Trocar types in laparoscopy

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Background

Description of the condition

Surgery is by nature invasive and inevitably associated with complications and trauma. Laparoscopic surgery, also known as minimally invasive surgery, was developed to minimise surgical trauma as opposed to the open abdominal surgical technique (that is laparotomy). A laparoscopic procedure is an abdominal or pelvic operation conducted through small incisions in the abdominal wall. In gynaecology, laparoscopy began in the late 1970s and was primarily used for diagnostic procedures. The first widely accepted laparoscopic procedure was tubal ligation [1]. Thereafter; gynaecological surgeons began to explore other applications, including diagnostic procedures for pelvic pain, ectopic pregnancies and appendicitis. In the early 1980s, additional operative procedures were introduced including adnexal surgery, uterine myomectomy and hysterectomy [2]. Less visible scarring, less postoperative pain and rapid recovery have fueled patient advocacy and enabled an increasing use of laparoscopy. For healthcare providers, laparoscopy has the benefit of shorter hospital stays and thus reduced inpatient costs. The benefits for the surgeon include the magnified optics and no-touch operative technique [2,3]. There is indeed evidence that laparoscopy has advantages compared to laparotomy, which include fewer surgical injuries, fewer postoperative complications, less postoperative pain and shorter hospital stay [4-6]. At present, with advanced laparoscopic operations for pelvic organ prolapse, urinary incontinence and gynaecological cancers, laparoscopy has become completely integrated into the field of gynecologic surgery. In general surgery and urology, laparoscopy is increasingly being used for different purposes as well.

The first step in a laparoscopic procedure involves the introduction of a primary instrument (that is a Veress needle or trocar) followed by the insufflation of carbon dioxide into the peritoneal cavity. This is called the primary entry, which is applied to create a pneumoperitoneum. Different primary entry techniques are used in practice. Ahmad et al. performed a Cochrane review on laparoscopic entry techniques and compared the different techniques in terms of their influence on intraoperative and postoperative complications [3]. They found no evidence of benefit in terms of safety of one technique over another. Intraperitoneal access for laparoscopic instruments is provided via ‘ports’.


**Trocar types: blunt, blunt conical, sharp conical and sharp pyramidal**

*Description of the intervention*

Specific cannulas, called trocars, are introduced through the abdominal wall to create these ports. A distinction needs to be made between primary and secondary trocar ports. The first port for primary entry is located in or near the umbilicus. This port is used for the introduction of the laparoscope. Secondary or ancillary ports are intended for the introduction of laparoscopic instruments. The secondary port locations depend upon the location in the abdomen where the surgical procedure is to take place. In general a minimum of two secondary ports are created. The trocars are placed to facilitate operating in line with the camera while maintaining a comfortable operating position for the surgeon with triangulation of the instruments around the surgical focal point within the abdomen. Trocar designs include a myriad of device designs, including over 100 brands from more than 20 manufacturers [7]. A distinction can be made between reusable and disposable trocars. Reusable trocars are made of metal and have a perforator tip. Completely blunt trocars, with a cone-shaped perforator tip, and sharp or cutting trocars with a conical, pyramidal, triflanged or excentric tip can be differentiated. Disposable trocars are made of plastic materials and are provided with bladed or bladeless tips. Shielded disposable trocars are provided with a retractable shield that covers the tip before and after
insertion. Dilatation systems represent yet another technical alternative in trocar techniques. These trocars are equipped with a radially expanding sleeve that can be dilated from 5 mm to 12 mm in diameter. This radially expanding access (REA) trocar was developed to minimise tissue trauma and, in theory, its use would result in fewer vascular and visceral injuries. Optical access trocars allow laparoscopists to view the cutting tip as it penetrates the tissues. Many other different trocar designs are described, for example trocars with a threaded sleeve or an expandable arm [8-11]. The diameters of trocars vary from 2 mm to 12 mm, depending upon the largest instrument needed for a particular port. For exceptional indications (for example extirpation of large cysts) larger or modified trocars are available [9]. The rapid evolution of instrumentation has led to the development of new minimally invasive techniques such as natural orifice transluminal endoscopic surgery (NOTES), laparo-endoscopic singlesite surgery (LESS) and minilaparoscopy. NOTES refers to surgery via natural orifices, where procedures are performed with transluminally placed instruments to gain access to the abdominal cavity. Transvaginal, transanal, transvesical, transesophageal, transgastric and transoral approaches for NOTES are described [12]. LESS surgery is an advanced minimally invasive approach that allows laparoscopic operations to be undertaken through a single small (12 mm to 15 mm) incision, typically placed at the patient’s umbilicus [13]. Minilaparoscopy involves the use of smaller incisions, smaller instruments and fewer ports to further reduce perioperative morbidity and enhance cosmesis. Other terms for minilaparoscopic surgery include miniport or microlaparoscopic surgery [14]. NOTES, LESS and minilaparoscopy are in their early stages of development. NOTES, LESS and minilaparoscopy are not included in this review since these techniques are different from traditional laparoscopy.

