



Prospective Observational Study of Comparison Between Direct and High-Pressure Primary Trocar Entry in Gynaecological Laparoscopy in Teaching Hospital

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Abstract

Background Laparoscopic port entry is crucial and vital step in any laparoscopic surgery. As laparoscopy is widely used, complications related to it are also increasing which are not seen in conventional laparotomy.

Aim The present study was undertaken to compare the ease of primary trocar entry after pneumoperitoneum at 20 mmHg pressure and direct trocar entry without pneumoperitoneum.

Methods Total 100 nulliparous patients who presented for elective gynaecologic laparoscopic surgery were enrolled for the study. In operating theatre, randomization of patients was done using a sealed envelope technique which divides patients into two equal groups and assigned as either low-pressure group or high-pressure group. Verres needle insertion and trocar entry was done by fellowship trainee in laparoscopy assisted by senior laparoscopy surgeon.

Result In high-pressure group we had trocar entry in first attempt in 80% of patient, second attempt in 20% where as in direct trocar entry group required first attempt in 88%, second attempt in 10% and third attempt in 2%. Time taken for trocar entry between two groups was significantly different requiring 4.42 ± 0.55 min for high pressure and 1.2 ± 0.28 min for direct trocar entry.

Conclusion The study concluded that high-pressure trocar entry requires more time; require less attempts, easier and surgeon will be more comfortable in repeating the same technique than direct trocar entry.

Keywords Trocar Entry · Laparoscopy · Pneumoperitoneum · Laparotomy · Nulliparous · Gynaecologic

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Introduction

Laparoscopic surgery has evolved over the past two decades to now be accepted as the method of first choice for tackling most gynaecological problems [1]. Laparoscopic port entry is crucial and vital step in any laparoscopic surgery. The abdominal entry is the most challenging procedure in laparoscopy because of serious complications due to injuries to bowel and major vessels. Most of these injuries are caused by the insertion of the primary trocar [2]. The incidence of bowel and major vessel injuries even though low are potentially life-threatening.

There are two methods by which a pneumoperitoneum is created the classic closed technique (Verres needle technique) and open classic technique (Hasson technique) which are commonly used procedures in laparoscopy to entry into the peritoneal cavity. The Verres needle was developed by Dr. Verres in 1938 and it is the most commonly used in diagnostic and therapeutic endoscopy, especially

in gynaecological procedures. The most common insertion site for the Verres needle is the umbilicus, because it is the thinned part of the abdominal wall [3]. Pneumoperitoneum is created after confirming intraperitoneal position of tip of needle. Next step of primary trocar entry can be done in two setting low pressure and high pressure. In current practice only high-pressure trocar entry is recommended.

Direct trocar entry technique was first published in 1978 by Dingfelder [4] and it involves only one blind step as compared to three blind steps in closed technique. In direct trocar entry, trocar is introduced without the creation of pneumoperitoneum [5]. Several studies have suggested that direct trocar entry is a safe alternative to Verres needle entry, but few were prospective and only 3 were randomized. Although direct trocar is faster than any other method of entry, it is the least performed laparoscopic technique. Complications of laparoscopic surgery appear to be primarily entry-related and independent of surgical complexity. Several studies have suggested that the initial trocar insertion is the most dangerous step in minimally invasive surgery [6].

With the advances in field of camera vision and energy sources laparoscopic surgery is increasingly being used for various expanding indications. Hence the present study was undertaken to compare the ease of primary trocar entry after pneumoperitoneum at 20 mmHg pressure and direct trocar entry without pneumoperitoneum. Both groups were compared with number of passes, number of attempt, time taken and complications. Trocar entry was done by fellow in laparoscopy and consultant laparoscopic surgeon. Difficulty in each group was analysed by using Likert scale.

Materials and Method

The present prospective observational study was conducted in 100 Nulliparous patients of age 18–50 years, ASA grade I-II, posted for elective gynaecologic laparoscopic surgery in the Department of Obstetrics and Gynaecology at Nowrojee Maternity Hospital over a period of 6 months. After approval from Departmental Review Board and research Ethics Committee, written informed consent was obtained from all the patients. An exclusion criterion includes patient refusal, patient with scared abdomen due to previous surgery, BMI ≥ 32 and ASA III-IV.

