

Study of two laparoscopic entry techniques Closed (Veress needle) technique and Open (Hasson's) technique to evaluate safety, efficacy and their associated complications

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Abstract

Background: In present days of clinical practice laparoscopy is widely used for both diagnostic and therapeutic purposes. Present study was conducted to compare the two techniques in terms of access related complications and time spent on creation of pneumoperitoneum. **Material and Methods:** Present study was single-center, prospective, comparative study, conducted in patients of age: 16 - 65 years, of either sex, undergoing laparoscopic surgeries and willing to participate in study. By using sequential numbered brown opaque envelop method patients were randomized into groups as Closed (group A) (n = 65, patients who underwent laparoscopic procedure with pneumoperitoneum created by Veress needle) and open (Group B) (n = 65, patients who underwent laparoscopic procedure with pneumoperitoneum created by Hasson's method). **Results:** A total of 130 patients undergoing laparoscopic surgeries were included in the study. All demographic parameter age, weight, height, sex distribution is comparable in two groups, with no significant difference. In study most of patients were acute appendicitis 78(60%), chronic(recurrent) appendicitis 17(13.1%), cholelithiasis 22(16.9%), chronic pain abdomen 3(2.3%), hollow viscus perforation 2 (1.5%), acute cholecystitis 4(3.1%), pseudocyst of pancreas 1(0.7%), perforated appendicitis 2(1.5%), achalasia cardia (0.7%). There were no vascular injury and subcutaneous emphysema and mortality in either of the study group and there were no peri-operative mortalities. Only access time and gas leakage had a significant difference with P-value < 0.001. Other complications had no significant difference between both the groups and were comparable. **Conclusion:** Open technique had a time advantage over the closed method, but gas leakage was significantly more in open group. While complications are more in patient with history of previous abdomen surgery and in overweight, obese patients during gaining access into the peritoneal cavity irrespective of method used. **Keywords:** laparoscopic entry techniques, Veress needle, Hasson's method, laparoscopy.

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INTRODUCTION

Laparoscopy (Laparo– abdomen, scope in-to examine) is the art of examining the abdominal cavity and its contents.¹ In present days of clinical practice laparoscopy is widely used for both diagnostic and therapeutic purposes. In spite of technical advances in laparoscopic surgery, the creation of pneumoperitoneum and introduction of instruments is associated with lethal first step that can lead to serious injuries to the viscera and major retroperitoneal vessels. The reported incidence of vascular and bowel injuries ranges between approximately 0.05 to 0.5/100

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laparoscopic procedures.^{2,3} But documented incidence of trocar injuries are under estimated of the true incidence, since a lot of accidents are not mentioned for obvious reasons. The event of major vascular and undetected bowel injuries is serious usually leading to morbidity and mortality. The overall mortality reported to be 4% is increasing to 21% for unrecognized bowel injuries.^{4,5} In addition it has been estimated that one half of all laparoscopic complications are due to entry technique.^{1,6} There are two most commonly used techniques to create pneumoperitoneum and enter into abdominal cavity. First is with Veress needle (closed) technique, blind procedure to create pneumoperitoneum followed by trocar insertion. Another is Hasson’s (open) technique, in this trocar is inserted without creation of pneumoperitoneum. In this method, small laparotomy is done and layer by layer skin, subcutaneous, rectus sheath, peritoneum are incised under direct vision followed by blunt Hasson’s or usual trocar insertion and subsequently pneumoperitoneum created.^{2,7} Present study was conducted to compare the two techniques in terms of access related complications and time spent on creation of pneumoperitoneum.

MATERIAL AND METHODS

Present study was single-center, prospective, comparative study, conducted in Department of General Surgery at KLE’s Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi, between January 2014 to December 2014 (1 year). Study was approved by Institutional Ethical committee, Jawaharlal Nehru Medical College, Belagavi..

Inclusion criteria: Patients of age: 16 - 65 years, of either sex, undergoing laparoscopic surgeries and willing to participate in study.

Exclusion criteria: Patient who refuses to give consent to study: Co-morbid conditions like Chronic liver disease, Chronic renal failure, Malignancy. Immunocompromised patient.

Patients who were undergoing laparoscopic procedure for some surgical abdominal conditions are screened for eligibility by detailed history, physical examination, investigations and indication for surgery by trained residents in the Department of General surgery.

RESULTS

A total of 130 patients undergoing laparoscopic surgeries were included in the study. All demographic parameter age, weight, height, sex distribution is comparable in two groups, with no significant difference.

