

LAPROSCOPIC ENTRY: SAFETY AND EFFICACY OF DIRECT TROCAR TECHNIQUE WITHOUT PRIOR PNEUMOPERITONEUM VS VERRES NEEDLE TECHNIQUE IN LAPAROSCOPIC GYNAECOLOGICAL SURGERY IN A TERTIARY CARE HOSPITAL SETTING: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT:

Objective: To determine whether Direct Trocar Insertion (DTI) umbilical entry without prior pneumoperitoneum can be a safe and effective alternate to access abdominal cavity as compared to insertion after prior pneumoperitoneum as in conventionally practiced VN (Verres Needle) technique in patients undergoing various gynecologic laparoscopic procedures.

Methods: It was randomized clinical trial at department of Obstetrics & Gynaecology, Post graduate medical institute/Ameer-u-din medical college/Lahore General Hospital Lahore, over a period of two years from March 2018 to Feb 2020. It was performed on 150 patients admitted for either diagnostic or operative laparoscopic procedures. These patients were divided into two groups and randomly allocated to either DTI (Group A, n=75) or VN (Group B, n=75). Procedure was performed by highly experienced consultant gynecologist trained in laparoscopy.

Results: No major complication was observed in either group. Minor complications were 1.3% in DTI Group (A) while 5.3 % of patients suffered minor complications in VN Group (B). Mean time for laparoscopic abdominal entry was significantly less in DTI Group (1.79 ± 2.39 min) than in VN Group (3.63 ± 0.64 min) $p < 0.001$

Conclusion: DTI technique is a safer one step effective and faster alternative for laparoscopic access to abdominal cavity as compared to conventional VN technique with additional advantage of eliminating complications related to VN technique.

Key Words: DTI, VN, Laparoscopic entry, Laparoscopic complications.

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INTRODUCTION

Over the last two decades laparoscopic gynecological surgery has gained much popularity amongst surgeons and patients because of its faster recovery, lesser postoperative pain, shorter Hospital stay and better cosmesis. However, laparoscopy involves additional complications, which are unique, related to the process

of gaining access to peritoneal cavity. These entry related complications account for 50% of the laparoscopic complications and 25% of these go unrecognized till postoperative period thus increasing morbidity and mortality.^{1,2} Hence safe laparoscopic entry with creation of pneumoperitoneum is very vital and probably the foremost important initial step.

VN technique been most widely used along its complications particularly preperitoneal insufflation, gas embolism, visceral and vascular injury.³⁻⁶ There have been continuous attempts on the part of laparoscopic surgeons to find safer and reliable alternates to the conventional techniques. DTI was first reported by Dingfielder in 1978⁷ and found it to be actually much safer and faster as it's a one-step technique. later Bryon et al⁸ used this technique due to

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fewer complications and less operating time. Moreover in 2017, Society of Obstetricians and Gynecologists of Canada also recommended Direct Trocar insertion technique as a safe alternate to Verres Needle technique.⁹⁻¹⁰

OBJECTIVE of this study was to compare Direct Trocar Insertion (DT) technique without prior pneumoperitoneum with (VN) insertion technique at laparoscopic gynecological procedures regarding laparoscope insertion time and frequency of complications.

METHODS

This study was conducted in the department of OBGYN PGMI/AMC/ LGH Lahore for a period of 2 years from March 2018 to Feb 2020. 150 patients admitted through Gynae OPD LGH for various laparoscopic procedures were enrolled in the study fulfilling the inclusion criteria. Patients with comorbid conditions in which laparoscopy is contraindicated were excluded from the study. All patients gave informed consent and approval of study was taken from the ethical committee of the institution. These patients were divided into two groups i.e. Group A (DT, n=75) and Group B (VN, n=75) using random number table. Patient details including demographics, indication for laparoscopic procedures, operate technique, time taken for insertion of laparoscope, major and minor complications were entered on a pre-designed Performa.

Laparoscopic procedures were performed by highly experienced consultant gynecologist following standard laparoscopic entry techniques and its safety guidelines.

Closed laparoscopic entry with umbilicus as the site of primary entry was chosen. For DTI 10 mm metallic reusable trocars and cannula were used and in VN standard size Verres needles were used. Patients demography, Time taken for laparoscopic access of abdominal cavity, any intra-operative & post-operative complications were noted .Patients were called for follow up 7 days later in Gynae OPD for any problem.

All data were analyzed using SPSS system with a p value of < 0.001 regarded as significant.

RESULTS

In this study patients in both groups had similar demographic characteristics (table 1 a &b).The mean duration required for insertion of laparoscope was significantly less in Group A(1.79±2.39) minutes as compared to Group B (3.63±0.64) minutes which is statistically significant p-value <0.001 (table2).There were no major complications in both groups(vascular or visceral).The rate of minor complications was 1.3% in

DTI group(A) and 5.3% in VN group(B)(table3). Post-operative recovery was uneventful in both groups

Table 1a: Demographic data of the groups.