A detail history was taken and patients were thoroughly examined. Patient's BMI, pre-anaesthetics assessment and ASA grading was noted. After the patient arrival in the operating theatre, randomization of patients was done using a sealed envelope technique which divides patients into two groups and assigned as either low-pressure group (50 patients) or high-pressure group (50 patients). Routine monitoring (ECG, heart rate, non-invasive arterial pressure, and pulse oximeter) and intravenous access was obtained. A

standard general anaesthesia regime was employed in both group of patients consisting of propofol (2.5 mg/kg), fentanyl (3 mcg/kg) and vecuronium (0.1 mg/kg) immediately post-induction. Maintenance of anaesthesia was by sevoflurane (0.4–0.8 MAC). Lithotomy position was given followed by bladder emptied by sterile catheter. In laparoscopy surgery Verres needle and trocar entry was done by fellow in laparoscopy with the assistance of laparoscopy surgeon and consultant gynaecologist. Same surgeon was not doing only one method of trocar entry. Fellow in laparoscopy joined for training in laparoscopy had been taught both methods of trocar entry by their guide. Also fellow were assisted by senior experienced laparoscopy surgeon while performing trocar entry.

Verres Needle Insertion

With Surgeon standing on left of patient who was in supine position, the primary incision for laparoscopy was vertical from the base of the umbilicus (not in the skin below the umbilicus). Care was taken not to incise so deeply as to enter the peritoneal cavity. The Verres needle will be checked for sharpness, with a good spring action. The operating table was horizontal (not in the Trendelenburg tilt) at the start of the procedure. The abdomen was palpated to check for any masses and for the position of the aorta before insertion of the Verres needle. The angle of the Verres needle insertion should vary accordingly from 45° in non-obese women to 90° in very obese women [7]. Abdominal wall was elevated using towel clips or Allis forceps applied within and 2 cm from the umbilicus [8]. Two clicks are usually heard and felt as these layers are penetrated.

Excessive lateral movement of the needle was avoided, as this may convert a small needle point injury in the wall of the bowel or vessel into a more complex tear. Initial intraperitoneal Verres needle tip position was confirmed by initial intraperitoneal insufflation pressures < 10 mmHg indicating correct Verres needle placement [9–11]. Only two attempts were given for Verres needle insertion otherwise next procedure was carried out by laparoscopic surgeon or senior gynaecology surgeon.

High-Pressure Group

The correct placement of Verres needle was confirmed by [4]. (1) Aspiration of content: Aspiration using a 5 mL syringe with a Verres needle. Intraperitoneal position is confirmed when no material was aspirated (2) Injections test: injection of 5 mL of saline solution through the Verres needle. Intraperitoneal position of needle tip is confirmed when moderate resistance to liquid flow was observed. (3) Recovery test: after injection of 5 mL of saline solution, aspiration was performed, tip of needle confirmed when

the liquid injected was not recovered. (4) Saline drop test: saline was poured into the needle. Liquid flow was observed. Intra-peritoneal tip of needle is correct when the liquid disappeared immediately and (5) Initial intra-peritoneal pressure test: Needle correctly positioned inside the peritoneal cavity when initial intra-peritoneal pressure was 8 mmHg or lower during the initial ten seconds of insufflation. High-pressure group Co2 was insufflated under 14 mmHg initially and once position of the tip of Verres needle was confirmed to be in intra-peritoneum pressure setting was increased to 20 mm Hg. Umbilical skin incision will be enlarged till 11 mm. Primary trocar was inserted at around 45° depending upon obesity of patient. Trocar and cannula were palmed such that only 1 cm of sharp tip will be beyond index figure. Trocar insertion was direct without lifting up abdominal wall. Intra-peritoneal position of trocar was confirmed by using laparoscope. Once trocar position was confirmed by laparoscope pneumoperitoneum pressure setting was reduced to 14 mmHg immediately. Visual inspection of abdominal cavity will be done initially to look for injury to omentum, bowel, bladder and vessel. Time was noted from skin incision to insertion of primary trocar.