Why it is important to do this review
Laparoscopic trocars are the most common device named in malpractice injury claims associated with laparoscopic procedures, representing one-third of all claims [10]. The incidence is estimated to be 3 to 4 per 1000 procedures [15,16]. Trocar-related complications represent all types of complications due to the contribution of the trocar, including intra-abdominal vascular injury, intra-abdominal visceral injury, trocar site bleeding, trocar site herniation and trocar site infection. Of all trocar-related complications, vascular and visceral injuries are associated with the highest morbidity and
mortality [17]. By inserting a trocar, the trocar tip can damage abdominal wall vessels (for example the epigastric artery), intra-abdominal vessels (for example the aorta, vena cava, iliac artery or iliac vein) or visceral organs (for example the bowel, stomach and bladder). Although vascular injury is often noticed directly during laparoscopy, bowel injuries are more likely to go undetected during the procedure [10]. When vascular or visceral injury occurs, additional surgical intervention is often required. Cardinet et al. reported vascular and visceral injuries in 51 out of 4007 (1.3%) patients undergoing a laparoscopic procedure. At least 14 (27.5%) of these patients required a subsequent surgical, endoscopic or radiological intervention under general anesthesia [16]. Mortality is reported occasionally after vascular or visceral injury [16,18]. An important postoperative trocar-related complication is trocar site herniation. A trocar site hernia (TSH) is a protrusion of intestine or omentum through a remaining defect in the peritoneum, abdominal fascia or musculature at the trocar insertion site. TSHs occur postoperatively, which can vary from shortly following surgery to several years postoperation. Whereas TSH is uncommon, with an estimated prevalence of 0.5% in patients operated on laparoscopically, it is a potentially serious complication. Patients with TSH may require emergency reoperation for bowel obstruction or strangulation [19]. Less severe trocar-related complications are trocar site bleeding, trocar site infection and pain. Although pain is not always classified as a complication, it is considered clinically important and is an indicator for recovery. The use of trocars inevitably leads to risks of trocar-related complications. Major complications such as vascular and visceral injury can have serious consequences including conversion from laparoscopy to laparotomy, other invasive interventions, medical therapies and prolonged hospitalisation. When discovered postoperatively, occasionally emergency or revision surgery is required, resulting in longer hospital stay or readmission and additional costs. Minor complications might also result in the need for additional pharmacological treatment and compromise postoperative recovery. All these deviations from a normal intra- and postoperative course after laparoscopy potentially have a negative effect on patients' quality of life and satisfaction.

A difference in trocar-related complications may be attributable to different types of trocars and the experience of the surgeon according to the trocar type. The Cochrane review from Ahmad et al. studied different trocar systems. Eight RCTs were found where different trocar designs were compared. In four, REA trocars were compared with standard trocars. A meta-analysis
demonstrated fewer trocar site bleeding episodes when using REA trocars compared to standard trocars for the primary laparoscopic entry [3]. In two RCTs cutting trocars were compared to blunt trocars for primary and secondary port insertion, and no significant difference in any type of complication was demonstrated. Two RCTs compared the REA trocar with a conventional cutting tip trocar for secondary port entry. REA trocars were associated with lower rates of trocar site bleeding compared to standard secondary port trocars. Our review differs from Ahmad et al. in that we will search for differences in the outcome of postoperative pain. Specific types of trocars could relate to higher or lower risks on any of the trocar related complications or for postoperative pain. The sharpness of disposable cutting trocars is usually better compared to that of reusable cutting trocars. This sharpness of disposable trocars facilitates smooth insertion. Reusable trocars do lose their sharpness through repetitive insertion. Reusable trocars require a relatively high puncture force for penetration through the abdominal wall. Increased entry force could result in an abrupt and uncontrolled introduction of the trocar that may result in a deeper penetration and potential serious visceral and vascular injury [20]. The cutting trocar mechanism of sharp trocars may result in occasional bleeding from the trocar port. Conical blunt tipped trocars are designed to stretch, rather than cut, the abdominal wall to enable port placement. The use of conical reusable trocars compared to sharp cutting disposable trocars was associated with fewer trocar-related bleeding events and trocar site hernias in a non-randomised prospective study [21]. A larger trocar diameter creates a larger defect in the abdominal wall and potentially results in an increased risk of trocar site herniation. In 1993, a retrospective study demonstrated an increased risk of trocar site herniation when trocars with a diameter of 12 mm were used compared to 10 mm [22]. This Cochrane review aims to determine whether specific trocar designs can be recommended for use in patients undergoing laparoscopy, with a goal to minimise trocar-related complications and postoperative pain.

**Objectives**

The objective of the current review is to analyse the rates of trocar-related complications and postoperative pain for different trocar types used in patients undergoing laparoscopy.
Methods

Types of studies
Only randomised controlled trials are to be considered. Quasirandomised (for example randomised by birth date, chart number, alternating inclusion), cluster randomised studies and studies with a ‘split-mouth design’ are not to be included.

