Journal of Pediatric Surgery 56 (2021) 569–572

Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.elsevier.com/locate/jpedsurg

Safety of Veress needle for laparoscopic entry in children: Myth or reality?

Alessio Pini Prato [a,*], Federico Palo [b,c], Maria Grazia Faticato [a], Claudio Carlini [a], Girolamo Mattioli [b,c]

[a] The Children Hospital, Umberto Bosio Center for Digestive Diseases, Pediatric Surgery Unit, AO SS Antonio e Biagio e Cesare Arrigo, Alessandria, Italy
[b] Pediatric Surgery Unit, Istituto Giannina Gaslini, Genova, Italy
[c] DINOGMI, Università degli Studi di Genova, Genova, Italy

ARTICLE INFO

Article history:
Received 22 March 2020
Received in revised form 15 May 2020
Accepted 30 May 2020

Key words:
Veress needle
Laparoscopy
Complications
Bleeding
Mortality

ABSTRACT

Introduction: Recent reports suggested that blind laparoscopic entry techniques, including Veress needle (VN), might increase the risks of potentially fatal complications.
Materials and methods: All consecutive patients who underwent laparoscopy in two Pediatric Hospitals with the use of a Veress needle during a 14-year period have been included. In all cases the first trocar was a radially expanding one (STEP). Complications related to the insertion technique are reported as well as those related to the whole laparoscopic technique.
Results: A total of 3463 patients younger than 18 years of age underwent laparoscopy between January 2006 and December 2019. Of these, 205 (5.9%) were younger than 6 months of age at surgery. Two-hundred-eighty-four patients (8.2%) previously underwent abdominal surgery. During first trocar insertion no major or minor vascular injuries occurred. Two patients (0.06%) experienced bowel lesions. Nine (0.26%) experienced failed entry. Fourteen patients (0.4%) experienced postoperative issues related to trocars positioning, namely, 9 omental eviscerations through port site insertion and 5 cases of hemoperitoneum owing to epigastric vessels lesion during operative trocar positioning. No other issues strictly related to laparoscopic entry technique have been recorded during the study period. No specific risk factors predisposing to complications have been identified but the presence of a positive history of previous abdominal procedures proved to be significantly related to a higher occurrence of bowel injury during Veress needle insertion ($p = 0.0067$).
Discussion and conclusions: Although with a number of biases and limitations, our study suggests that creation of pneumoperitoneum with VN combined to first trocar entry with STEP technology in children can represent a safe alternative. An exception is represented by patients who underwent previous abdominal surgeries who should be approached with caution, possibly with an open approach. Anyway, given the relatively poor quality of high-quality studies on this regard, we strongly support the implementation of well-designed RCT in children in order to answer this delicate topic.
Type of study: Retrospective.
Level of evidence: IV

Some reports suggested that pneumoperitoneum (PP) creation with Veress needle (VN) could lead to potentially serious complications owing to major vascular injuries, bowel lesions or parenchymal tearing [1–3]. Nonetheless, most randomized controlled trials (RCTs) comparing different routes for PP creation in adults failed to identify the preferred option for a safe laparoscopy [4–8]. A recent prospective study by Wolthuis AM, belonging to the Belgian Group of Endoscopic Surgery [9], suggested that Veress needle entry is safe to create pneumoperitoneum, at least in adults.

Nonetheless, since 2016 the French Haute Autorité de Santé stated that "In accordance with the literature, the open route (open laparoscopy) should be preferred in infants" and that "…the open route is imperative in children to reduce morbidity, particularly in young children" [10]. The French Authority basically reported these statements on the grounds of theoretical risks more than on evidence. Of note, the authors themselves recognized that "whenever it is difficult to recommend a technique based on evidence-based data, it remains possible to raise awareness about technical recommendations validated by the profession and the barriers that can be used to prevent complications or reduce their severity" [10].

* Corresponding author at: The Children Hospital, Umberto Bosio Center for Digestive Diseases, Pediatric Surgery Unit, Azienda Ospedaliera SS. Antonio e Biagio e Cesare Arrigo, Alessandria, Italy, EU, Spalto Marengo, 46, 15121 Alessandria, Italy. Tel.: +39 0131207372, +39 33471327431 (mobile).
E-mail addresses: apini@ospedale.al.it a.piniprato@gmail.com (A. Pini Prato).

https://doi.org/10.1016/j.jpedsurg.2020.05.042
0022-3468/

Although we agree that a number of key-point are crucial for the correct creation of PP, above all full knowledge of the instrumentation used by the operator as well as the confidence and skills of the operator who is performing the procedure, we do believe that some more evidence regarding the use of VN for the creation of PP is needed before being able to address this issue with absolute statements and recommendations.