Direct Trocar Entry Group

In this technique umbilical skin incision was around 11 mm wide enough to accommodate the diameter of a sharp trocar. The anterior abdominal wall was elevated by hand or by pulling on two towel clips placed 2 cm on either side of the umbilicus and the trocar was inserted directly into the peritoneal cavity, aiming towards the pelvic hollow at around 45° depending upon the obesity. On removal of the sharp trocar, the laparoscope is inserted to confirm the presence of omentum or bowel in the visual field.

Statistical Analysis

All data were analysed using SPSS 17 Software. Analysis of demographic data was done using Chi-square test. The continuous outcomes were measured using the Student's t test or

the Mann–Whitney U test. Qualitative data were expressed in the form of frequency and percentage. Quantitative data were expressed in the form of Mean \pm SD. A *p* value < 0.05 was considered significant.

Observations and Results

Table 1 shows that in high-pressure group mean age was 32.1 ± 6.13 year and direct trocar entry group was 33.7 ± 7.35 years and the difference between two groups was not statistically significant (*p* 0.380). So both groups were comparable.

There was statistically significant difference observed between two groups in regards to mean height (*p* value 0.013), while difference was not significant in regards to mean weight, mean BMI and number of passes. The mean procedure time required in high-pressure group was more than direct trocar entry group and difference between two groups was statistically highly significant, (0.000) as shown in Table 2.

Table 3 shows that in high-pressure group we had trocar entry in first attempt in 80% of patient, second attempt in 20% where as in direct trocar entry group required first attempt in 88%, second attempt in 10% and third attempt in 2%. *P* value was 0.262; hence difference was not statistically significant.

As per the Likert scale scoring, the data revealed that 8% in high-pressure group and 28% in direct trocar entry group feel that procedure was difficult, whereas 92% in high pressure and 72% in direct trocar entry group feel that procedure was not difficult. By Chi square test, *p* value was 0.00 which was highly significant. The data also showed that 88% would repeat the high-pressure technique next time, whereas only 76% think so in direct trocar entry group. Also 12% in high-pressure group and 24% in direct trocar entry group would not repeat the same procedure next time. Difference between the groups to repeat the same technique next time was not significant (*p* value 0.174) (Table 4). It has been also found that there were minor complications in both groups which

Table 1 Distribution of patients according to age between two groups

Age group	High-pressure group (<i>n</i> = 50) No. (%)	Direct trocar entry group (<i>n</i> = 50) No. (%)	Mann–Whitney Test	<i>p</i> value
15–24	05 (10)	04 (08)	– 0.877	0.380 Not significant
25–34	31 (62)	26 (52)		
35–44	12 (24)	14 (28)		
45–54	02 (04)	06 (12)		
Mean \pm SD	32.10 \pm 6.13	33.78 \pm 7.35		
Median	32.50	32.00		

Table 2 Measurement of various parameters in both groups

Parameter	High-pressure group	Direct trocar entry group	Mann–Whitney Test	<i>p</i> value
Height (cm)	153.96 ± 8.63	149.84 ± 6.32	– 2.478	0.013 (s)
Weight (kg)	57.24 ± 9.08	55.06 ± 8.26	– 1.301	0.193 (ns)
BMI	24.13 ± 3.26	24.33 ± 2.72	– 0.241	0.809 (ns)
Procedure time (min)	4.42 ± 0.55	1.226 ± 0.28	– 8.649	0.000 (hs)
No. of passes	1.2 ± 0.40	1.14 ± 0.40	– 1.030	0.303 (ns)

Table 3 Comparison of number of attempt in patients between two groups

No. of attempt	High-pressure group No. (%)	Direct trocar entry group No. (%)	Fisher Exact Test	<i>p</i> value
1	40 (80)	44 (88)	2.744	0.262 Not significant
2	10 (20)	05 (10)		
3	0 (00)	01 (02)		
Total	50 (100)	50 (100)		

Table 4 Difficulty in each group analysed by Likert scale

Likert scoring	High-pressure group (n = 50) (%)	Direct trocar entry group (n = 50)(%)	χ^2	<i>p</i> Value	High-pressure group (n = 50) (%)	Direct trocar entry Group (n = 50)(%)	Fisher Exact Test	<i>p</i> Value
<i>Do you feel that procedure is difficult?</i>				<i>Do you follow the same technique next time?</i>				
Strongly agree	02	18	46.20	0.00 High significant	04	12	5.57	0.17 Not significant
Agree	06	10			84	64		
Disagree	82	62			10	16		
Strongly disagree	10	10			02	08		
Total	100(%)	100(%)			100(%)	100(%)		

were comparable and no major complications seen in both the groups.

