Original Research Article

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Comparison between direct trocar versus Veress needle for laparoscopic access: a randomized controlled study

Divya Kirti¹, Dinesh Jain¹, Kedar Patil¹, Deepak Phalgune^{2*}

¹Department of Surgery, ²Department of Research, Poona Hospital and Research Centre, Pune, Maharashtra, India

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*Correspondence: Dr. Deepak Phalgune,

E-mail: dphalgune@gmail.com

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ABSTRACT

Background: The existence of numerous techniques for creation of pneumoperitoneum at laparoscopy indicates that none has been proven totally efficacious or complication free. There is dearth of study in India comparing these techniques. The aim of present study was to compare the safety and duration for creating pneumoperitoneum between direct trocar (DT) and Veress needle (VN) technique.

Methods: One hundred-fourteen patients aged between 18 and 70 years were included in this single-blind randomized controlled study. Group DT and group VN patients underwent laparoscopic surgery after trocar placement by direct trocar insertion technique and Veress needle technique respectively. The primary outcome measure was the incidence of complications whereas secondary outcome measures were number of items required and time needed to introduce the laparoscope. Intergroup comparison of categorical and continuous variables was done using the Chi-square test/Fisher's exact test and unpaired t-test respectively.

Results: The number of attempts for trocar placement, and complications were comparable between direct trocar and Veress needle group. The mean duration of trocar placement at the first attempt was 102.6 and 142.3 seconds in direct trocar and Veress needle group respectively (p value =0.001).

Conclusions: Veress needle is a safe, efficient, and rapid alternative technique as compared to direct trocar.

Keywords: Complications, Direct trocar, Laparoscopy, Pneumoperitoneum, Veress Needle technique

INTRODUCTION

One of the challenges of laparoscopic surgery is the insertion of surgical instruments through small incisions. Majority of complications arise during this time and a great majority of these occur during the insertion of the primary umbilical trocar. In spite of significant advances endoscopic techniques and instrumentation, inadvertent and potentially avoidable complications related to abdominal entry continue to occur, including life threatening complications such as damage to major abdominal vessels, bowel injuries, bladder injuries and extra peritoneal emphysemas.^{1,2} Therefore, the safest technique of laparoscopic entry and creation of pneumoperitoneum is very important.

To address these complications, various techniques have evolved to gain access to the peritoneal cavity. These include closed Veress needle (VN), open (Hasson), direct trocar (DT) insertion, the use of disposable shielded trocars, radially expanding trocars and visual entry systems along with their various modifications. The laparoscopic intraperitoneal access is associated with injuries to the gastrointestinal tract and major blood vessels. There are many significant complications occur with VN insufflation such as gas embolism, extra peritoneal emphysema, failed pneumoperitoneum with resultant failed laparoscopy and visceral insufflations.^{3,4} DT method access has shown to minimize vascular injuries but does not reduce bowel injury. Also, open access may be complicated by gas leak and port

instability. DT without prior pneumoperitoneum has many benefits such as shorter operation time, immediate recognition of vascular and visceral injuries, decrease incidence of entry failure and less insufflation-related complications such as gas embolism.^{5,6}

There have been many studies comparing the efficacy and safety of the numerous access techniques. The metareviews of these have turned out to be inconclusive; warranting the need for further evidence. Given this uncertainly, the choice of method is usually left to the surgeon's preference. This works for experienced surgeons but is an area of confusion for residents and younger surgeons. The existence of numerous techniques for creation of pneumoperitoneum at laparoscopy indicates that none has been proven totally efficacious or complication free. There is dearth of study in India comparing these techniques. The aim of present study was to compare the safety and duration for creating pneumoperitoneum between DT and VN technique.

METHODS

This single-blind randomized controlled study was conducted between May 2021 and April 2022 in Poona Hospital and Research Centre. After approval from the institutional ethics committee (Letter No. RECH/ECBHR/2020-21/0036), a written informed consent was obtained from all the patients prior to enrolment explaining the risks and benefits of the procedure.

Inclusion criteria

Patients aged between 18 and 70 years who underwent laparoscopic surgery were included.

Exclusion criteria

Patients who have undergone previous midline laparotomy for any infective pathology in abdomen, patients receiving antiplatelet agents or anticoagulants, liver cirrhosis, known immunodeficiency were excluded.