Types of participants
Inclusion criteria: participants aged 18 years and older, undergoing elective or emergency diagnostic, therapeutic or mixed laparoscopy for surgical, gynecological or urological conditions.
Exclusion criteria: participants under the age of 18 years and animal studies will be excluded.

Types of interventions
Inclusion criteria:
- Studies on different trocar designs used in laparoscopy, performed by either surgeons, gynecologists or urologists
- Both studies on trocars used for primary entry and for secondary entry will be included
- All variations of trocar types are to be included, e.g. sharp tipped trocars, blunt tipped trocars, pyramidal or conical tipped trocars, disposable (plastic) trocars, reusable (metal) trocars, trocars with a shielded tip, radially expanding trocars, trocars with a threaded sleeve, an expandable arm or an optical view

Exclusion criteria:
- Studies wherein other (than conventional) laparoscopic incisions are made (e.g. single port surgery (SILS, LESS), natural orifice surgery (NOTES) and minilaparoscopy)

Types of outcome measures
Primary outcomes: major trocar-related complications:
- mortality;
- conversion to laparotomy due to any trocar-related adverse event;
- visceral injury (such as perforation of the intestines or stomach, or injury of the bladder or liver);
vascular injury (such as perforation of the aorta, vena cava, iliac artery or iliac vein); and
other injuries that required intensive care (IC) or intensive care unit (ICU) management or a subsequent surgical, endoscopic or radiological intervention.

Secondary outcomes:
• Minor trocar-related complications, such as trocar site herniation, trocar site bleeding or postoperative wound hematoma, trocar site infection, extraperitoneal insufflation and other injuries that did not require IC or ICU management or a subsequent surgical, endoscopic or radiological intervention under general anaesthesia
• Postoperative pain, expressed on a self-reported scale (e.g. visual analogue scale (VAS), numerical rating scale (NRS))

Search methods for identification of studies
The clinical librarian (MW) will develop a comprehensive literature search strategy in consultation with the Trials Search Coordinator of the Cochrane Menstrual Disorders and Subfertility Group. The search strategy will be based on that in the Cochrane Menstrual Disorders and Subfertility Group module. The key search terms have been developed in accordance with the structured question (participants, intervention, comparators, outcomes (PICO)).
P: patients undergoing laparoscopic procedures
I: different types of trocars used for intraabdominal entry
C: different types of trocars used for intraabdominal entry
The outcomes were not incorporated in the search strategy. They were used as criteria for selection of studies within the search results, based on titles, abstracts and/or full text of the articles. The relevant subject indexing terms used within individual databases have been identified and added to the strategy as appropriate. Where databases offer facilities such as truncation, explosion and proximity searching these will be used as appropriate. The searches will be focused to the study designs of interest by using RCT search filters. No language restriction will be used.

Data collection and analysis
Two review authors will independently perform the selection of studies, risk of bias (RoB) assessment and extraction of qualitative and quantitative data. A
third review author (FWJ or SMR) will be contacted if an arbiter is necessary. The review authors have a background in surgery (HS), gynaecology and clinical epidemiology (CC).
In the case of multi-arm trials a study will be given multiple study IDs so that the data can be separately for use in meta-analysis.

Selection of studies
Titles and abstracts from the search results will be screened. Potentially relevant studies will be obtained in full text and independently assessed for inclusion. Full papers, abstracts and proceedings from congresses and any other ‘grey literature’ will be evaluated. Disagreements will be resolved by discussion with a third review author (FWJ or SMR). No language restriction will be applied.

Data extraction and management
Data will be extracted, applying the inclusion and exclusion criteria, through a predefined and tested data selection list by the two review authors (HS and CC) working independently. Since the review authors are already familiar with the literature, they will not be blinded to the names of the authors, institutions, journal of publication and results when they apply the eligibility criteria. The methodological details (concealed assignment, technique of randomisation, time of randomisation (pre- or intraoperatively), number of randomised patients, number of patients not randomised with explanation, the presence of blinding) and descriptive study characteristics (for example country where the study was conducted, recruitment modality, source of funding), characteristics of the participants (for example age, gender, body mass index (BMI), previous abdominal surgery), description of the trocar type and size (diameter), description of the entry method, description of the port creation and closure (desufflation, closure of peritoneum, fascia and the skin), co-interventions (for example local anesthetics at trocar sites), and outcomes (types of outcomes, documentation of drop-outs, follow-up, standardisation of outcome assessment, and whether an intention-to-treat analysis was employed) and the authors’ results and conclusions will be extracted. Any disagreements will be discussed and an arbiter (FWJ or SMR) will be consulted when necessary. Key findings will be summarised in a narrative format. The outcome data will be extracted per patient. A differentiation of outcomes will be made regarding primary trocar ports and secondary trocar ports. For primary port outcomes, these
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will be differentiated for open, Veress needle and direct entry methods. Data relating to the defined outcomes will be assessed for inclusion in the meta-analyses. Final scores for means and measures of variance will be extracted for continuous outcomes (for example VAS) while the number of patients experiencing an event and the number randomised will be extracted for adverse events (for example incidence of trocar site bleeding).

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References