



Fédération de chirurgie
viscérale et digestive



How can we reduce the risks associated with the creation of a pneumoperitoneum in digestive surgery?

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What is it?

Laparoscopy requires a pneumoperitoneum, the creation of which entails specific risks: bowel injuries and vascular injuries (aorta, vena cava, iliac vessels). More than 250,000 digestive surgical procedures are performed via laparoscopy each year in France (PMSI data) and all these laparoscopic procedures require the creation of a pneumoperitoneum. We can estimate the incidence of potentially life-threatening vascular injuries to be approximately 100 cases per year in France.

Several recommendations for clinical practice were published regarding the prevention of risks related to pneumoperitoneum creation.

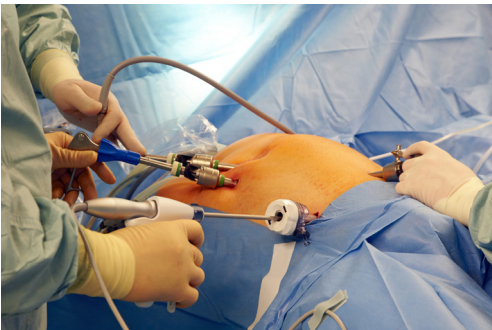
None of these recommendations allowed a clear cut decision for a given technique because the literature data and the scarcity of complications cannot be used to make a choice.

The Cochrane systematic review came to the same conclusions. When it is difficult to recommend a technique based on the only evidence-based data available, it remains however possible to raise awareness about the technical recommendations validated by the profession and the barriers that can be used to prevent complications or reduce their severity.

The severity of these accidents, along with the non-decisional nature of published clinical research, more so than their incidence, have resulted in the development of this risk management strategy for professionals, related to pneumoperitoneum creation.

Background

The consequences of injuries occurring when creating a pneumoperitoneum were analysed in the experience feedback database (REX database) by surgeons from the approved accreditation body for visceral and digestive



surgery. Pneumoperitoneum creation and the introduction of the first laparoscopic trocar was a near-miss event (NME) targeted by the benchmark risks of the proprietary medicinal product.

Thus, 204 care-related adverse events (CRAEs), including both near-miss events as and serious adverse events, were reported between 2008 and 2010, before the Federation of Visceral and Digestive Surgery (Fédération de chirurgie viscérale et digestive; FCVD) Day devoted to this theme in March 2011. Analysis of these NMEs/CRAEs resulted in the consensual recommendations validated by the scientific committee and working committee of the FCVD in November 2011, and which were the subject of a publication.

Since the publication of this document in 2012, the database analysis found 478 new CRAEs (from January 2012 to April 2014), 299 of which occurred during a closed technique and 179 during an open technique.

- For CRAEs during the closed technique, surgeons had taken the FCVD recommendations into account in 37% of cases. They did not take them into account in 42% of cases (21% indeterminate responses).
- For CRAEs during the open technique, the percentages were 29% and 35%, respectively.

How to reduce this high-risk situation?

Choosing between the 2 pneumoperitoneum creation techniques involves:

- managing the risks associated with each technique;
- knowing, for each technique, the methods (barriers) that can be used to perform prevention, recovery and mitigation actions.

Context of paediatric surgery

In accordance with the literature, the open route (open laparoscopy) should be preferred in infants.

A child's abdominal wall is very different to that of an adult.

Paediatric open-laparoscopy must be performed via a short umbilical approach, with the first trocar being inserted either trans, supra or infra-umbilically.



What can we do prior to the creation of pneumoperitoneum (PREVENT)?

Regardless of which technique is chosen, safety prerequisites are recommended (Table 1).