Variable	DT	VN
	Group A (n=75)	Group B (n=75)
Age (years)	36.9 ± 4.8	35.2 ± 5.1
BMI	24.6 ± 3.1	23.5 ± 2.8
Parity		
1- Nulli Para	45 (60%)	43 (57.3%)
2- Multi Para	30 (40%)	32 (42.7%)
Previous Surgical Operations	24 (32%)	26 (34.6%)

Table 1b: Indications of laparoscopic procedures.

Procedures	DT	VN
Diagnostic		
Infertility	16 (21.3 %)	15 (20%)
Chronic Pelvic Pain	18 (24%)	19(25.3%)
Primary Amenorrhea	13(17.3%)	14(18.6%)
Operative		
Ectopic pregnancy	5 (6.6%)	4(5.3%)
Adhesiolysis	10 (13.3%)	11 (14.6%)
Tuboplasty	2 (2.6%)	4 (5.3%)
Endometriosis	3 (4%)	2 (2.6%)
Total laparoscopic hysterectomy	6 (8%)	4 (5.3%)
Retrieval of lost IUCD	2 (2.6%)	2 (2.6%)

Table 2: Time difference between two groups.

Type of entry	Time (Minutes) Mean ± SD	P Value
Direct trocar (DT)	1.79 ± 2.39	
Verres Needle (VN)	3.63 ± 0.64	<0.001

Table 3: Comparison of complication of DTI vs VN technique for laparoscopic entry.

Complication	DTI (n=75)	VN (n=75)
Major Complications (Vascular & Visceral Injury)		
	0	0
Minor Complications		
No. of attempts (>1)	0	1
Port site bleeding	0	0
Omental vessel Injury	0	0
Preperitoneal insufflation	0	2
Port site sinus	1	1
Total	1	4

DISCUSSION

Laparoscopic surgery is becoming more popular in present era mainly because of its minimal access approach, shorter hospital stay, minimal complication

rate, early return to daily activities and good cosmesis. Creation of pneumoperitoneum is the first and most crucial step in laparoscopy.^{9,20} Studies have proven that more than 50% of complications occur at time of first entry. Studies have shown that 13 to 50% of vascular injuries and 30 to 50% of bowel injuries remain undiagnosed initially at the time of injury leading to increased morbidity and mortality^{12,22}. One of the advantages of DT insertion is early recognition of any intra-abdominal major complication before insufflation. Although Verres needle was the primary technique for first entry to create pneumoperitoneum but it is not free of complications as it involves three steps (needle insertion, insufflation and trocar insertion) to create pneumoperitoneum as compared to Direct trocar (DT) which involves only one step^{13,18,19}. Other advantages are avoidance of complications associated with Verres needle (VN) like preperitoneal or intestinal insufflation, failed pneumoperitoneum and CO₂ Gas embolism.^{14,15,22,23}

Direct trocar insertion technique is more rapid as it creates immediate pneumoperitoneum leading to shorter duration of procedure.^{16,17,18} In present study mean time duration required for laparoscope insertion is significantly less in DTI technique (1.79±2.39)minutes than in VN technique (3.63±0.64)minutes. This is also proven by Bryon et al⁸ who reported mean insertion time of 2.2 min and 5.9 min for DTI and VN technique respectively.

No major complications reported in present study, this is in close agreement with the reports of Dingfelder⁷. Minor complications were 5.3% in Group B(VN) vs 1.3% in Group A (DT).In a meta analysis by Jiang et al¹⁶ comparing DT insertion technique with Verres needle insertion technique, seven randomized studies were included consisting of 2940 women (VN 51.88%, n=1525; DT 48.12%, n=1415). Although there was no statistically significant difference in the risk of major complications between two groups, a significantly higher risk of minor complications was detected in the VN group (RR=10.78[6.27-18.51] with 95% confidence interval. In their randomized prospective study, Nezhat et al.¹⁷ reported 22 and 6% of minor complications after VN and DT insertion techniques respectively. In authors experience, DTI technique needs to be practiced more widely due to its fewer complications and less operating time. Also there is need for further research to compare DTI technique with other laparoscopic entry techniques to make optimal choice easier. Moreover it is important to improve surgical experience as well to decrease complications rate.

CONCLUSION

Our study concluded that Direct trocar insertion technique as first entry, is one step safe and effective alternative to Verres needle technique for creation of pneumoperitoneum in various laparoscopic surgical procedures with the advantage of its being faster and avoidance of complications related to VN technique.

ETHICAL APPROVAL

The study was approved by the Ethical Review Committee of Postgraduate Medical Institute, Ameer ud Din Medical College, Lahore, Pakistan.

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AUTHOR’S CONTRIBUTION:

MA: Conceived, editing of manuscript

NA: Data collection and analysis

RA: Collection of references

MZA: Data collection

MAFZ: Supervision of research