion
Wills et al. [21]/2001	40 Double-blind 2 groups Fundoplication	21–standard 19–heated		Increased temperature, pain (VAS) and analgesic consumption in heated group	Heated CO ₂ provides no benefit but may be associated with increased early pain

CCE cholecystectomy

cial precautions to minimise gas leakage are essential in laparoscopic surgery for the purpose of reducing the risk of hypothermia.

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