



Major and minor complications in Veress needle (VN) and direct trocar insertion (DTI) for laparoscopic closed-entry techniques: an updated systematic review and meta-analysis

C. Taliento¹ · G. Pontrelli² · A. Rondoni¹ · M. Desgro² · M. Steinkasserer³ · G. Scutiero¹ · G. Vizzielli⁴ · P. Greco¹

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Abstract

Objective Directinsertion of the trocar is an alternative method to Veress needle insertion for the creation of pneumoperitoneum. We conducted a systematic review and meta-analysis to compare these two entry closed techniques.

Data source A systematic review of the literature was done on PubMed, MEDLINE, Embase, Scopus, and EBSCO.

Methods The literature search was constructed until May 01, 2022, around search terms for “Veress,” “direct trocar,” “needle,” “insertion,” and “laparoscopic ways of entry.” This systematic review was reported according to the PRISMA Statement 2020.

Results Sixteen controlled trials (RCTs) and 5 observational studies were included in the systematic review. We found no significant differences in the risk of major complication during the access manoeuvres between DTI and VN: bowel injuries (OR = 0.76, 95% CI: 0.24–2.36, $P=0.63$), major vascular injuries (OR = 1.74, 95% CI 0.56–5.38, $P=0.34$), port site hernia (OR = 2.41, 95% CI: 0.28–20.71, $P=0.42$). DTI has a lower risk of minor complications such as subcutaneous emphysema (OR = 5.19 95% CI: 2.27–11.87, $P<0.0001$), extraperitoneal insufflation (OR = 5.93 95% CI: 1.69–20.87, $P=0.006$), omental emphysema (OR = 18.41, 95% CI: 7. 01–48.34, $P<0.00001$), omental bleeding (OR = 2.32, 95% CI: 1.18–4.55, $P=0.01$), and lower number of unsuccessful entry or insufflation attempts (OR = 2.25, 95% CI: 1.05–4.81, $P=0.04$). No significant differences were found between the two groups in terms of time required to achieve complete insufflation (MD = - 15.53, 95% CI: - 91.32 to 60.27, $P=0.69$), trocar site bleeding (OR = 0.66, 95% CI, 0.25–1.79, $P=0.42$), and trocar site infection (OR = 1.19, 95% CI, 0.34–4.20, $P=0.78$).

Conclusion There were no statistically significant differences in the risk of major complications during the access manoeuvres between DTI and VN. A lower number of minor complications were observed in DTI compared with those in Veress access.

Keywords Veress needle · Direct trocar insertion · Laparoscopy · Complications · Ways of entry

✉ C. Taliento
cristina.taliento1@gmail.com

G. Pontrelli
giovepontre@gmail.com

A. Rondoni
albarondine@gmail.com

M. Desgro
marcello.desgro@gmail.com

M. Steinkasserer
martin.steinkasserer@unicatt.it

G. Scutiero
g.scutiero@hotmail.com

G. Vizzielli
giuseppe.vizzielli@uniud.it

P. Greco
greptl@unife.it

¹ Department of Medical Sciences, Institute of Obstetrics and Gynecology, University of Ferrara, Ferrara, Italy

² Policlinico Abano Terme, Abano Terme, Padua, Italy

³ Department of Obstetrics and Gynecology, Bolzano Hospital, Bolzano, Italy

⁴ Department of Medical Area (DAME), Clinic of Obstetrics and Gynecology, University of Udine, Santa Maria Della Misericordia” University Hospital, Azienda Sanitaria Universitaria Friuli Centrale, Udine, Italy

Abbreviations

VN	Veress needle
DTI	Direct trocar insertion
BMI	Body mass index
RCT	Randomized-control trials
OR	Odds ratio
MD	Mean difference
SD	Standard deviation

Introduction

In recent decades, laparoscopy has become the first-choice surgical approach in the treatment of many gynecological conditions [1]. Compared to open surgery, it is associated with a significant reduction in pain and postoperative infections, a shorter hospital stay, and a faster convalescence [2]. At the same time, laparoscopy has proven to be a safe and effective surgical method, with a rate of complications at the moment of the first trocar entry of about 1% [3]. Interestingly, almost half of the complications reported in the literature occur during the creation of the pneumoperitoneum [4]. This percentage has not changed over the years, although new techniques and tools have been progressively introduced [1, 5].

Complications of the closed-entry technique were commonly classified into two groups: major complications were defined as those requiring reintervention or conversion to an open procedure such as vascular and bowel injuries or solid organ laceration and bleeding, while minor complications were defined as those didn't prolong the postoperative length of hospital stay [6-9].

Nowadays, there are two main closed techniques for creating pneumoperitoneum: blind Veress Needle (VN), and direct trocar insertion (DTI) [10, 11]. The DTI technique requires the advancing of the trocar with a blind twisting motion into the peritoneum after the elevation of the anterior abdominal wall with one hand or with towel clamps. If visual inspection with the camera confirms proper placement, pneumoperitoneum is established with the insufflation of a gas. VN requires the insertion and retraction of a spring-loaded needle with an external diameter of 2 mm. When the tip of the needle penetrates through tissues and enters the peritoneal cavity, the inner stylet springs forward. Then, carbon dioxide is insufflated creating a pneumoperitoneum [12].

Although some studies have shown that there are no significant differences in terms of complications between these techniques, there are still reticences in the use of direct access [13, 14]. Probably, this is due to the fear of causing vascular or intestinal damage.

In this systematic review and meta-analysis, we focused on blind VN and DTI evaluating major and minor

complications related to each of these laparoscopic entry techniques.

Material and methods

We conducted this SR following the Cochrane Handbook version 6.3. This study was conducted with high methodology quality where every step of the PRISMA 2020 Checklist was carefully followed [15]. PROSPERO registration N° CRD42022361004.

Eligibility criteria, information sources, and search strategy

The search strategy comprised the following electronic databases: PubMed, MEDLINE, Embase, Scopus, EBSCO, Google Scholar, and ClinicalTrials.gov. The literature search was constructed until April 01, 2022, around search terms for "Veress," "direct trocar," "needle," "insertion," and "laparoscopic ways of entry." Additional reference lists of identified original articles or reviews were searched manually.

We included both randomized controlled trials (RCTs) and observational studies. Studies in control interventions that compared VN with DTI in terms of major and minor complications and time required to access the first trocar were all considered eligible. No restrictions regarding the study period, surgery type, age, BMI, or comorbidities were applied. All the trials compared VN with DTI in a patient who underwent laparoscopic surgery. We used the Rayyan online software (www.rayyan.com) to expedite the title/abstract and full-text screening phases and to eliminate duplicate records [16].

Two reviewers (TC and RA) independently screened the title and abstract of all papers and, according to their judgment, obtained full-text reports. A conflict of reviewers' decision on the inclusion or exclusion of any study was discussed with a third reviewer (DM) until a consensus was reached.

Data extraction

Data on design, participants, interventions, and outcomes were extracted by two reviewers (TC and RA) independently. A consensus among all authors resolved any disagreement regarding papers to be included in the analysis.

Assessment of risk of bias

Two reviewers (TC and RA) independently performed the risk of bias assessment in each study using the Risk of Bias tool for non-randomized studies of Interventions (ROBINS-I) tool for the observational studies and the RoB 2 tool for RCTs [17]. A

“low risk” judgment defines a study that uses a valid methodological approach, “some concerns” defines studies susceptible to some bias, while a “high risk” judgment indicates significant bias that may invalidate the conclusions (Appendix).

Data synthesis

Statistical analysis was performed using Cochrane Review Manager version 5 software. For categorical data, we related the number reporting an event to the number at risk in each group to derive a relative odds ratio (OR) and 95% confidence interval. The continuous variable -time required to achieve complete insufflation- was presented as 95% confidence intervals (CI) of mean difference (MD) or standard mean difference (SMD). In a systematic review, heterogeneity may be defined as any kind of variability among studies. There are three different types of heterogeneity in meta-analysis: clinical heterogeneity which describes variability in the participants, interventions, and outcomes studied; methodological diversity that defines variability in study design and risk of bias; and statistical heterogeneity that refers to variability in the intervention effects being evaluated in the different studies. Heterogeneity was analyzed using the I^2 statistics, one of the most commonly used heterogeneity measures that provides an estimate of the proportion of variability in a meta-analysis that is explained by differences between the included studies rather than by sampling error. The level of heterogeneity was classified as low when $I^2 < 25\%$, moderate when $I^2 = 25\text{--}49\%$, substantial when $I^2 > 50\%$. In our analysis, I^2 statistics was low, revealing that there were very little variations between trials. However, we used the DerSimonian-Laird random effects model as a conservative approach to account for different sources of heterogeneity among studies.