Table 1: Distribution of Demographic Data in two groups

Parameters	Closed (Group A) (Mean ± SD)	Open (Group B) (Mean ± SD)	P Value
Age(years)	34.3±13.79	33.7 ± 13.47	0.792
Height(meters)	1.62 ± 0.08	1.63 ± 0.09	0.626
Weight(Kg)	60.4 ± 13.44	64.63 ± 0.09	0.54
Sex(Male/Female)	32/33	31/34	0.861

Those fulfilling the selection criteria were explained about the purpose of the study, its complications and the need for randomization. A written informed consent was obtained from all the participants before the enrolment. After enrolment, demographic data, history, previous surgical history details, BMI and indication for surgery is obtained. Routine physical examination and per abdominal examinations was carried out and data was recorded on a predesigned proforma.

By using sequential numbered brown opaque envelop method patients who were undergoing laparoscopic procedure were randomized into groups as below.

1. Closed (group A) (n = 65): included patients who underwent laparoscopic procedure with pneumoperitoneum created by Closed (Veress needle) method.
2. Open (Group B) (n = 65): included patients who underwent laparoscopic procedure with pneumoperitoneum created by Open (Hasson’s) method.
3. Operations performed by experienced surgeons senior / junior residents, post graduate doctors and the series include the learning curve of any surgeons involved.

All patients are taken under general anaesthesia.. All insertion done through infraumbilical OR supraumbilical 1 cm to 1.5 cm transverse incision. Variables taken into consideration includes the ability to create pneumoperitoneum, the time taken to establish it, leakage of carbon dioxide gas from the margins of the access site, conversion to laparotomy, mortality and the known complications of laparoscopic surgeries which include abdominal wall hematoma, subcutaneous insufflations of gas, failures, penetrating injuries to blood vessels and intraabdominal viscera. Complications will be prospectively recorded and retrieved from the database.

The data obtained was coded and entered into Microsoft Excel Worksheet. The categorical data was expressed as rates, ratios and proportions and continuous data was expressed as mean ± standard deviation (SD). The data was analysed using chi-square test and Fischer’s exact test. p value of less than or equal to 0.05 was considered as statistically significant.

ASA (Grade I/II)	58/7	59/6	0.675
Previous history of surgery (Virgin abdomen/ Non-virgin abdomen)	49/16	48/17	0.840
BMI (Kg/m ²) (<25 / >25)	48/17	36/29	0.712

The groups were comparable for parameters like pulse rate, temperature, haemoglobin, total leucocytes count, platelet count, PT INR with no significant difference was noted. Except respiratory rate which had significant difference, with P value 0.006.

Table 2: Comparison of baseline parameters between two groups.

Parameters	Closed (Group A)	Open (Group B)	T130	P value
	Mean ± SD	Mean ± SD		
Pulse (beats/min)	89.9 ± 13.25	92.4 ± 14.46	1.018	0.311
Respiratory Rate (cycles/min)	16.8 ± 2.18	18.1 ± 3.19	2.826	0.006
Temperature(°F)	99.2 ± 0.98	99.1 ± 0.84	1.014	0.312
Haemoglobin (g%)	12.58 ± 1.83	12.24 ± 1.76	0.407	0.685
TLC (Count/mm ³)	9617 ± 2907	9957 ± 2986	0.658	0.512
Platelet(Lac/mm ³)	3.75 ± 1.08	3.95 ± 1.09	1.021	0.309
PT INR	1.3 ± 0.25	1.3 ± 0.17	1.255	0.212

In study most of patients were acute appendicitis 78(60%), chronic(recurrent) appendicitis 17(13.1%), cholelithiasis 22(16.9%), chronic pain abdomen 3(2.3%), hollow viscus perforation 2 (1.5%), acute cholecystitis 4(3.1%), pseudocyst of pancreas 1(0.7%), perforated appendicitis 2(1.5%), achalasia cardia (0.7%). In both the groups as mentioned in table no.9 were comparable with fisher exact test, no significant difference P value 0.507 seen in two groups.

Table 3: showing distribution of diseases included into study in both groups

Diseases	Closed (Group A)	Open (Group B)	Total No.(%)
	No. (%)	No. (%)	
Acute appendicitis	35(53.8%)	43(66.2%)	78(60%)
Chronic(recurrent)appendicitis	8(12.3%)	9(13.8%)	17(13.1%)
Cholelithiasis	13(20%)	9(13.8%)	22(16.9%)
Chronic pain abdomen	2(3.1%)	1(1.53%)	3(2.3%)
Hollow viscus perforation	2(3.1%)	0(0%)	2(1.5%)
Acute cholecystitis	2(3.1%)	2(3.1%)	4(3.07%)
Pseudocyst pancreas	1(1.5%)	0(0%)	1(0.7%)
Perforated appendicitis	2(3.1%)	0(0%)	2(1.5%)
Achalasia cardia	0(0%)	1(1.53%)	1(0.7%)

In study total 97 (76.4%) laparoscopic appendectomy, laparoscopic cholecystectomy 26 (20%), diagnostic laparoscopy 3 (2.3%), laparoscopic perforation closure 2(1.5%) laparoscopic Heller's myotomy and laparoscopic cystogastrostomy 1(0.7%) each. Calculating with Fischer exact test, there was no significant difference with P-value 0.303 between the two groups with respect to various laparoscopic surgeries included in the study and groups were comparable.