Table 1

SAFETY PREREQUISITES, IRRESPECTIVE OF THE TECHNIQUE		
PLAYERS	STEP	ACTIONS
Surgeon Anaesthetist and resuscitation specialist	1. INFORMATIONS 1.1. To the patient: ● benefits/risks; ● possible conversion of laparoscopy to laparotomy. 1.2. On the clinical condition of the patient.	■ Ensure that the patient was given information about the risks inherent to the procedure and has understood this information. ■ Check absence of risk factors known to be responsible for complications during the creation of pneumoperitoneum.
Surgeon	2. 2. EQUIPMENT CHECK and VERIFICATION of the availability of a specialised skill (use of assistance).	■ Ensure that the equipment is familiar and functional: ● needle ; ● insufflator ; ● trocars. ■ Verify the availability of the equipment in the event of an emergency LAPAROTOMY to inspect the large vessels.
Surgeon Anaesthetist, and ruscitation specialist	3. PRIOR TO ANY PUNCTURES	■ Discuss the intubation conditions and the quality of the neuromuscular blockade with the anaesthesiologist-resuscitation specialist.
Surgeon Anaesthetist and resuscitation specialist State registered theatre nurse (IBODE)	4. DURING CO₂ INSUFFLATION <i>in adults</i>	■ Discuss the flow parameters, pressure parameters, haemodynamic parameters and capnography of the patient with the theatre nurse and the anaesthesiologist doctor (or by delegation the anaesthesiologist nurse)
	4. DURING CO₂ INSUFFLATION <i>in children</i> ■ The insufflation flow rate varies with age and type of surgery. It should be constantly modulated, in close collaboration with the anaesthetist. ■ Pressures vary with age, from 4 mmHg in infants to 12 mmHg in older children, and should be determined in close collaboration with the anaesthetist.	■ Whatever the technique used, the size of the incision made to insert the first trocar should be 1 to 2 mm larger than the gauge of the trocars used (diameter: 3 or 5 or 10 mm).



KEYS POINTS

"Closed" technique

"Open" technique

ADULTS

The key points are the insertion of the needle into the left upper hypochondrium, away from large vessels in a patient in supine position and communication with the anaesthesia team concerning mask ventilation and/or intubation conditions (see « Reference technique for the closed method », page 9).

The key points are the incision of all the parietal layers down to the peritoneum, which should be opened under visual guidance, and the introduction of the trocar without a stylet or with a foam stylet (see « Technical Reference of the open method », page 10).

CHILDREN

- In older (pre-adolescents and adolescents) or obese children, a closed route may be necessary.
- A lateral left puncture point should be performed and the technique then conforms to guidelines for adults.

The open route is imperative in children to reduce morbidity, particularly in young children:

- due to the very short distance between the abdominal wall and the large pre-spinal vessels;
- due to anatomical and physiological specificities:
 - liver protrusion beyond the rib canopy,
 - position of the bladder, that may be high under the umbilicus.



DO NOT

"Closed" technique

"Open" technique

Do not make rotational movements with the needle in the peritoneal cavity.

Do not make several puncture attempts with the needle.

Do not make a small skin incision that is not much larger than the diameter of the trocar.

Do not try to introduce a trocar without being certain beforehand that the peritoneum has been opened.

Do not use a trocar fitted with a cutting stylet.

→ *In all cases of outpatient surgery, a next-day follow-up call must be made.*

What to do in case of accident during pneumoperitoneum creation?

What to detect and which prospective approach?

Prior to insufflation of the pneumoperitoneum, any massive haemorrhage passing through the trocar when it is introduced or detected in the haemodynamic parameters justifies an immediate conversion to laparotomy and, if necessary, asking for additional help.

After insufflation of the pneumoperitoneum, the optic is introduced and the peritoneal cavity is explored, while being aware of the diagnostic limitations of laparoscopic exploration.

■ If blood is present in the peritoneal cavity:

- a. systematically investigate the source of bleeding;
- b. and at the same time, alert the anaesthesia team and check:
 - ▶ the haemodynamic values,
 - ▶ presence and amount of CO₂ in the blood plasma.