When we identified substantial heterogeneity, we examined clinical and methodological differences between studies, and we took any statistical heterogeneity into account when interpreting the results. We found that the included studies were conducted with similar clinical approaches and statistical methods.

When we suspected methodological heterogeneity, we investigated differences in clinical factors between studies and we performed a *sensitivity analysis* for outcomes which included studies that selected bariatric patients with BMI > 35.

Results

Study selection

The number of records identified and the reasons for exclusion are summarized in the PRISMA flow diagram (Fig. 1).

We included studies with the following inclusion criteria: (1) studies comparing the efficacy and safety of direct trocar insertion and Veress needle in laparoscopic surgery in terms of major and minor complications; (2) studies enrolling patients undergoing laparoscopic surgery including gynecological, urological, bariatric and general type surgery; (3) studies reporting complete data about the outcomes of interest. We did not include case reports, case series, reviews, meta-analysis, unpublished studies, and studies with incomplete data.

We also excluded studies comparing VN or DTI with other laparoscopic entry techniques. The main outcomes were major complications (major vessel injuries, bowel injuries, port site hernia) and time required to access the first trocar. Secondary outcomes were minor complications (omental bleeding, omental emphysema, subcutaneous emphysema, extraperitoneal insufflation, multiple trocar insertions, trocar site bleeding, trocar site infection).

The literature search totaled 543 articles. In all, 470 records were excluded because they were duplicated or did not meet all predefined inclusion criteria. Full-text articles were screened for eligibility. Twelve were excluded because they presented data about minor and major complications without differentiating them in terms of a single complication [18, 19]. Twenty-one articles with a total of 9214 participants were included in the SR and in the meta-analysis.

Study characteristics

The baseline characteristics, namely, the author, year, country, and number of participants in the control and experiment group of the 21 included studies are shown in Table 1.

According to inclusion and exclusion criteria, we included studies containing participants who underwent laparoscopic surgery with the two laparoscopic techniques, VN and DTI (Fig. 1). The present analysis included a total sample of 9214 patients (Table 2).

The 21 included studies comprised 16 RCTs and 5 observational studies where the only criterion for the technique selection was the surgeon's preference. They were performed in 9 countries: 4 in the USA [20–23], 5 in Turkey [24–28], 2 in Italy [29, 30], 2 in India [31, 32], 2 in Pakistan [33, 34], 1 in Spain [35], 1 in Iran [36], 1 in Egypt [37], 1 in Mexico [38], 1 in the Netherlands [39], and 1 in Nigeria [40].

Risk of bias of included studies

All studies had some risk of bias, as assessed by the Risk of Bias Assessment tool for Nonrandomized Studies (Robins I) and the Cochrane risk-of-bias tool for randomized trials (RoB 2). Due to the nature of the intervention, none of the RCTs were blinded; moreover, little information was given about the process of randomization and allocation

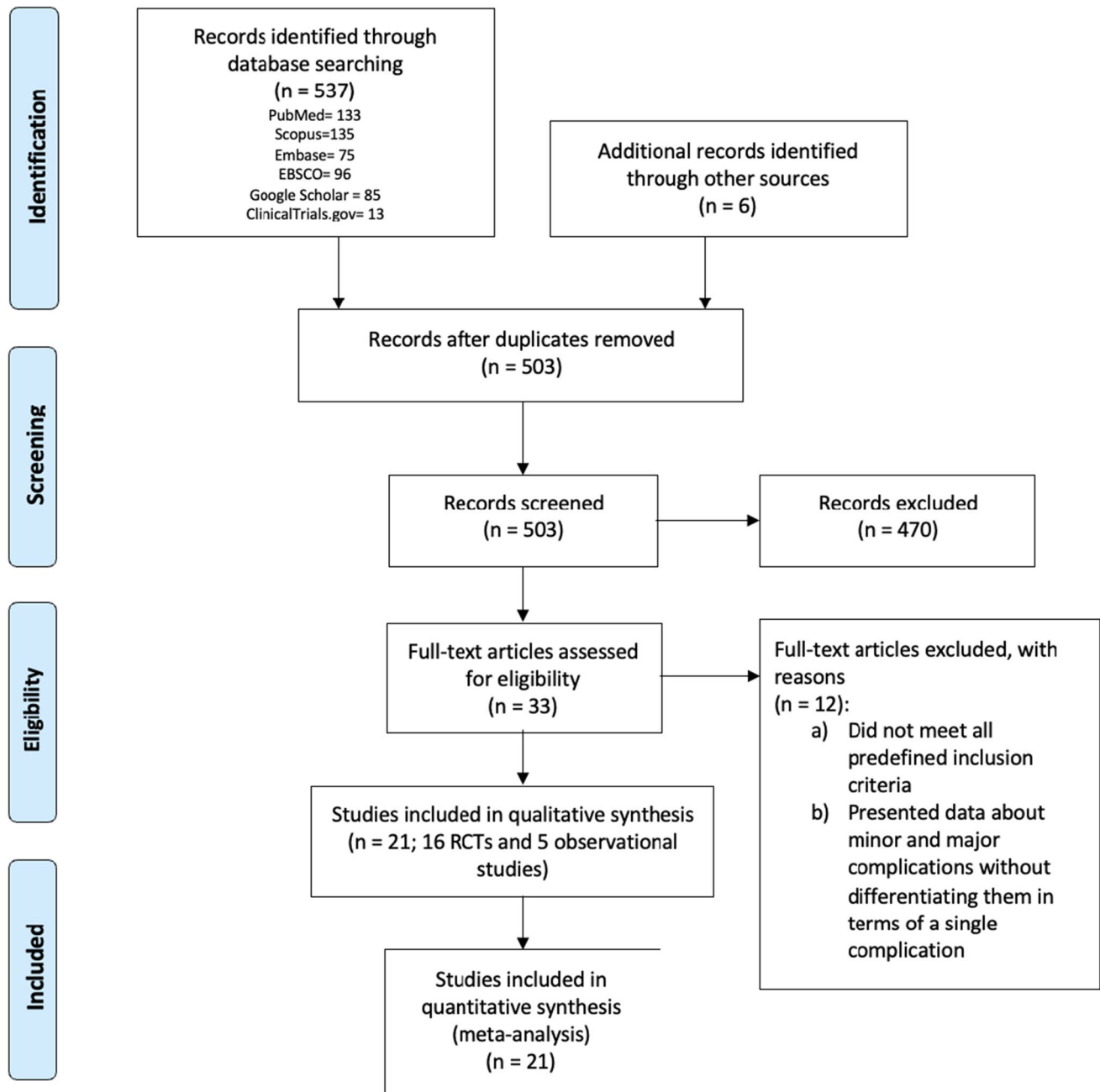


Fig. 1 PRISMA study flow diagram. Literature search and screening process

concealment. (Supplementary Material Figs. 1–2). Funnel plots showed that no clear evidence of publication bias was noted (Supplementary Material Fig. 3). Review Manager 5 software was used to build a visual bias graph and summary.

The risk of publication bias was evaluated for each meta-analysis and funnel plots were generated using Review Manager 5 software. A symmetrical funnel plot signifies no evidence of a high risk of publication bias.