On the grounds of these considerations, we aimed at reporting a bicentric experience with VN creation of PP in order to report the incidence of complications and discuss the possible role of closed entry in pediatric population undergoing laparoscopic surgery.

1. Materials and methods

The notes of all consecutive patients younger than 18 years of age who underwent laparoscopic surgery at Giannina Gaslini Institute, Genoa and at The Children Hospital, Alessandria between July 2006 and December 2019 were retrospectively reviewed.

Details regarding age, weight, gender, previous laparoscopic or open procedures, technical details regarding PP creation, level of expertise of the operator who performed the procedure, intraoperative major or minor complications, deaths and all surgical-related issues have been collected. Other issues, such as the impact of patients' specific variables (previous surgery, age, gender), were addressed in order to determine high risk and low risk patients to be dealt with.

1.1. Definition of complications

- Related to VN positioning and PP creation
  - o Failed entry requiring subsequent open access for laparoscopy
  - o Failed entry requiring conversion to open surgery
  - o Major bleeding (requiring blood transfusion and/or operative intervention)
  - o Parenchymatous organ injury
  - o Bowel injury
  - o Air embolism
- Other injuries during positioning of operative trocars (from 2nd trocar on)
- Postoperative complications related to trocars or VN positioning

1.2. Technical aspect

VN positioning for PP creation and trocar positioning were similar in both centers owing to the common education of the chief surgeons. We can summarize as follows.

- Unless the patient underwent previous open surgical procedures involving the umbilicus, the site for VN insertion and PP creation should be the umbilicus.
- Alternatively, the Palmer's point in the left hypochondrium is used as a second choice for VN insertion and PP creation.
- The abdominal wall of the patients should be lifted by the surgeon's left hand in order to stay away from intraabdominal organs.
- The skin incision should be 50% longer than the size of the trocar that will be inserted (i.e. 10 mm trocars require 15 mm incisions) to avoid tension and excessive force during trocar positioning
- The VN should be held as a pen and inserted with a vertical 90° angle in the umbilicus in order to find the shortest way to the abdominal cavity.
- A double “click” feeling should confirm the correct insertion of the VN
- A syringe filled with saline should be connected to the VN in order to perform suction and irrigation tests. The former should determine minimal air aspiration and the latter should allow the saline to flush freely and passively inside the cavity
- The insufflator should be now connected to the VN and a low-flow CO_2 insufflation should begin (we usually maintain the flow between 1 and 5 l per minute) rising pressure up to 6 to 12 mmHg according to patients' age and weight (6 for newborns, 8 for infants, 10 to 12 for older children and adolescent).
- Provided the patient is paralyzed, a correct insufflation should maintain intraabdominal pressure below 6 mmHg confirming the absence of obstacles during insufflation and subsequently the correct positioning of the VN.
- The first trocar we use is always a radially expanding trocar (RET) based on Step technology (Versastep® trocars, Covidien Medtronic 710 Medtronic Parkway, Minneapolis, Minnesota 55432-5604 USA) in order to minimize the risk of secondary lesions.
- The operative ports can be either disposable or reusable and are positioned under direct vision. Their removal at the end of the procedure is similarly performed under direct vision to exclude delayed bleeding from the port sites.

1.3. Statistical analysis

Descriptive statistics were reported as absolute frequencies and percentages. Median and ranges or mean and standard deviation were used to describe semiquantitative and quantitative variables. Two tailed Fisher's exact test was used to compare categorical variables. Unpaired t test was used to compare continuous variables. A p lower than 0.05 was considered to be statistically significant.

2. Results

During 14-year study period a total of 3762 patients younger than 18 years of age underwent laparoscopic surgery at Giannina Gaslini Institute, Genoa and The Children Hospital, Alessandria. Of these, 3463 patients (92%) underwent closed entry for laparoscopy using a VN approach for the creation of PP. We resorted to an open entry technique in case of technical issues (see below) or of lack of devices required to perform a safe approach (either lack of VN or RET or both).

2.1. Demography

Male to female ratio was 1.72:1. Median age at surgery was 8.8 ± 5.4 years. Two-hundred and five patients (5.9%) were younger than 6 months of age at surgery (Table 1).