If the source is not detected after this first exploration and if the haemodynamic values allow it, the pneumoperitoneum is evacuated with the trocar in place, then insufflated again for a new visual exploration to detect a haemorrhage that might have been hidden by the gaseous counter-pressure.

Laparoscopic surgery may only continue if the source of bleeding is accurately detected and the haemostasis values allow it. In all other cases, the decision is made to convert to laparotomy.

■ If digestive fluid, unexplained by the expected pathology, is found:

- a. the source must be found by a thorough and careful examination of the bowel loops;
- b. any uncertainty or non-identification of the injury justifies conversion to laparotomy.

How to recover?

When an accident is suspected or known, immediately alert the anaesthetist-resuscitation doctor and the whole team, and continue care (table 2).

Table 2

SUSPECTED OR OBSERVED INJURY, HOW TO REACT?			
Nature of the injury		Actions to perform with the patient	Actions to perform with the professional team
Vascular injury	Adults and children	Conversion must be performed IMMEDIATELY in the event of haemorrhage that cannot be immediately controlled.	■ Inform the entire operating theatre team. ■ Calling upon additional resources for technical assistance should be the norm.
Bowel injury	Adults	Make the decision to repair the injury and continue the intervention, depending on the lesions and the operator's expertise.	■ Inform the entire team of the accident.
	Children	Digestive perforations are rare, but frequently discovered late. Appropriate abdominal wall relaxation followed by careful trocar insertion, while pulling on the wall, under strict laparoscopic visual control, is essential in all cases of paediatric laparoscopic surgery.	

What to do after an incident related to pneumoperitoneum creation?
(monitoring actions to mitigate risks to patients)

A wait-and-see approach, and a falsely reassuring image are deleterious, because they result in an accumulation of errors, a delay in care and an escalation of therapy. It is therefore recommended to perform a second-look, via laparotomy or laparoscopy, as soon as a complication is suspected.

The following actions need to be performed:

If an accident occurs	Actions to be implemented	Actor
Within the first 24 hours	■ Monitor the haemodynamic values, diuresis and at least haematocrit. ■ Perform an abdominopelvic scan if there is any abdominal pain, haemodynamic changes, hyperthermia, abnormal abdominal physical examination or transit disorders that might suggest postoperative peritonitis or active bleeding. ■ Inform the team of any incident likely to influence postoperative monitoring and patient discharge conditions. The occurrence of peritoneal signs may be delayed and expose the patient to a loss of opportunity in terms of his/her management.	■ Surgeon, team.
In the patient file	■ Track the information given to the patient and the monitoring information in the file. ■ Specify in the surgical report the technical conditions for creating the pneumoperitoneum and introducing the first trocar and the occurrence of any abnormal events associated with this procedure.	■ Surgeon.
With regards to the patient	■ Tell them about the nature of the damage. ■ Monitor the patient's condition for a period of time that will be dictated by the type of complication, the recovery and its possible consequences.	■ Surgeon, team.
With regards to the primary care doctor	■ Send a letter. ■ Give the patient a copy. ■ Contact the primary care doctor if necessary.	■ Surgeon.
With regards to the institution	■ Report the incident to the team and the reference persons at the institution.	

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If an accident occurs	Actions to be implemented	Actor
If a complication is observed	■ Tell the patient about the damage and manage it. ■ Analyse and treat the complication in collaboration with all members of the team who will be in charge of his/her treatment and monitoring. ■ Prepare an internal report for the institution. ■ Provide patient support.	■ Surgeon, team.
With regards to the FCVD	■ Report the incident via a declaration form. ■ For accredited doctors, declare the event information on the accreditation information system.	■ Surgeon not part of the accreditation system. ■ Surgeon part of the accreditation system for physicians.