Synthesis of results

Bowel injuries

There were 11 studies reporting results for the proportion of patients with bowel injuries.[20–22, 26, 28–30, 32, 35, 36, 40]. Of the 11 studies reporting this outcome, 4 studies found no cases either in the VN group and the DTI group [21, 22, 32, 40]. According to the results of the

Table 1 Characteristics of included studies

Study name, year	Country	Study type	Surgery type/inclusion and exclusion criteria	Participants and number of procedures (DTI vs VN)	Site of insertion	Comment
Borgatta 1990	USA	RCT	Surgery type: Gynaecological Inclusion criteria: patients who underwent operative laparoscopy Exclusion criteria: not mentioned	Tot=212 (DTI=102; VN=110)	Not mentioned	Lower risk of complications and operative time in DTI
Nezhat 1991	USA	RCT January 1990- September 1990	Surgery type: Gynaecological Inclusion criteria: patients who underwent operative laparoscopy Exclusion criteria: not mentioned	Tot=200 (DTI=100; VN=100)	1 cm transverse subumbilical incision	No significant difference between DTI and VN
Byron 1993	USA	RCT	Surgery type: Gynaecological Inclusion criteria: patients who underwent operative laparoscopy Exclusion criteria: not mentioned	Tot=252 (DTI=111, VN=141)	Not mentioned	Reduced failure of entry and extraperitoneal insufflation in DTI compared with VN. Higher risk of minor complications in VN
Yerdel 1999	Turkey	Prospective observational study Between November 1992 and May 1998,	Surgery type: Gastrointestinal Inclusion criteria: patients scheduled to undergo laparoscopic cholecystectomy Exclusion criteria: previous abdominal incision (except for an incision of appendectomy)	Tot=1500 (DTI=1030; VN=470)	All insertions were done through an infraumbilical 1 to 1.3 cm transverse incision	Lower risk of complications in DTI
Bemelman 2000	Netherlands	RCT June 1999-November 1999	Surgery Type: Gastrointestinal Inclusion criteria: All patients eligible for laparoscopic surgery Exclusion criteria: age < 18, prior midline laparotomy or laparoscopy, and body weight < 40 kg	Tot=40 (VN=20, DTI=20)	Umbilical	No significant difference in terms of complications between the VN group and the DTI group

Table 1 (continued)

Study name, year	Country	Study type	Surgery type/inclusion and exclusion criteria	Participants and number of procedures (DTI vs VN)	Site of insertion	Comment
Jacobson 2002	USA	Retrospective study September 1993—June 2000	Surgery type: Gynecological Inclusion criteria: patients who underwent operative laparoscopy during the study years Exclusion criteria: not mentioned	Tot = 1385 (DTI = 1223, VN = 133)	Umbilical 91(68.4%); Left upper quadrant (sub-costal margin) 33(27.1%); Parumbilical (Left middle quadrant) 5(3.8%); Supraumbilical 1(0.75%); Undocumented 3(2.25%)	No significant differences in terms of complications between the VN group and the DTI group
Agresta 2004	Italy	RCT January 2002–2004	Surgery type: Gastrointestinal Inclusion criteria: non-obese pediatric and adult patients referred for urgent or scheduled laparoscopic and gynecologic procedures. No age limit Exclusion criteria: BMI > 27 kg/m ² ; the presence of massive bowel distension; and a history of two or more abdominal operations	Tot = 598 (DTI = 323, VN = 275)	Umbilical or in the right upper quadrant	In terms of major complications, there is no difference between DTI and VN. Fewer minor complications with DTI in thin and very thin patients of any age category with no previous abdominal surgery
Gunenc 2005	Turkey	RCT	Surgery type: Gynecological Inclusion criteria: patients scheduled to undergo diagnostic laparoscopy Exclusion criteria: not mentioned	Tot 578 (VN = 301) DTI = 277)	DTI: 12- to 13-mm transverse subumbilical incision	No significant differences between the groups in terms of minor and major complication rates
Prieto-Diaz-Chavez 2006	Mexico	RCT From December 1997 to July 1999	Surgery type: Gastrointestinal/Gynecological Inclusion criteria: patients undergoing laparoscopic cholecystectomies during the study period Exclusion criteria: patients with previous superior or high abdominal surgery	Tot 84 (VN = 42, DTI = 42)	1 cm semilunar incision was made above the umbilical cicatrix, initially using obtuse dissection and perforating the anterior aponeurosis of the rectus with a haemostatic clamp	Major complications and the number of failed attempts were more frequent in the VN group, whereas there was no significant difference between the two groups concerning the rest of the complications

Table 1 (continued)

Study name, year	Country	Study type	Surgery type/inclusion and exclusion criteria	Participants and number of procedures (DTI vs VN)	Site of insertion	Comment
Zakherah 2010	Egypt	RCT	Surgery type: Gynecological Inclusion criteria: patients scheduled to undergo diagnostic laparoscopy Exclusion criteria: not mentioned	Tot = 1000 (VN = 500; DTI = 500)	Intra-umbilical skin incision	DT entry is a safe alternative to the VN entry technique for the creation of pneumoperitoneum. Such an approach has further advantages such as less instrumentation, rapid creation of pneumoperitoneum, less CO ₂ use, and fewer minor complications
Angioli 2013	Italy	RCT February 2007–May 2011	Surgery type: Gynecological Inclusion criteria: non-obese adult patients (BMI < 30 kg/m ²) referred for scheduled laparoscopic gynecological procedures for benign pathology. The age range was 18–70 years Exclusion criteria: previous abdominal surgery by laparoscopy or laparotomy, history of pelvic inflammatory disease (PID), irritable bowel syndrome, suspicion of malignancy or malignancy at the histological examination	Tot = 595 (VN = 193, DTI = 187, OP = 215)	A small incision, 1 cm long, is made through the skin of the lower edge of the umbilical fossa	DTI lower number of minor complications compared with the Veress access
Shayani-Nasab 2013	Iran	Prospective multicentric observational study January 2005–January 2011	Surgery type: Urological/gynecological Exclusion criteria: BMI > 40, previous abdominopelvic surgery, uncorrectable coagulopathy, intestinal obstruction, wall infection, massive hemoperitoneum or hemoretroperitoneum, generalized peritonitis, and suspected malignant ascites,	Tot = 453 (DTI = 105; VN = 168; OA = 180)	12-mm incision below the umbilicus	More occurrences of major life-threatening complications in DT than in other groups (P = 0.04). Although minor complications were in the VN group

Table 1 (continued)

Study name, year	Country	Study type	Surgery type/inclusion and exclusion criteria	Participants and number of procedures (DTI vs VN)	Site of insertion	Comment
Imran 2014	Pakistan	RCT August 2013–July 2014	Surgery type: Gastrointestinal Inclusion criteria: all patients undergoing laparoscopic cholecystectomy during the study period were enrolled Exclusion criteria: Age < 20 years and > 65 years) and those with comorbid conditions	Tot = 60 (DTI 30, VN 30)	Not mentioned	With a lower complication rate, DTI is a safe alternative to the VN insertion technique for the creation of pneumoperitoneum
Karaca 2014	Turkey	RCT between the dates January 2007 and July 2009	Surgery type: Gastrointestinal Inclusion criteria: patients undergoing laparoscopic cholecystectomy during the study period Exclusion criteria: not mentioned	Tot = 400 (VN = 200; DTI = 200)	A 10 mm subumbilical incision was made following the general anesthesia and relaxation of the patient	No statistically significant safety-related difference between the DTI and VN insertion techniques if the pneumoperitoneum will be created using the closed technique
Ertugrul 2015	Turkey	RCT	Surgery Type: Bariatric Inclusion criteria: patients with BMI > 40 kg/m ² or BMI of 35–40 kg/m ² with comorbidities related to obesity were selected for surgery Exclusion criteria: history of abdominal surgery	Tot = 81 (DTI = 39; VN = 42)	Not mentioned	DTI in obese patients significantly shortens the entry time, but there can be severe complications with DTI when a nonoptical bladed trocar is used blindly
Godara 2020	India	RCT January 2015–October 2016	Surgery type: Gastrointestinal Inclusion criteria: patients underwent diagnostic/staging/therapeutic laparoscopic surgery Exclusion criteria: pregnant women, age < 18 years, previous abdominal operations, uncorrected coagulopathy, peritonitis	Tot = 100 (DTI = 50, VN = 50)	An initial supraumbilical transverse skin incision was followed by a small nick in the linea alba (2–3 mm),	Direct trocar insertion is a safe and effective method of peritoneal access for minimal laparoscopy complications, and less instrumentation hence cost

Table 1 (continued)

Study name, year	Country	Study type	Surgery type/inclusion and exclusion criteria	Participants and number of procedures (DTI vs VN)	Site of insertion	Comment
Choudhry 2019	Pakistan	RCT September 2017–September 2018	Surgery type: Gastrointestinal Inclusion criteria: Patient of 30–75 years old. Patients undergoing laparoscopic cholecystectomy during the study period Exclusion criteria: Patient with history of advanced procedure and previous laparotomy. Chronic liver disease, ischemic heart disease, para-umbilical hernia	Tot = 608 (DTI = 304, VN = 304)	Not mentioned	DTI is a safe alternative to VN insertion in laparoscopic cholecystectomy. It requires a smaller number of attempts for the successful creation of Pneumoperitoneum as compared to the VN
Pantoja-Garrido 2019	Spain	Prospective observational cohort study June 2013–April 2016	Surgery type: Gynecological Inclusion criteria: gynaecological laparoscopic surgery for both benign and oncological pathologies, entry, or insufflation methods must have been performed at the umbilical level Exclusion criteria: not mentioned	Tot = 600 (VN = 446; DTI = 154)	Umbilical (transverse or vertical)	There were no significant differences in the risk of complication during the DTI and VN. DTI has shorter duration of access manoeuvres, lower number of unsuccessful entry or insufflation attempts
Ikechebelu 2021	Nigeria	RCT November 2015–October 2018	Surgery type: Gynecological Inclusion criteria: reproductive age (from 16 to 49 years) women with a BMI \geq 30 Exclusion criteria: previous multiple abdominal and pelvic surgeries, postmenopausal age, and perioperative examination finding of pelvic mass \geq 18 weeks of gestation in size	Tot = 135 (VN = 67, DTI = 68)	Not mentioned	No significant differences between the DTI group and the VN group