Table 1
Overview, demographics and complications of our series of patients. All complications proved to occur regardless of the experience of the operator performing the procedure. The only bleeding occurred during the insertion of an operative trocar (2nd trocar) under direct vision (iliac vein laceration). Complications (visceral lesions) proved to be significantly more frequent in patients who previously underwent abdominal surgery.

Total patients	3463	p[a]
Male to female ratio	1.72:1	*n.s.*
Median age at surgery (range)	8.8 ± 5.4 years	*n.s.*
Patients younger than 6 months of age	205 (7.1%)	*n.s.*
Previous abdominal surgery	284 (8.2%)	*0.0067*
Performed by senior surgeons	2390 (69%)	*n.s.*
Performed by resident under supervision	1073 (31%)	
Overall complications	**26 (0.75%)**	
Intraoperative complications	**12**	
Bleeding	1	
Visceral lesions	2	
Air embolism	0	
Failed entry	9	
Conversion to open entry	7	
Conversion to laparotomy	2	
Postoperative complications	**14**	
Bleeding	5	
Omental evisceration	9	

Legend: *n.s.* = not significant (p *value* > *0.05*).
[a] Statistical assessment comparing the incidence of complications according to gender, age, previous abdominal surgery and surgical expertise.

2.2. Series

Procedures included foregut (fundoplication, hypertrophic pyloric stenosis, cholecystectomy, duplication cysts), midgut (Meckel diverticulum, intestinal malrotation, bowel resections for inflammatory bowel diseases) and hindgut surgeries (appendectomy, pull-through for Hirschsprung and anorectal malformations), tumors and others, including atresia, diaphragmatic hernias and rare complex congenital malformations.

2.3. Reoperations and operator expertise

Two-hundred-eighty-four patients (8.2%) previously underwent either open or laparoscopic surgical procedures and were therefore included as reinterventions.

In 1073 cases (31%), the procedure, including VN insertion, PP creation and first trocar positioning, was entirely performed by a resident under senior consultant supervision.

Intraoperative complications (12 out of 3463 procedures = 0.35%) (Table 1)

- **Failed entry** was experienced in 9 cases (0.3%). Seven required subsequent open insertion of first trocar; 2 required conversion to open surgery (both for acute appendicitis).
- No **major bleeding** related to vascular injury occurred during VN or first trocar insertion. In 4 patients, small hematomas of the abdominal wall without significant blood loss or need for further intervention were reported.
- No **major parenchymal organ lesions** were observed but there was one minor hepatic tearing that did not require any specific intervention.
- Two patients (0.06%) experienced **bowel injury** related to the insertion of both the VN and first trocar in a bowel loop. Both patients previously underwent multiple laparotomies (2 out of 284 patients for a 0.7% incidence of visceral lesion). Both cases required conversion to laparotomy demonstrating the presence of adhesive intestinal obstruction with thick adhesions. Both bowel lesions were sutured, and the procedures were carried out with conventional laparotomy.
- None of the patients experienced **air embolism.**
- One patient (0.03%) experienced **iliac artery laceration** during right operative trocar positioning under direct vision (2nd trocar, not VN for PP creation). This issue was presumably because of poor visualization during positioning. The patient (underwent laparoscopy for undescended testis) required immediate conversion to open surgery and suturing of the iliac artery. He was discharged on postoperative day 15.

Early postoperative complications (14 out of 3463 procedures = 0.4%) (Table 1)

- Omental eviscerations through port site (either umbilicus or operative port sites) occurred in 9 cases (0.26%).
- Postoperative hemoperitoneum owing to epigastric vessels laceration occurred during operative trocar positioning (never during VN, PP creation, or first trocar positioning) and was reported in 5 cases (0.14%). All were appendectomies. Those children required blood transfusion and reoperation (laparoscopic approach in all cases).

No other issues strictly related to the chosen approach have been recorded during the study period. With regard to specific risk factors predisposing to complications we could identify a significant relationship of bowel lesions ($p = 0.0067$) and VN use for PP creation in previously operated patients (we could not address if this correlation is proportional to the number and type of previous procedures). If we filter only for patients who underwent primary laparoscopy (no previous abdominal procedures) and experienced VN-related issues, intraoperative complications were represented by 9 failed entries (0.28%). Gender, age and type of procedures proved not to be significantly correlated to the likelihood of complications. Similarly, the incidence of complications proved not to be significantly correlated to the expertise of the operator, at least in this series (Table 1).