Reference technique for the closed method

Operating time	Recommendations
Puncture with a needle	1. If intubation has proven difficult, a gastric tube is inserted and the stomach is emptied.
	2. Puncture in the left hypochondrium away from large vessels, perpendicular to the wall, on a patient in the supine position, or in the right upper hypochondrium if the patient is in a left lateral decubitus position (a).
	3. The lifting of the abdominal wall, needle in place and prior to any gas insufflation, should result in a negative pressure on the sensor.
Insufflation	4. Begin insufflation with a low flow rate (≤ 3 l/min); the abdominal pressure gradually increases and the flow varies with the respiratory movements(b).
	5. Verify the double click which provides information about the intraperitoneal position of the needle despite its poor reliability.
	6. In the event of an initial failure, make a second puncture attempt at the same place and using the same method.
	7. In the event of a second failure, choose a new puncture site or opt for the open method.
Introduction of the first trocar	8. Once the intra-abdominal pressure has stabilised at more than 10 mmHg and a homogeneous pneumoperitoneum is obtained (a stable pressure up to 15 or even 20 mmHg is acceptable for the introduction of the first trocar, if the anaesthesiologist or, by delegation, the state registered anaesthesiologist nurse (IADE) authorises it).
	9. On a variable site depending on the procedure (the two iliac fossae are contraindicated), away from the course of the epigastric vessels.
	10. After a skin incision > 10 mm ($>$ diameter of the first trocar) and systematic incision of the anterior leaflet of the aponeurosis, particularly in thin patients (BMI < 20 kg/m ²).
	11. Valve open, a gas leak indicates the presence of gas in the peritoneal cavity and the stoppage of all pressure on the trocar.
	12. In patients with a history of laparotomy, the first trocar is introduced away from the incision; tests on the syringe at the first trocar insertion site, with injection and aspiration of serum or the simple aspiration of carbon dioxide, are recommended but have not clearly demonstrated their reliability.

(a) Preoperative imaging of the liver and spleen volume is recommended in cases of suspicion of splanchnomegaly in order to adjust the choice of puncture site. In **obese patients** the puncture site will be moved down (left lobe of the liver), without crossing the umbilical line, and the pneumoperitoneum will be created before putting the patient in the ventral decubitus position (operative position).

(b) The transition to a higher insufflation flow rate is only possible if all these conditions are met. Verification of the insufflation pressures is the most reliable criterion for the creation of pneumoperitoneum under good conditions.

Reference technique for the open method

Situation	Recommendations
Regardless of the situation	1. Begin insufflation with a low flow rate (≤ 3 l/min); the abdominal pressure gradually increases and the flow varies with the respiratory movements.
No history of umbilical midline laparotomy	2. Skin incision, horizontal periumbilical or paraumbilical, or vertical at the base of the umbilicus or in the supraumbilical region in obese patients (large distance between the xiphoid process and umbilicus).
	3. Size of the skin incision always greater than the diameter of the trocar.
	4. Push the subcutaneous tissue back to the aponeurosis.
	5. Grip the aponeurosis on the white line, then make a transverse incision in the aponeurosis with a cold bistoury. If a paramedian approach is used, both aponeuroses of the sheath are incised.
	6. Exposure of the peritoneum which is grasped between 2 clamps and incised under visual guidance.
	7. Insert a surgical retractor to verify that the peritoneal cavity is open.
	8. Introduction of the trocar without a pointed or sharp-edged stylet or with a foam-tip stylet.
No history of periumbilical midline laparotomy	9. Create the pneumoperitoneum away from the midline and on the opposite side of the organ to be operated on (e.g. left upper hypochondrium for biliary tract surgery, right iliac fossa for left colon surgery).
	10. Create the pneumoperitoneum via puncture in the left hypochondrium, in the event of failure of the closed technique.
	11. Explore the midline to perform a possible adhesiolysis prior to the introduction of the trocar.

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For more information

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Paediatric specificities

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PHYSICIAN ACCREDITATION

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Additional documents are available on the HAS website
www.has-sante.fr/portail/jcms/r_1439188/fr/securite-du-patient

This Patient Safety solution (PSS) meets the criteria of the PSS development guide approved by the HAS Board in May 2012.



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