Table 1 (continued)

Study name, year	Country	Study type	Surgery type/inclusion and exclusion criteria	Participants and number of procedures (DTI vs VN)	Site of insertion	Comment
Datey 2021	India	RCT December 2018–May 2020	Surgery type: Gastrointestinal (cholecystectomy, appendicectomy, liver abscess drainage) Inclusion criteria: patients belonging to the age group of 15 to 65 years were enrolled in the study Exclusion criteria: patients who have undergone previous midline laparotomy, BMI > 35, pregnant women, coagulopathy, peritonitis	Tot = 50 (DTI 25; VN 25)	Supraumbilical (an initial supraumbilical transverse skin incision)	Both techniques are equally effective safe and feasible for creation of pneumoperitoneum during LPS procedures
Altun 2007	Turkey	Prospective observational study January 2002–December 2004	Surgery type: Gastrointestinal Inclusion criteria: patients undergoing laparoscopic cholecystectomy during the study period Exclusion criteria: history of previous open or laparoscopic abdominal surgery	Tot = 283 (VN = 135; DTI = 148)	10-mm incision below the umbilicus	No statistically significant difference between both groups in terms of minor and major complications

Table 2 Outcomes and included studies

Outcome or subgroup title	Author, year	No. of studies	Effect size
Bowel injuries	Agresta 2004, Angioli 2013, Borgatta 1990, Byron 1993, Ertugrul 2015, Godara 2019, Ikechebelu 2021, Karaca 2014, Nezhat 1991, Shayani-Nasab 2013, Pantoja-Garrido 2019	11	OR = 0.76, 95% CI: 0.24–2.36, $P = 0.63$
Major vascular injuries	Agresta 2004, Altun 2007, Angioli 2013, Byron 1993, Ertugrul 2015, Godara 2019, Ikechebelu 2021, Imran 2014, Jacobson 2002, Karaca 2014, Nezhat 1991, Pantoja-Garrido 2019, Shayani-Nasab 2013, Yerdel 1999	14	OR = 1.74, 95% CI 0.56–5.38, $P = 0.34$
Port site hernia	Jacobson 2002, Imran 2014, Godara 2019, Shayani-Nasab 2013	4	OR = 2.41, 95% CI: 0.28–20.71, $P = 0.42$
Omental bleeding	Angioli 2013, Borgatta 1990, Ertugrul 2015, Godara 2019, Ikechebelu 2021, Nezhat 1991, Yerdel 1999	7	OR = 2.32, 95% CI: 1.18–4.55, $P = 0.01$
Omental emphysema	Nezhat 1991, Yerdel 1999, Zakherah 2010	3	OR = 18.41, 95% CI: 7.01–48.34, $P < 0.00001$
Subcutaneous emphysema	Agresta 2004, Altun 2007, Datey 2021, Godara 2019, Gunenc 2005, Karaca 2014, Nezhat 1991, Pantoja-Garrido 2019, Shayani-Nasab 2013, Yerdel 1999	10	OR = 5.19 95% CI: 2.27–11.87, $P < 0.0001$
Extraperitoneal insufflation	Agresta 2004, Altun 2007, Angioli 2013, Godara 2019, Ikechebelu 2021, Imran 2014, Prieto-Diaz-Chavez 2006, Zakherah 2010	8	OR = 5.93 95% CI: 1.69–20.87, $P = 0.006$
Multiple trocar insertions	Angioli 2013, Borgatta 1990, Choudhry 2019, Datey 2021, Ertugrul 2015, Godara 2019, Ikechebelu 2021, Nezhat 1991, Prieto-Diaz-Chavez 2006, Zakherah 2010	10	OR = 2.27 95% CI: 1.17–4.39, $P = 0.01$
Trocar site bleeding	Angioli 2013, Datey 2021, Ertugrul 2015, Godara 2019, Ikechebelu 2021, Imran 2014	6	OR = 0.66, 95% CI, 0.25–1.79, $P = 0.42$
Trocar site infection	Angioli 2013, Datey 2021, Godara 2019, Imran 2014, Jacobson 2002, Prieto-Diaz-Chavez 2006	6	OR = 1.19, 95% CI, 0.34–4.20, $P = 0.78$
Time required to access the first trocar (seconds from incision to 15 mmHg pneumoperitoneum)	Angioli 2013, Bemelman 2000, Borgatta 1990, Ertugrul 2015, Ikechebelu 2021, Imran 2014, Zakherah 2010	7	MD = -15.53, 95% CI: -91.32 to 60.27, $P = 0.69$

present meta-analysis from random-effects model, no significant differences were found between the two groups (OR = 0.76, 95% CI: 0.24–2.36, $P = 0.63$, Fig. 2A).

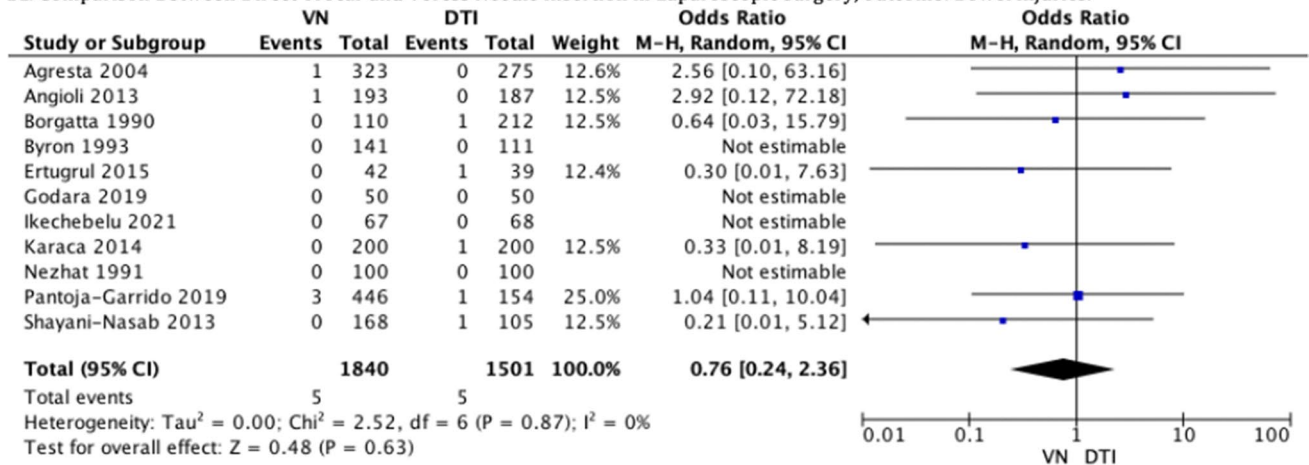
Low heterogeneity was observed between the studies ($I^2 = 0\%$). When we performed a sensitivity analysis excluding studies that selected obese participants, this finding did not change substantially (OR = 0.86, 95% CI: 0.29–2.57, $P = 0.79$). In the subgroup analysis containing only RCTs, we exclude two observational studies [35, 36], but we found similar results (OR = 0.87, 95% CI: 0.21–3.64, $P = 0.84$).