Table 4: Laparoscopic surgeries

Procedure	Closed (Group A)	Open (Group B)	Total
	No. (%)	No. (%)	
Laparoscopic Appendectomy	45 (69.2%)	52 (80%)	97(74.6%)
Laparoscopy Cholecystectomy	15 (23.1%)	11 (16.9%)	26(20%)
Diagnostic Laparoscopy	2 (3.1%)	1 (1.5%)	3(2.3%)
Laparoscopic Heller's Myotomy	0 (0%)	1 (1.5%)	1(0.7%)
Laparoscopic Cystogastrostomy	1(1.5%)	0(0%)	1(0.7%)
Laparoscopic Perforation Closure	2(3.1%)	0(0%)	2(1.5%)

The time to establish pneumoperitoneum was much less in the Hasson cannula technique (5.28±1.1 minutes) as compared to the Veress needle technique (6.02 ± 0.7 minutes, p = < 0.001). Pneumoperitoneum was achieved in 128 cases except in 2 cases in closed group; there was failure of technique in one patient due to malfunctioning of Veress needle and other due to intra-abdominal adhesions. In the open group, gas leakage occurred in 14 (21.53%) cases and zero in closed group, bowel injury occurred in 2(1.53%) patients, one(1.5%) in each group (in open group- trocar injury to transverse colon , closed group- Veress needle perforated the stomach), extra-peritoneal insufflations in 3 patients(2.30%) with 2(3.1%) in closed group and one(1.5%) in open group, 3 (2.3%)patients had need for conversion one(1.5%) in open group due to transverse colon injury and 2(3.1%) in closed group ; one due to Veress needle perforating the stomach, another due to dense intra-abdominal adhesion, port-site hematoma occurred in 2 (1.53%) one in each group.

There were no vascular injury and subcutaneous emphysema and mortality in either of the study group and there were no peri-operative mortalities. Only access time and gas leakage had a significant difference with P-value < 0.001. Other complications had no significant difference between both the groups and were comparable.

Table 5: showing major and minor complications, access time in two groups

Complication	Closed (Group A) No. (%)	Open(Group B) No. (%)	TOTAL	P value
Gas Leakage	0(0%)	14(21.5%)	14(10.7%)	<0.001*
Extra-peritoneal Insufflation	2(3.1%)	1(1.5%)	3(2.3%)	1
Bowel Injury	1(1.5%)	1(1.5%)	2(1.5%)	1
Need For Conversion	2(3.1%)	1(1.5%)	3(2.3%)	1
Failure Of Technique	2(3.1%)	0(0%)	2(1.5%)	0.496
Port Site Hematoma	1(1.5%)	1(1.5%)	2(1.5%)	1
Av. Time To Access	6.02±1.4 mins	5.28±0.94 mins	-	<0.001*

DISCUSSION

In last couple of decades, laparoscopic surgery has advanced rapidly to be considered a well-established procedure. But still laparoscopy is comparatively a newer technique, leading to controversy, especially with respect to the ideal method for the creation of the pneumoperitoneum.⁸ The two most commonly used basic techniques to achieve access into the peritoneal cavity during laparoscopic procedures are blind Veress needle/trocar insertion and the open technique by placement of the trocar under direct vision. Both of these techniques have positive and negative points with various advantages and disadvantages. The most serious and life-threatening complication during insertion of a Veress needle or of the first trocar is major vascular injury, with a mortality of 15%.⁹ Hasson about 3 decades ago described the advantages of the open technique for achieving access into the abdominal cavity.⁹ Direct vision gives option of safe entry by preventing bowel injury, and even if it occurs, allows immediate recognition and surgical repair. The learning curve had to be passed simultaneously by many surgeons resulting in an increase in major complications.¹⁰ In a pursuit to minimize the complications that occur during gaining access into the abdominal cavity, studies using modified techniques of both open and closed basic approaches have been carried out while others are underway. In our study only two bowel injuries in each group and no vascular injuries were noted as major complications, with zero mortality and rate of bowel injury 1.5%, vascular injuries 0.0% in both groups were comparable with no significance difference. This study contradicts previous studies, where visceral and vascular injuries were as 0.08%, 0.07% in closed group and 0.05%, 0% in open group with significant difference.⁶ Mortality rates after closed and open laparoscopy were respectively 0.003% and 0%.¹⁶ Similarly Vilos GA *et al.*,¹ analyzed six reports, one survey of open laparoscopy and 6 reports of closed laparoscopy conducted by gynecologists. With rates of bowel and major vessel injury in the closed entry technique, were 0.04% and 0.02% and in the open entry