Out of 130 patients assessed for eligibility, after exclusion 114 patients were randomly divided with the help of www.randomizer.org (Figure 1). The program was known as research randomizer. The program produced two sets of random numbers out of the range of numbers provided by taking user input on having uniqueness of the numbers to be generated. For the present study, the program produced two sets of unique numbers per set. The sheet of the random numbers was ready before the study was started.

Group direct trocar insertion

Patients in group DT (direct trocar insertion) had undergone laparoscopic surgery after trocar placement by direct trocar insertion technique.

Group Veress needle technique

Patients in group VN (Veress needle technique) had undergone laparoscopic surgery after trocar placements after insufflation by VN technique.

The patients were blind regarding the two groups. The candidates for the study were the cases undergoing elective and emergency laparoscopic surgeries like cholecystectomy, appendicectomy, ovarian cystectomy etc. Laparoscopic surgery was performed according to the conventional port technique for particular surgery. Patients had undergone laparoscopic surgery according to the following study protocol:

The working port was introduced at a carbon dioxide pneumo peritoneum pressure of 14 mmHg in both groups DT and VN. In all the cases, general anesthesia was used. The blunt trocar was used in DT group of patients. The duration and attempts for successful placement of trocar, the duration of surgery, post trocar placement findings (by surveying after trocar placement for any injury), intraoperative complications (vessel injury, bleeding, visceral injury) along with reason for conversion, if any were recorded. The data were collected by using predesigned and pretested proforma, such as age, gender, technique of laparoscopic entry, number of attempts for successful trocar placement, time taken for laparoscopic entry (from umbilical incision to entry of telescope).

Pneumoperitoneum was created by following techniques in two groups:

DT insertion

The patient was placed in a supine position. A 10 to 12 mm transverse incision was given supra umbilically or infra umbilically. Abdominal wall was elevated with towel clamps and the trocar was inserted into the abdominal cavity, turned 30 degrees to the horizontal and directed towards the pelvis.

VN group

With the patient in supine position, a small stab incision was made at the desired site. Veress needle was introduced at a 45° angle toward the pelvis. Two "pops" from the fascia and peritoneum were heard before entering the abdominal cavity. The needle was aspirated and intra peritoneal location was verified with the saline drop test before initiating insufflations into peritoneal cavity at a pressure of 12-14 mmHg. After this, other trocars were inserted under vision.

The primary outcome measures were the incidence of complications such as subcutaneous emphysema, extra peritoneal insufflations, air embolism, bowel/omental/vascular/mesenteric/bladder/liver/spleen injury. The secondary outcome measures were number of items required and time needed to introduce the laparoscope.

On the basis of a previously published study by Zakherah intraoperative complications were observed in 2/500 (0.4%) and 70/500 (14.0%) patients in DT and VN groups respectively.⁸ A sample size of 52 patients was calculated for each group by a formula $N = [2p_{av} \ (1-p_{av}) \ (Z_{\alpha} + Z_{\beta})^2] / \Delta^2$, where N is the number of subjects in each group, Δ is the difference between two proportions and pav is the anticipated average proportion.⁹ We have taken Z_{α} a standard normal variate at 5% type 1 error (p value <0.05) = 1.96, and Z_{β} a standard normal deviate for at β power 80 % at type II error =0.84 to reject the null hypothesis. We included 57 patients in each group (DT and VN).

Statistical analysis

Data collected were entered in Excel 2007 and analysis of data was done using Statistical Package for Social Sciences for Windows, Version 20.0 from IBM Corporation, Armonk, NY, USA. The data on categorical variables are shown as n (% of cases) and the data on

continuous variables are presented as mean and standard deviation (SD). The comparison of quantitative variables and qualitative variables between the groups was done using unpaired student's t-test and the Chi-square test or Fisher's exact test respectively. The underlying normality assumption was tested before subjecting the study variables to unpaired student's t-test. The confidence limit for significance was fixed at 95% level with a p value <0.05.

RESULTS

The present single-blind randomized controlled study was conducted to compare the complications of DT and VN technique for laparoscopic surgery. Of 130 patients assessed for eligibility, 16 were excluded because previous midline laparotomy (6), patients received antiplatelet agents or anticoagulants (2), liver cirrhosis (2) and withdrew from study before randomization (6). One hundred-fourteen patients were randomized into two groups, 57 in DT and 57 in VN group (Figure 1).

Table 1: Comparison of demographic characteristics between direct trocar and Veress needle groups.