Major vascular injuries

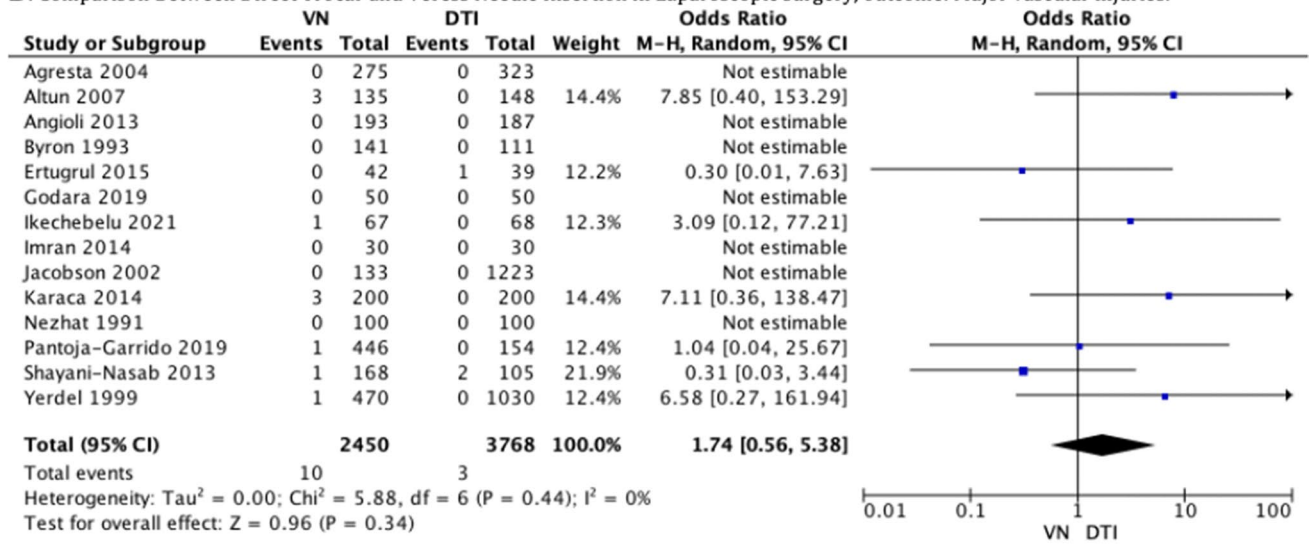
There were 14 studies reporting results for major vascular injuries [21–24, 26–30, 32, 34–36, 40]. No vascular lesion occurred in 7 studies [21–23, 29, 30, 32, 34].

The random-effects model was used for the pooled analysis. No significant differences were found between the two groups (OR = 1.74, 95% CI 0.56–5.38, $P = 0.34$, Fig. 2B). After the removal of studies that included patients who underwent bariatric surgery in a sensitivity analysis, the difference between DTI and VN remains statistically

A: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Bowel injuries.



B: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Major vascular injuries.



C: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Port site hernia.

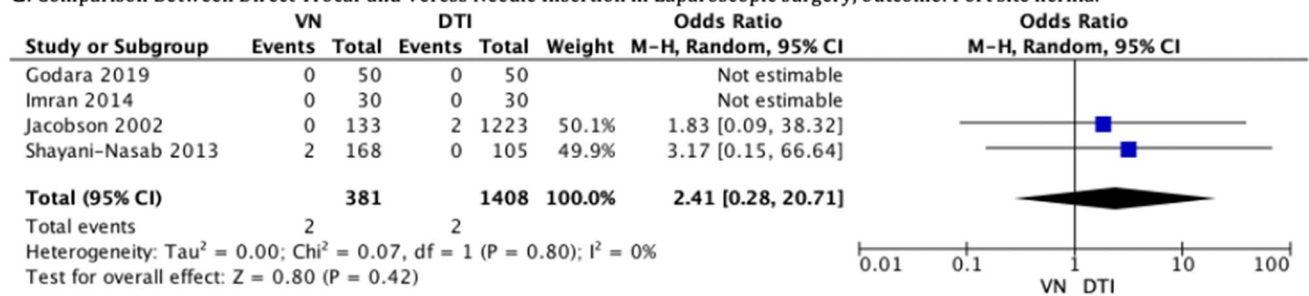


Fig. 2 Meta-analysis of Major complications. **A** Forest plot of comparison: Comparison Between Direct Trocar Insertion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: bowel injuries. **B** Forest plot of comparison: comparison between direct trocar inser-

tion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: major vascular injuries. **C** Forest plot of comparison: comparison between direct trocar insertion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: port site hernia

insignificant (OR = 2.22, 95% CI: 0.67–7.40, $P = 0.19$). We also performed a subgroup analysis considering RCTs only (OR = 2.02, 95% CI: 0.32–12.86, $P = 0.46$).

Port site hernia

Of the 4 studies [23, 32, 34, 36] reporting data about port site hernia, in 2 studies [32, 34] no cases with either VN or DTI entry techniques occurred. No differences were observed in terms of port site hernia between the two groups (OR = 2.41, 95% CI: 0.28–20.71, $P = 0.42$, Fig. 2C). Heterogeneity was absent ($I^2 = 0\%$), a random-effects model was applied. Data were insufficient to perform any sensitivity analysis.

Omental bleeding

Data about omental bleeding were available from 7 studies [20, 21, 24, 26, 30, 32, 40]; no cases in both groups were encountered in 1 of the 7 studies [40]. The meta-analytic effect was statistically significant showing that the DTI group had a lower risk of omental bleeding compared to the VN group (OR = 2.32, 95% CI: 1.18–4.55, $P = 0.01$, Fig. 3A). The random-effects model was used although the low heterogeneity between the studies ($I^2 = 2\%$). After the removal of studies that included patients who underwent bariatric surgery in a sensitivity analysis, this finding did not change substantially (OR = 2.33, 95% CI: 1.00–5.42, $P = 0.05$, $I^2 = 21\%$).

Omental emphysema

According to the results of the present meta-analysis from the random-effects model, the DTI group had a lower risk of omental emphysema compared to the VN group (OR = 18.41, 95% CI: 7.01–48.34, $P < 0.00001$, $I^2 = 0\%$, Fig. 3B). Data were insufficient to perform any sensitivity analysis.

Subcutaneous emphysema

There were 10 studies reporting results for subcutaneous emphysema defined as findings of gas within subcutaneous soft tissue [21, 24, 25, 27–29, 31, 32, 35, 36]. As shown in Fig. 3C, the pooled result from the random-effect model showed that the Veress needle was associated with an increased risk of subcutaneous emphysema compared with DTI (OR = 5.19, 95% CI: 2.27–11.87, $P < 0.0001$). We also performed a sub-group analysis after the removal of four observational studies and we found that the difference between DTI and VN remains statistically significant (OR = 6.60, 95% CI: 2.45–17.74, $P = 0.0002$) [24, 27, 34, 35].

Extraperitoneal insufflation

There were 9 studies reporting results for extraperitoneal insufflation [27–30, 32, 34, 37, 38, 40]. The random-effects model was used because of the moderate heterogeneity between the studies ($I^2 = 63\%$). As shown in Fig. 4A, the pooled result from the random-effects model showed that the Veress needle was associated with an increased risk of extraperitoneal insufflation compared with DTI (OR = 5.93, 95% CI: 1.69–20.87, $P = 0.006$). The subgroup analysis considering RCTs only showed similar statistically significantly different between the two groups (OR = 6.93, 95% CI: 1.42–33.76, $P = 0.02$).

Trocar site bleeding

The pooled results from the random-effects model showed that there was no significant difference in the incidence of trocar site bleeding between the VN group and the DTI group (OR = 0.66, 95% CI: 0.25–1.79, $P = 0.42$). Heterogeneity between the studies was statistically insignificant ($I^2 = 0\%$). (Fig. 4B). We performed sensitivity analysis after the removal of studies that included bariatric patients, we found that results remained similar to the main analysis (OR = 0.86, 95% CI: 0.27–2.41, $P = 0.69$).