3. Discussion

The results of our study support safety and effectiveness of VN use in children. The overall incidence of complication is well below 1%, with most complications represented by trivial issues. When addressing major intraoperative complications (major bleeding, air embolism, and visceral lesions) we basically did not observe any life-threatening complications but two bowel lesions, thus confirming the safety of VN as laparoscopic entry technique. Visceral lesions have been reported with an average incidence of 0.3% in adult series [5,6]. The incidence observed in our series is even lower and supports an increased safety of VN for laparoscopic entry in children. A number of papers suggested that VN may increase the risk of failed entry during PP creation for laparoscopic procedures [5–8]. The average reported incidence of failed entry in adult reports ranges between 1% and 14% [5], whereas that of children has never been addressed so far. The incidence of failed entry in our series proved to be well below 1%, thus suggesting that VN is even more effective in children compared to adults on this regard.

These considerations are not surprising given the thinner abdominal wall of pediatric patients, even those overweight or adolescent, compared to that observed in adults. In fact, a lighter, thinner and less consistent abdominal wall makes the use of VN easier, as it allows a better control of the device and an increased sensation of needle penetration through layers, thus avoiding excessive progression of the sharp needle and subsequent visceral or vascular injuries.

Although all procedures have been performed according to careful technical details and security key-points (both insertion and extraction of operative trocars under direct vision) more than half of complications experienced in our series occurred as a consequence of operative trocars positioning that represents, per se, a vulnerability of laparoscopic procedures unrelated to VN or other approaches to PP creation. The use of RET might reduce the risk of postoperative or unrecognized intraoperative bleeding as well as that of postoperative omental evisceration (smaller size of fascial defects) as confirmed by a number of reports addressing this issue [13,14]. Although we could not track back which kind of trocar was used in all cases for operative ports, given the lack of standardization regarding this specific aspect of our protocol, we could speculate that a systematic use of RET for operative accesses might reduce these complications.

Statistical analysis showed that previously operated patients have a higher likelihood of bowel lesions when VN is used for PP creation, compared to nonoperated ones. Even so, the incidence of these complications is lower compared to other reported series [5–8]. We cannot exclude that alternative approaches would have ended with the same outcome, but this subset of patients might deserve an open approach with first trocar positioning and PP creation under direct vision to promptly detect visceral lesions.

Interestingly, our series also demonstrated that both well-experienced pediatric surgeons and junior residents can safely use VN device with minor to marginal risk of damaging vital structures. In fact, provided the procedure is performed under direct senior supervision, the incidence of complications proved not to be statistically increased in case of junior resident involvement. Furthermore, we could confirm that VN is a versatile device that can be used in all pediatric ages without any subset of pediatric patients particularly suitable for this approach to PP creation.

Our study has several limitations. 1) the long time-span limits the consistency and reproducibility of results as most procedures have been performed under diverse and evolutive environmental circumstances as well as with different versions of devices; 2) the lack of randomization and comparison with other techniques for PP creation limits the reliability of our results that can be only compared to

literature data available mostly in reports belonging to adult patients and practice; 3) most important, the retrospective nature of this study implies a number of inclusion biases and limits the possibility to address a number of interesting variables that could have helped in interpreting the results in a more convincing and reliable way. Of note, it has been recently demonstrated that a striking underreporting of complications occurred during VN positioning in retrospective notes review compared to direct prospective observation with a subsequent 5-folds underestimation of complications [15].

Even so, the results of our retrospective study suggested that the 2016 statement of the French Haute Autorité de Santé was somehow overreaching as the French Authority suggested to ban an approach based on assumed preconceptions more than on scientific evidences. In fact, a number of meta-analyses, prospective studies, case series [5–12] and, last but not least, our experience all failed in finding VN dangerous for the creation of PP in patients younger than 18 years of age. At least, none found VN to be worse than other alternative methods for creating PP for laparoscopy. These data are abundant in adults but seem to lack in children where only a minority of outdated reports speculated on possible increased risk of VN for PP creation [1–3], without demonstrating any sure benefit of a specific technique over the others.

Although only RCTs could provide definitive answers on this regard, we are well aware that such demanding studies would take thousands of patients with a low likelihood of detecting statistically significant differences. Based on the results of our series we thus suggest considering VN for PP creation in children as a safe alternative entry technique provided a RET is used as first trocar after PP creation. This laparoscopic entry technique proved to be reproducible and can be adopted by experienced surgeons as well as by residents provided adequate supervision is ensured. Previously operated patients might deserve open approach and extreme care for PP creation though the likelihood of visceral lesions remains well below literature ranges. We could speculate that these impressive results are strictly correlated to the whole procedure and to the combination of VN and RET that increases safety, reliability and reproducibility of the procedure. To conclude, based on the results of our series of 3463 pediatric patients, VN for PP creation with the use or RET for first trocar positioning is a valid alternative laparoscopic entry technique that ensures safety, reproducibility and versatility from neonates to adolescents.