Discussion

The present observational study compared the two most widely used techniques of trocar entry, i.e. Verres needle technique with initial creation pneumoperitoneum and direct trocar entry without creation of pneumoperitoneum. As this procedure is mostly operator dependent, we tried to found out which procedure of trocar entry required less time and with which the surgeon is confident and comfortable. Both the groups were comparable in regards to age, weight and BMI. Time taken for trocar entry was significantly more in high-pressure group as compared to direct trocar entry group which is similar to the study done by Zakherah [12]. There was no significant difference in number of passes when

compared both the groups. We defined the pass as manipulation of angle of insertion of trocar with skin through layers of skin without removing from skin incision. We wanted to know whether precreation of pneumoperitoneum reduces the number of passes as stretching of skin due to increased intraabdominal pressure makes the skin layers into single unit. Operating surgeon usually manipulates angle of insertion of the trocar with skin through layers of skin when first attempt doesn't success for entry into peritoneal cavity. The study doesn't recommend this as standard practice as it results in trauma in subcutaneous and extra peritoneal tissues. This leads to ecchymosis and bruise in skin. We didn't find any article comparing number of passes through skin for trocar entry in laparoscopy surgery.

Number of attempts defined as number of times trocar is removed completely out from skin in case of failed attempt. In high risk group 80% of times and 88% times in direct trocar entry group, resulted trocar entry in peritoneal

cavity in first attempt. This result is correlated well with the study done by Agarwal et al. [13]. In their study, they compared the Verres needle entry and trocar entry with results contracting with our study in regards to number of attempts. The present study also accessed level of difficulty on Likert score by putting question to operating surgeon after insertion trocar. In aspect of difficulty felt by surgeon we found that 8% in high-pressure group and 28% in direct trocar entry group feel that procedure was difficult, whereas 92% in high pressure and 72% in direct trocar entry group feel that procedure was not difficult (easy). The difference was statistically significant. This feeling of operating surgeon may be associated with force required for trocar entry was more in direct entry than in high-pressure entry. Also initial pneumoperitonization may also give the surgeon secure feeling while insertion of trocar than feeling of stab in abdomen in direct trocar group.

In continuation of perception of surgeon regarding difficulty we questioned about who will repeat the same technique next time. We found that 88% will repeat the high-pressure technique next time, whereas only 76% think so in direct trocar entry group. Also 12% in high-pressure group and 24% in direct trocar entry group will not repeat the same procedure next time. Difference between the groups in repeating the same technique next time is not significant. There was no major vascular or bowel complication in current study which is in close agreement with Zakherah [12], Theodoropoulou et al. [14] and Sinha and Malik [15]. Omental injury was seen in one patient in high-pressure group and in two patients in direct trocar group. Extra peritoneal entry seen in high-pressure group, this might be due false confirmation of Verres needle tip position. Subcutaneous swelling seen in one patient in direct trocar group may be due to trocar entry in false passage in two attempts.

Limitation of study is that as sample size is less, number of complications is less and hence comparison between two groups regarding complications was not possible in our study. Study was performed by small number of laparoscopic surgeons, so a greater number of surgeons should be involved in study to generalize the outcomes for all surgeons.

Conclusion

The study concluded that high-pressure trocar entry requires more time; require less attempts, easier and surgeon will be more comfortable in repeating the same technique than direct trocar entry. In teaching hospital high-pressure trocar entry should be initially taught to residents to boost their confidence in laparoscopy.

Author's contribution GDB designed the study model, reviewed the article. HRN wrote the article, helped in compilation and analysis of data. TKN assisted in the surgeries, compiled and analysed the data, and helped in writing the article to us. GDB and HRN done and assisted in surgeries.

Declarations

Conflict of interest The authors have no conflicts of interest.

Ethical standard Ethical approval from Departmental Review Board and research Ethics Committee.

Informed consent Consent was signed by patients posted for elective gynecological surgery.

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high risk pregnancy, infertility, and laparoscopy not only benefits women but also students learn a lot from her vast experience in field of obstetrics and gynaecology

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