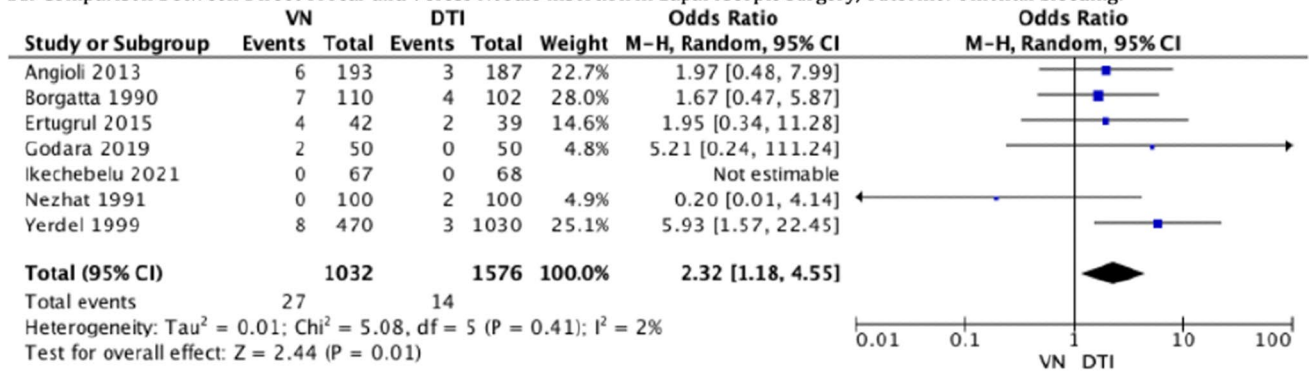
Trocar site infection

The pooled results from the random-effects model showed that there was no significant difference in the incidence of trocar site infection between the VN group and the DTI group (OR = 1.19, 95% CI: 0.34–4.20, $P = 0.78$) (Fig. 4C). We also performed a subgroup analysis considering RCTs only. We excluded the study by Jacobson et al.; however, the difference between the two groups remained statistically insignificant (OR = 1.33, 95% CI: 0.28–6.39, $P = 0.72$).

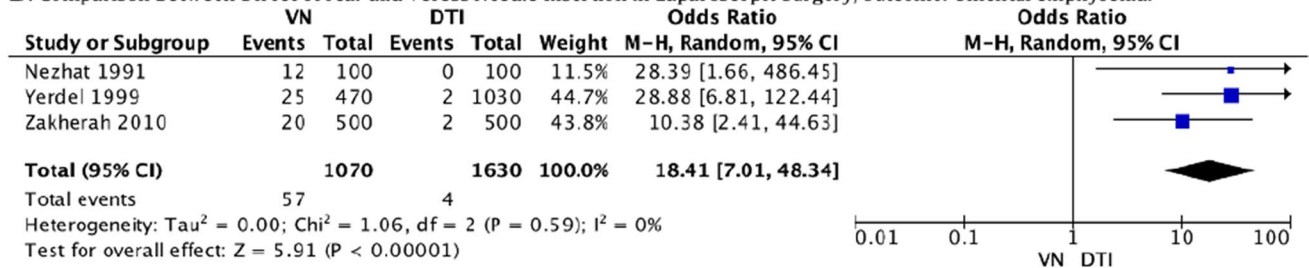
Multiple trocar insertions

The pooled results from the random-effects model showed that VN was associated with a higher number of attempts compared with DTI (OR = 2.27, 95% CI: 1.17–4.39, $P = 0.01$) (Fig. 5A). When we performed a sensitivity analysis excluding studies that selected obese participants, this finding did not change substantially (OR = 2.25, 95% CI: 1.05–4.81, $P = 0.04$).

A: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Omental bleeding.



B: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Omental emphysema.



C: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Subcutaneous emphysema.

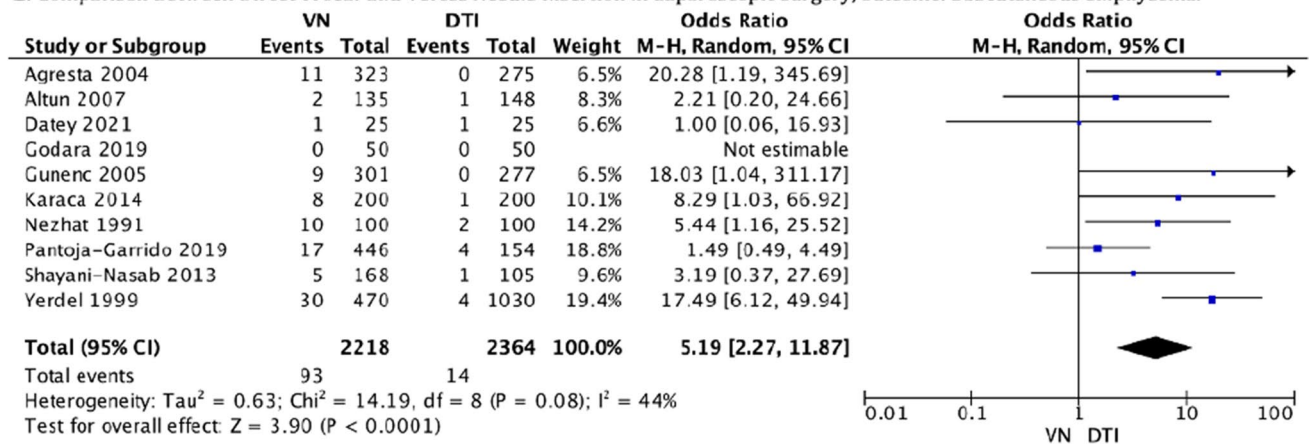


Fig. 3 Meta-analysis of minor complications (1). **A** Forest plot of comparison: comparison between direct trocar insertion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: omental bleeding. **B** Forest plot of comparison: comparison between direct trocar

insertion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: omental emphysema. **C** Forest plot of comparison: comparison between direct trocar insertion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: subcutaneous emphysema

Time required to achieve complete insufflation

Data about the time required to achieve complete insufflation (seconds from incision to 15 mmHg pneumoperitoneum) were available from 7 studies [20, 26, 30, 34, 37, 39, 40]. No differences were observed in terms of seconds from incision to 15 mmHg pneumoperitoneum between the two groups (MD = -15.53, 95% CI: -91.32 to 60.27, $P = 0.69$, Fig. 5B). The random-effects model was used because of the substantial heterogeneity between the studies ($I^2 = 96\%$). The sensitivity analysis after the exclusion

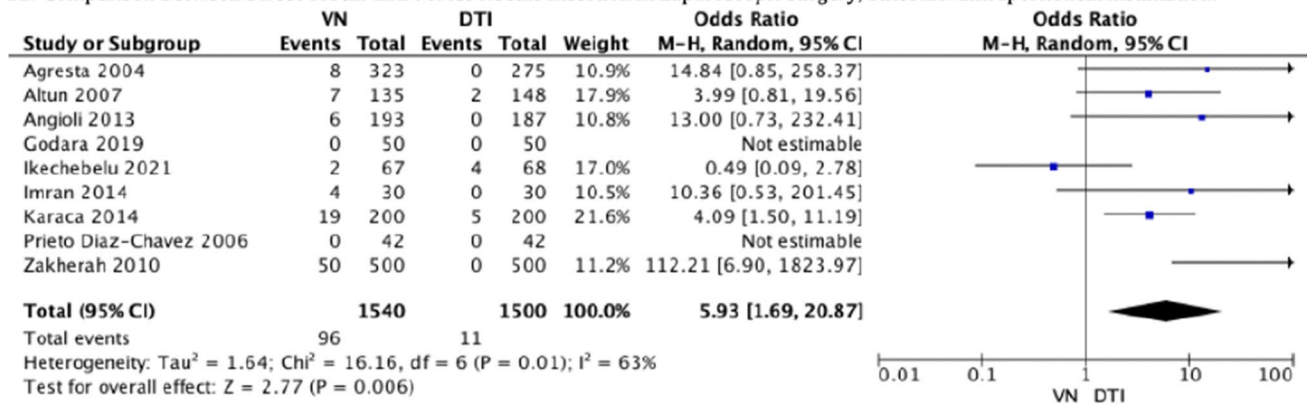
of bariatric patients generated similar results to the main analysis ($P = 0.49$).

Discussion

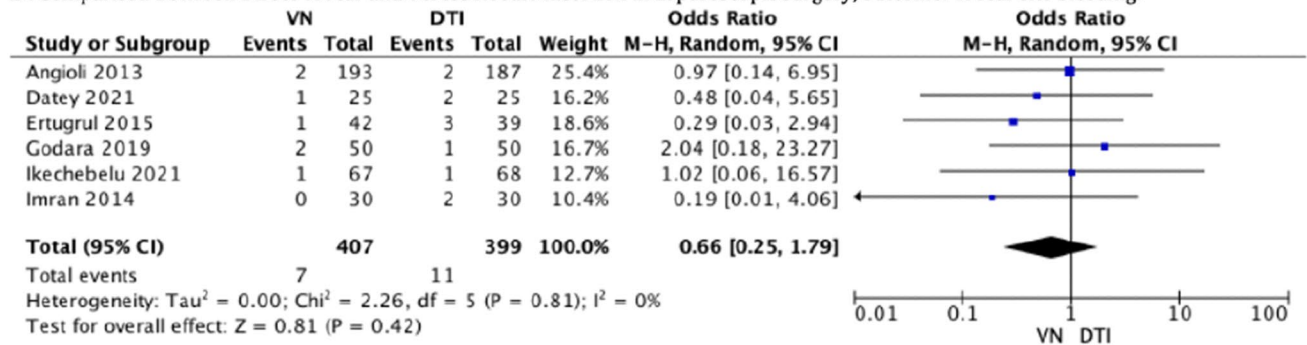
Principal findings

According to the results of the current meta-analysis, there were no significant differences in the risk of major complications during the access manoeuvres between DTI and VN. DTI has a lower risk of minor complications such

A: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Extraperitoneal insufflation.