technique 0.5% and 0% respectively. When they excluded survey report (n = 8000) the bowel injury rate decreased to 0.06% with the open technique. They concluded that open laparoscopy can be used as an adorable alternative technique that has reported to prevent the chance of major injury almost nil in anatomically normal positioned intra-abdominal structures.¹ In a systemic review reported bowel injuries 0–1.3% using the open technique and 0.04% with closed technique, vascular injuries 0– 0.03% using open technique, whereas 0.003–1.33% in closed technique. This meta-analysis indicates a trend towards a decreased risk of major complications with open access technique.¹⁰ Another systemic review stated that Veress needle insertion in the abdominal midline, may cause serious chance injury to major vessel, viscera and risk to the life of patients and need more studies to investigate alternate sites for Veress needle insertion.¹¹ But there are other studies which has similar result as in our study like Swiss Association for Laparoscopic and Thoracoscopic Surgery (SALTS) studied on patients undergoing various laparoscopic surgeries in between 1995 and 1997 reporting total 8 bowel injury with six in closed group, two in open group and stated that open method is not superior when compared to closed method and failed to show any advantage.¹²

European Association for Endoscopic Surgery in its clinical practice guideline on the pneumoperitoneum for laparoscopic surgery stated that, in the randomized controlled trials no difference was found in major complications between open and closed group with inadequate sample but in large studies showed less complications in the closed group.¹ They found that the use of either techniques may have advantages in specific patient subgroups.^{1,8} However, most of major vascular injuries occur with the Veress approach. The panel conclusion cannot support the use of either technique in access to abdomen.⁸ But Molloy *et al.* in their studies saw that bowel injuries are more in Hasson’s method than with closed technique 0.11%, 0.04% respectively. But they also stated that this

may be due to selection bias in choosing patients as most who had previous abdominal surgery preferred open method, also smaller number of surgeon were involved in open technique which was also potential bias. Thus concluding that ideal method of laparoscopic entry in the low-risk patient remains unclear.¹ European Association for Endoscopic Surgery also reported that open approach is faster and associated with a lower incidence of minor complications.^{1,13} In our study minor complications like gas leakage had a significant difference when compared between open (21.53%) and closed (0%) technique, with P valve <0.001. Other complications like extraperitoneal insufflation and need for conversion occurred 3.1% in closed group and 1.5% open group, failure of technique 3.1% in closed group with 0% in open group, port site hematoma 1.5% in both group, no subcutaneous emphysema in both groups. Similarly Hurd *et al.* demonstrated gas leakage in 14% with modification of the Hasson's technique without using special instruments and recommended to use Veress technique routinely.⁸ In present day many newer techniques to create pneumoperitoneum are developed, but Veress needle (closed) technique and Hasson's (open) technique are the two techniques used most commonly especially in developing country like India, where there is limitation of resources, facilities and cost. Thus it is important to have a standard technique to which is cost effective, safe, and efficient. So we tried to compare techniques in respect time required to induce pneumoperitoneum, major and minor complication, results of our study gives an impression that both techniques are good in some aspect like open technique safer in patients with previously abdomen surgery, obese and Veress needle is better to virgin abdomen, will avoid mini-laparotomy, less gas leakage. In our study comparing major complications like vascular and bowel injury in two techniques, the sample size is not adequate to give a conclusion still further studies are required with large sample size to comment on which technique is better. Based on the findings of this study, we conclude that there is still controversy exist to support the superiority of one technique over the other and this view is supported by the literature like European Association for Endoscopic Surgery (EAES)^{1,13}, Swiss Association for Laparoscopic and Thoracoscopic Surgery (SALTS)¹¹ and many meta-analysis studies comparing closed technique and open technique

CONCLUSION

According to this study open technique had a time advantage over the closed method, but gas leakage was significantly more in open group. While complications are more in patient with history of previous abdomen surgery and in overweight, obese patients during gaining access into the peritoneal cavity irrespective of method used. Further studies are needed in multiple centers, on larger samples for conclusive evidence and surgeons should be competent in both techniques.

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