Demographic characteristics	DT group (n=57)	VN group (n=57)	P value
Mean age years±SD	53.0±13.1	46.0±16.0	0.12*
Gender			
Males	28 (49.1)	25 (43.9)	0.806**
Females	29 (50.9)	32 (56.1)	0.806***
Mean BMI kg/m ² ±SD	27.1±5.9	27.7±5.6	0.87*

^{*}Unpaired t-test was used. **Chi-square test was used

DT- Direct trocar; VN- Veress needle

Table 2: Comparison of outcome between DT and VN group.

Outcome	DT group N (%)	VN group N (%)	Total N (%)	P value
Number of attempts				
One	55 (96.5)	48 (84.2)	103 (90.4)	0.271*
Two	2 (3.5)	6 (10.5)	8 (7.0)	
Three	0 (0.0)	3 (5.3)	3 (2.6)	
Total	57 (100.0)	57 (100.0)	114 (100.0)	
Post placement trocar	13 (22.8)	16 (28.1)		0.842**
injuries				

^{*} Fisher's exact test was used. **Chi-square test was used

Table 3: Comparison of mean duration of trocar placement according to attempts in direct trocar and Veress needle groups.

	Mean duration of trocar		
Number of attempts	DT group (n=57)	VN group (n=57)	P value
	Mean±SD	Mean±SD	
One	102.6±12.7	142.3±30.3	0.001
Two	194.0±1.4	169.5±28.8	0.297
Three		178.0±96.2	

Unpaired t-test was used.

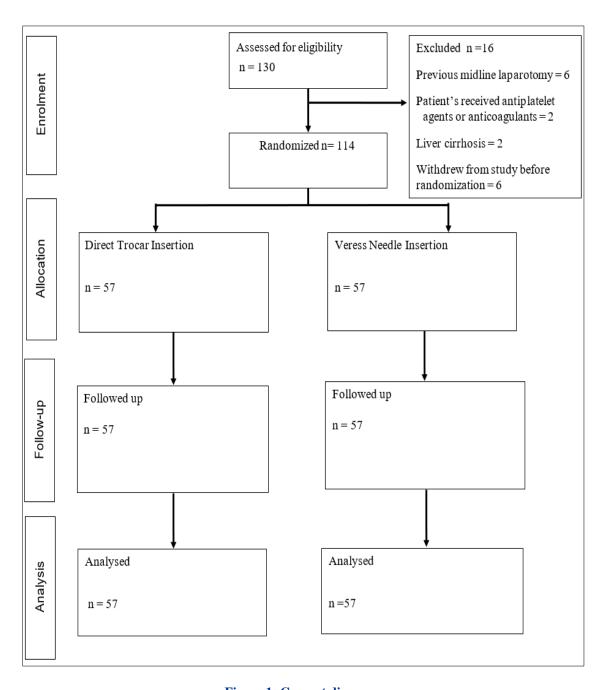


Figure 1: Consort diagram.

There was no statistically significant difference in the mean age, gender and mean BMI between the two groups (Table 1). The number of attempts for trocar placement, and complications were comparable between DT and VN group. (Table 2). Of 13 complications in DT group, 4, 3, 2, 3, and 1 patient's had air leak, bruising, difficulty in introduction, pre-peritoneal insufflation, and bowel injury respectively. Of 16 complications in VN group, 2, 4, 3, 3, 3, and 1 had bruising, difficulty in introduction, pre-peritoneal insufflation, bowel injury, omental injury, and mesentery injury respectively. The mean duration of trocar placement at the first attempt was significantly higher in VN group as compared to DT group, whereas there was no statistically significant difference in the

mean duration of trocar placement at the second attempt between the two groups (Table 3).

DISCUSSION

The present study was conducted at a tertiary care hospital, Pune, India. Laparoscopic procedure is the preferred surgical technique for surgeries now a days. It requires insertion of a cannula through the abdominal wall, insufflation of abdominal cavity with gas or air (pneumoperitoneum), visualization and examination of the abdominal contents through an illuminated telescope and then performing operative procedures. A critical component of laparoscopic surgery is CO₂ insufflation. CO₂ insufflation is achieved by placing Veress needle or

small surgical trocar in the abdominal wall and connecting one port to a CO₂ insufflator, using tubing.

In the present study, the number of attempts for trocar placement, and complications were comparable between DT and VN group. The mean duration of trocar placement at the first attempt was significantly higher in VN group as compared to DT group.