B: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Trocar site bleeding.



C: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Trocar site infection.

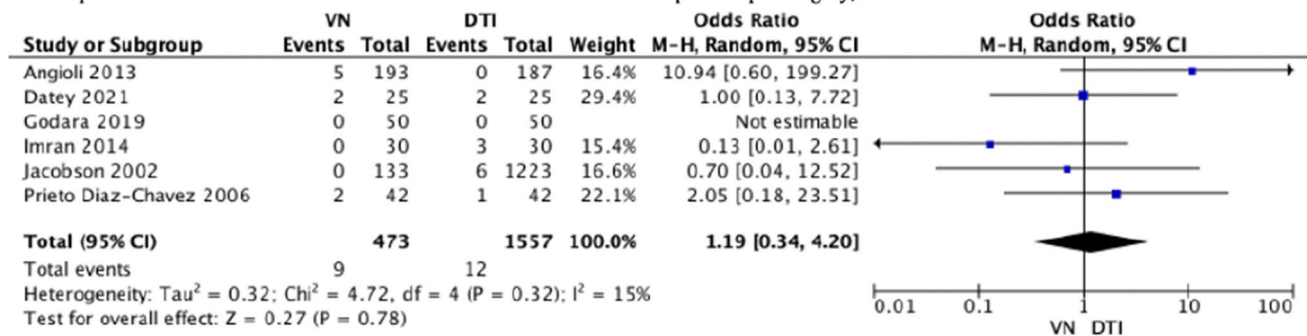


Fig. 4 Meta-analysis of minor complications (2). **A** Forest plot of comparison: Comparison Between Direct Trocar Insertion (DTI) and Veress needle (VN) in Laparoscopic surgery, outcome: extraperitoneal insufflation. **B** Forest plot of comparison: comparison between

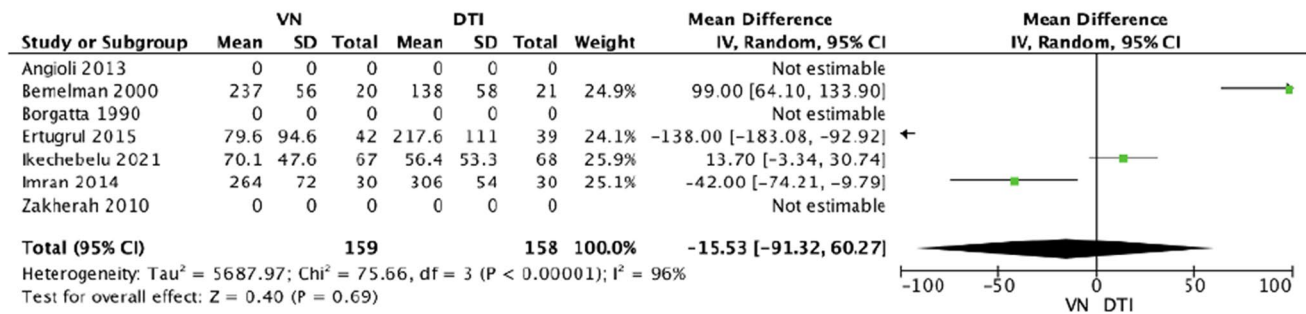
direct trocar insertion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: trocar site bleeding. **C** Forest plot of comparison: comparison between direct trocar insertion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: trocar site infection

as subcutaneous emphysema, extraperitoneal insufflation, omental emphysema and omental bleeding, lower number of unsuccessful entry, or insufflation attempts. No significant differences were found between the two groups in terms of time required to access the first trocar (seconds from incision to 15 mmHg pneumoperitoneum). Thus, DTI is most likely a comparatively safe intervention in laparoscopic surgery. Heterogeneity between the included studies ranges from low to moderate. Estimation bias remained small or moderate under most circumstances.

Comparison with existing literature

Several studies, both observational and RCTs, have been published on the safety of the DTI entry technique reporting lower incidence of complications commonly related to the use of VN such as failed pneumoperitoneum, extraperitoneal insufflation, bowel insufflation, or CO₂ embolism. However, the incidence was insufficient to support one of these two closed-entry techniques and no clear consensus has been reached among laparoscopic surgeons on the

A: Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Time required to access the first trocar (seconds from incision to 15 mmHg pneumoperitoneum).



B: 9 Comparison Between Direct Trocar and Veress Needle Insertion in Laparoscopic surgery, outcome: Multiple trocar insertions.

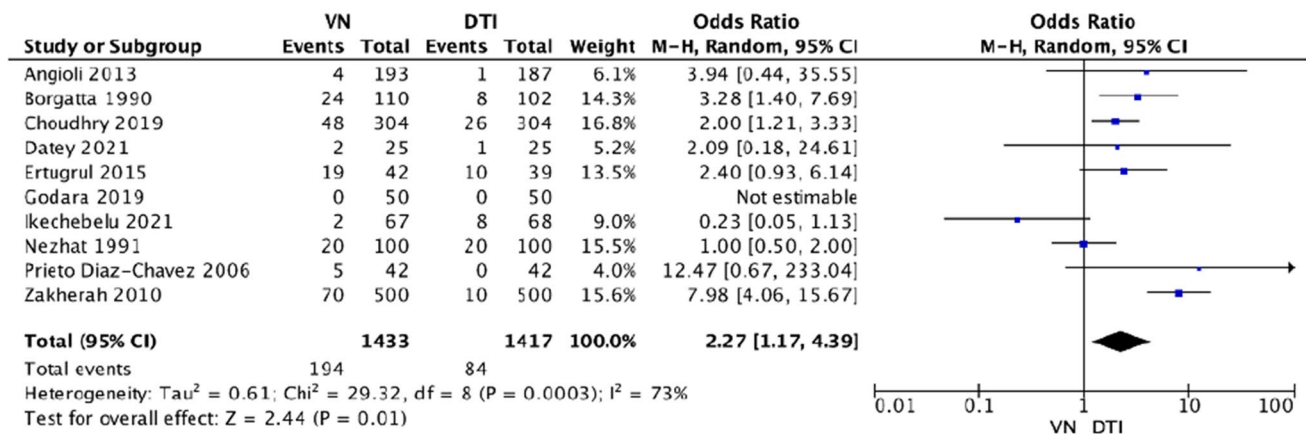


Fig. 5 Meta-analysis, secondary outcomes. **A** Forest plot of comparison: comparison between direct trocar insertion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: multiple trocar insertions. **B** Forest plot of comparison: comparison between direct trocar

insertion (DTI) and Veress needle (VN) in laparoscopic surgery, outcome: time required to access the first trocar (seconds from incision to 15 mmHg pneumoperitoneum)

safest method of laparoscopic blind way of entry. Current guidelines do not support the use of a specific technique over another [41, 42].

As found in a review published in 2016 by Cornette et al., we found a higher incidence of minor complications and failed attempts using the VN method when compared to the DTI entry technique [12]. In a recent SR and meta-analysis by Marchand et. al including 7 RCTs, the authors found similar results to our review in terms of minor complications. The rate of extraperitoneal insufflation was found to be higher in the Veress needle entry group compared with the direct access entry group (OR = 0.177, 95% CI: 0.094–0.333, $P < 0.001$) [43]. Similarly, in a recent systematic review and meta-analysis of the Cochrane Database including 12 RCTs with a total of 4704 participants, Ahmad et al. found a lower incidence of both extraperitoneal insufflation and omental injuries in the DTI group [10]. However, for major complications, the authors concluded that evidence was insufficient to show a difference in rates of vascular injuries, visceral injuries, or solid organ injuries when DTI was compared with VN entry [10, 12].

In our study, we included 16 RCTs and 5 prospective studies with a total of 9214 participants. We performed a subgroup analysis based on the different types of major complications increasing the pool of the included study with recent literature [32, 35, 40].