References

[1] Esposito C, Ascione G, Garipoli V, et al. Complications of pediatric laparoscopic surgery. Surg Endosc. 1997;11(6):655–7.

[2] Esposito C, Porreca A, Esposito G. Vascular complications during laparoscopy. An analysis of a personal case. Minerva Chir. 1999;54(3):163–5 Review. Italian. PubMed PMID: 10352526.

[3] Esposito C, Mattioli G, Monguzzi GL, et al. Complications and conversions of pediatric videosurgery: the Italian multicentric experience on 1689 procedures. Surg Endosc. 2002;16(5):795–8 Epub 2002 Feb 8. PubMed PMID: 11997824.

[4] Cornette B, Berrevoet F. Trocar injuries in laparoscopy: techniques, tools, and means for prevention. A systematic review of the literature. World J Surg. 2016;40(10): 2331–41. https://doi.org/10.1007/s00268-016-3527-9. Review. PubMed PMID: 27146054.

[5] Ahmad G, Baker J, Finnerty J, et al. Laparoscopic entry techniques. Cochrane Database Syst Rev. 2019;1:CD006583. https://doi.org/10.1002/14651858.CD006583.pub5 PubMed PMID: 30657163; PubMed Central PMCID: PMC6353066.

[6] Ahmad G, Gent D, Henderson D, et al. Laparoscopic entry techniques. Cochrane Database Syst Rev. 2015;8:CD006583. https://doi.org/10.1002/14651858.CD006583.pub4 Review. Update in: Cochrane Database Syst Rev. 2019 Jan 18;1:CD006583. PubMed PMID: 26329306.

[7] Ahmad G, O'Flynn H, Duffy JM, et al. Laparoscopic entry techniques. Cochrane Database Syst Rev. 2012;15(2):CD006583. https://doi.org/10.1002/14651858.CD006583.pub3 Review. Update in: Cochrane Database Syst Rev. 2015;8:CD006583. PubMed PMID: 22336819.

[8] Ahmad G, Duffy JM, Phillips K, et al. Laparoscopic entry techniques. Cochrane Database Syst Rev. 2008;16(2):CD006583. https://doi.org/10.1002/14651858.CD006583.pub2 Review. Update in: Cochrane Database Syst Rev. 2012;2:CD006583. PubMed PMID: 18425957.

[9] Wolthuis AM. Veress needle creation of a pneumoperitoneum: is it risky? Results of the first Belgian group for endoscopic surgery-snapshot study. J Laparoendosc Adv Surg Tech A. 2019;29(8):1023–6. https://doi.org/10.1089/lap.2019.0243. Epub 2019 May 29. PubMed PMID: 31140894.

[10] Haute Autorité de Santé. Fédération de chirurgie viscérale et digestive (FCVD). How can we reduce the risks associated with the creation of a pneumoperitoneum in digestive surgery? 2016

[11] Powell-Brett S, Richardson M, Super P, et al. Veress needle creation of pneumoperitoneum: a safe technique. Obes Surg. 2020;17. https://doi.org/10.1007/s11695-020-04435-1. [Epub ahead of print] PubMed PMID: 32067165.

[12] Yanke BV, Horowitz M. Safety of the Veress needle in pediatric laparoscopy. J Endourol. 2007 Jul;21(7):695–7 PubMed PMID: 17705752.

[13] Bhoyrul S, Payne J, Steffes B, et al. A randomized prospective study of radially expanding trocars in laparoscopic surgery. J Gastrointest Surg. 2000;4(4): 392–7.

[14] Feste JR, Bojahr B, Turner DJ. Randomized trial comparinga radially expandable needle system with cutting trocars. Journal of the Society of Laparoendoscopic Surgeons. 2000;4:11–5.

[15] Jung JJ, Adams-McGavin RC, Grantcharov TP. Underreporting of Veress needle injuries: comparing direct observation and chart review methods. J Surg Res. 2019; 236:266–70. https://doi.org/10.1016/j.jss.2018.11.039. Epub 2018 Dec 24. PubMed PMID: 30694765.