In our study there was no major complication such as vascular, liver, spleen injury (retroperitoneal injury). Nezhat al reported that comparison pneumoperitoneum by Veress needle insertion with direct insertion of the reusable conventional laparoscopic trocar and direct insertion of the disposable shielded trocar revealed minor complication rates of 22, 6 and 0%, respectively. The study further stated that no major complications occurred in this series of 200 patients.¹⁰ Byron et al stated that there were no major complications associated with DT and VN technique. Minor complications (preperitoneal insufflation, failed entry or more than three attempts necessary to enter the peritoneal cavity with the trocar) were significantly more frequent (p value <0.05) in the VN technique group. 11 Borgatta et al reported that there were minor injuries to the omentum not requiring intervention in 7 women in the VN group, but 4 in the DT group. 12 Agresta et al stated that the minor complications were nil in the DT group and 19/323 (5.9%) in the VN group (p value <0.01). The study further stated that the latter group consisted of 11 cases (3.4%) of subcutaneous emphysema and eight cases extraperitoneal (2.5%)insufflation. complications were nil in the DT group and 4/323 (1.3%) among VN patients (p value >0.05).13 Zakherah reported that there were no major complications in DT and VN groups. Minor complications were significantly less in group DT 2/500 (0.4%), 95% CI 0.77-3.23) than in group VN 70/500 (14%), 95% CI 10.96-17.04; (p value <0.001).8 Altun et al reported that minor complications were observed in 9/135 (6.7%) and 3/148 (2.0%) patients in VN and DT groups respectively, whereas major complications were 3/135 (2.2%) and nil in VN and DT groups respectively (p values >0.05 in both).¹⁴ Prieto-Díaz-Chávez et al stated that the frequency of complications was 10/42 (23.8%) and 1/42 (2.3%) in VN and DT group respectively (p value =0.009). 15 Godara et al reported the complications were observed in 2/50 (4.0%) and 5/50 (10.0%) patients in DT and VN groups respectively (p value >0.05).16 Inan et al reported that the complications were observed in 7/136 (5.14 %) and 2/138 (1.44 %) patients in VN and DT groups respectively (p value <0.05). 17 Sinha et al stated that 17/754 (2.3 %) and 35/1158 (2.8%) developed complications in VN and DT groups respectively (p value >0.05).18 In the present study, complications were comparable between DT and VN group.

Byron et al stated that the mean laparoscope insertion time was 2.2 minutes and 5.9 minutes for the DT and VN techniques, respectively (p value <0.01).¹¹ Prieto-Díaz-

Chávez et al stated that the time required to insert the laparoscope was significantly different in both groups: 1.56±0.56 (SD) minutes for the DT group (range from 0.6 to 3.6 minutes) and from 3.02±0.41 (SD) minutes for the VN group (p value <0.001). Godara et al reported that the mean time taken (in seconds) to achieve adequate pneumoperitoneum in direct trocar technique was 138±17.45 seconds whereas in verses needle technique it was 209±25.88 seconds (p value =0.00001). In the present study, the mean duration of trocar placement at the first attempt was significantly higher in VN group as compared to DT group.

Hamid et al stated that in DT group, pneumoperitoneum was created successfully in 278 (91.4%), 20 (6.6%) and 6 (2.0%) patients in the 1st, 2nd and 3rd attempt respectively, whereas in VN group, pneumoperitoneum was successful in 256 (84.2%), 38 (12.5%), and 10 (3.3%) patients in the 1st, 2nd and 3rd attempt respectively (p value 0.02). ¹⁹ In the present study, pneumoperitoneum was created successfully in 48 (84.2%), 6 (10.5%) and 3 (5.3%) patients in the 1st, 2nd and 3rd attempt respectively in VN group, whereas in DT group, pneumoperitoneum was successful in 55 (96.5%), and 2 (3.5%) patients in the 1st, and 2nd attempt respectively (p value 0.271).

There were some limitations also. The present study was carried out by a group of surgeons with adequate training and experience in laparoscopic technique. However, the expertise of the surgeons may differ. It was a single-center study with a small sample size. Multicentric studies with a large sample size and long-term follow-up should be undertaken to substantiate the research findings described in this paper.

CONCLUSION

The number of attempts for trocar placement, and complications were comparable between DT and VN group. The mean duration of trocar placement at the first attempt was significantly higher in VN group as compared to DT group.

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