Contrary to these previous reviews, we found no significant difference between the two groups in terms of major vascular injuries (OR = 1.74, 95% CI 0.56–5.38, $P = 0.34$) and bowel injuries (OR = 0.76, 95% CI: 0.24–2.36, $P = 0.63$). However, it is important to note the rate of major vascular injury was low in these studies, with no case of vascular injury reported in 7 of the 14 studies [21–23, 29, 30, 32, 34].

Patient's characteristic of many included studies was based on a population that was never submitted to abdominal surgery and did not include obese patients. On the other hand, other studies did not fix any exclusion criteria. Then, a previous midline laparotomy is associated with a high risk of intra-peritoneal adhesions to the parietal scar [44–46], with a higher insufflation and first trocar insertion failure rate [46,47] and a higher risk of

complications [48]. In our SR only 12 of 21 studies have excluded patients with a history of midline laparotomy (Table 1).

Since obese patients and patients with a history of abdominal operations are usually associated with higher morbidity, this should be considered an influencing factor in the current study.

Extreme thinness ($BMI < 18.5 \text{ kg/m}^2$) and overweight or obesity ($BMI > 25 \text{ kg/m}^2$) have an important influence on the difficulty of accessing manoeuvres to the abdominal cavity, both in VN and DTI techniques [49]. Patients with $BMI < 18.5 \text{ kg/m}^2$ are more likely to have vascular injuries in large vessels since the distance between the skin and the aorta is below 2.5 cm [50]. On the other hand, in patients with $BMI > 25 \text{ kg/m}^2$, the distance between the skin and the peritoneum is about 6 cm, so the insufflation with VN requires a vertical entry of the needle to reach the cavity, and it is crucial not to produce emphysema or failed entry attempts [9, 49, 51]. However, in RCT involving around 100 women with $BMI > 25 \text{ kg/m}^2$, VN insufflation via the trans-umbilical route was compared with insufflation via the trans-uterine route. Results showed that there was no statistically significant difference in terms of complications or in terms of failure attempt to obtain pneumoperitoneum [51, 52].

In the study of Ertrugul et al., 81 bariatric patients with $BMI > 40 \text{ kg/m}^2$ or BMI of 35–40 kg/m^2 with comorbidities related to obesity were enrolled [26]. Results showed no significant difference in terms of major complications and omental injuries between the two groups using the closed technique.

This updated meta-analysis confirms that there is no statistically significant safety-related difference between DTI and VN insertion techniques. According to the Royal Australian and New Zealand College of Obstetrics and Gynecology (RANZCOG) and the Society of Obstetricians and Gynecologists of Canada (SOCG) clinical practice guideline of 2020 [41, 42] for those surgeons who feel comfortable with the VN entry technique and are not familiar with the DTI approach, it is not recommended for them to change their approach based on the results of the present literature. Instead, it is suggested to choose the best-dominated type of entry at the time of the intervention, that is the entry approach that the surgeon has been trained in and is familiar with. As explained by Cuss et al., this current recommendation reflects the fact that

the present evidence regarding laparoscopic entry is good as it gets because it is unlikely that appropriately powered comparative studies could be performed [1]. In agreement with this limitation, we corroborate the findings that VN is a safe method of entry, even if it still involves three blind steps, while the DTI technique only involves one blind step. On the other hand, DTI is associated with fewer insufflation complications and failed entries. However, consistent with the conclusion of Ahmad et al., we agree that more RCTs with obese and non-obese populations are needed because of the low number of major complications in the available studies [10].

Strengths and limitations

The main limitation of the present systematic review and meta-analysis is the different grades of difficulty for the operations, lack of restrictions regarding surgery type, body mass index (BMI), different experiences of the surgeons, and history of previous surgery. In addition, for many RCTs, we found that many studies did not report sufficient information about the process of randomization and the risk of biases. We decided to include also recent observational studies; however, when applicable, we performed a sub-group analysis containing only RCTs. Despite these limitations, to our knowledge, only one Cochrane review assessing the laparoscopic entry technique was recently performed (2019), our updated systematic review and meta-analyses cover a longer time interval and contain a larger number of recent randomized control trials. Furthermore, strengths include also low heterogeneity of the included studies, comprehensive search strategy, use of two reviewers to perform the literature search, data extraction, and the analysis of the risk of bias.

Conclusions

This systematic review and meta-analysis demonstrate that there is no statistically significant safety-related difference between DTI and VN insertion techniques in terms of major complications. However, a lower number of minor complications were found with DTI closed-entry technique compared with Veress access. Findings from this review support present guidelines and recommendations for further RCTs to assess the safety of these two approaches in obese and non-obese populations.

Appendix

Please see Table 3.

Table 3 GRADE summary of findings table for secondary outcomes

Outcomes	Relative effect (95% CI)	N _o of participants (studies)	Certainty of the evidence (GRADE)	Comments
Bowel injuries	OR = 0.76, CI: 0.24–2.36, <i>P</i> = 0.63	3341 (11 studies: 9 RCTs, 2 observational studies)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite bowel injuries
Major vascular injuries	OR 1.74, CI 0.56–5.38, <i>P</i> = 0.34	6218 (14 studies: 9 RCTs, 5 observational studies)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite major vascular injuries
Port site hernia	OR = 2.41, CI: 0.28–20.71, <i>P</i> = 0.42	1789 (4 studies: 2 RCTs, 2 observational studies)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite port site hernia
Omental bleeding	OR = 2.32, CI: 1.18–4.55, <i>P</i> = 0.01	2527 (7 studies: 6 RCTs, 1 observational study)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite omental bleeding
Omental emphysema	OR = 18.41, CI: 7.01–48.34, <i>P</i> < 0.00001	2700 (3 studies: 2 RCTs, 1 observational study)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite omental emphysema
Subcutaneous emphysema	OR = 5.19 CI: 2.27–11.87. <i>P</i> < 0.0001	4582 (10 studies: 6 RCTs, 4 observational studies)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite subcutaneous emphysema
Extraperitoneal insufflation	OR = 5.93 CI: 1.69–20.87. <i>P</i> = 0.006	3040 (8 studies: 7 RCTs, 1 observational study)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite extraperitoneal insufflation
Multiple trocar insertions	OR = 2.27 CI: 1.17–4.39. <i>P</i> = 0.01	2850 (10 RCTs)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite multiple trocar insertion
Trocar site bleeding	OR = 0.66, CI, 0.25–1.79. <i>P</i> = 0.42	806 (6 RCTs)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite trocar site bleeding
Trocar site infection	OR = 1.19, CI, 0.34–4.20. <i>P</i> = 0.78	2030 (6 studies: 5 RCTs, 1 observational study)	⊕⊕○○ Low certainty ^{a,b}	The evidence is uncertain about the way of entry (VN vs DTI) on composite trocar site infection
Time required to access the first trocar (seconds from incision to 15 mmHg pneumoperitoneum)	MD = -15.53, CI: -91.32 to 60.27, <i>P</i> = 0.69	317 (7 RCTs)	⊕○○○ Very low certainty ^{a,b,c}	The evidence is uncertain about the way of entry (VN vs DTI) on time required to achieve pneumoperitoneum

Explanations

- Downgrade by one level due to a high risk of bias in most of the included studies for this outcome (see the ROB assessment results with ROBINS I)
- Downgrade by one level due to probable publication bias (see the funnel plots and the results section)
- Downgrade by two levels due to very wide confidence intervals. Confidence interval range greater than 1.0 OR points
- Downgrade by one level due to wide confidence intervals. Confidence interval range greater than 0.5 OR points

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI)
CI, confidence interval; *OR*, odds ratio

GRADE working group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Explanations

- Downgrade by one level due to a high risk of bias in most of the included studies for this outcome (see the ROB assessment results with ROBINS I)
- Downgrade by one level due to probable publication bias (see the funnel plots and the results section)
- Downgrade by two levels due to very wide confidence intervals. Confidence interval range greater than 1.0 OR points
- Downgrade by one level due to wide confidence intervals. Confidence interval range greater than 0.5 OR points

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00423-023-02891-8>.

Author contribution TC, PG, and GP conceived and designed the study; TC and RA independently reviewed the literature according to the predefined strategy and criteria. TC performed the statistical analysis; TC and DM drafted the article; TC and SG contributed to the data collection and quality control; GP, VG, PG, SG, and SM made critical revisions to the manuscript. All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

Data Availability The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Competing interests The authors declare no competing interests.

Conflict of interest The authors declare no competing interests.

Informed consent Not applicable.

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