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EFFICACY AND OUT COMES OF CLOSED VERSUS OPEN LAPAROSCOPIC CHOLECYSTECTOMY: A COMPARATIVE PROSPECTIVE STUDY.

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Abstract:
Background: The word laparoscopy originated from the Greek word Laparo - which means abdomen, and scopion meaning to examine. Laparoscopy is the art of evaluating the abdominal cavity and its contents.
Laparoscopic cholecystectomy (LC) is the gold standard operation for gallstone disease. Both closed/Veress and open/Hasson's techniques are commonly employed and have their typical indications for use. A prospective study was carried out in the Department of General Surgery, DR KNSMIMS, GADIA, BARABANKI,UP, INDIA., from June 2024 to May 2025, with the aim to compare the efficacy, safety and post operative out comes of closed/Veress and open/Hasson's procedure of access to the abdomen during laparoscopic cholecystectomy (LC). A total of 100 patients, undergone LC who were randomly allotted into 2 groups with 50 cases each:
group A: closed/Veress needle method and group B: open/Hasson's method. All the patients that participated in this study were belonged to the age group of 18-70 years out of which majority were 21-45 years old. In this study, the mean time required to create pneumoperitoneum by closed method (group A) was 8.23 seconds while by open method (group B), it was 6.91 seconds with p value <0.001. There were 7 cases of gas leak from the port side, Six recorded in the open method of establishment of pneumoperitoneum. Closed/Veress and open/Hasson's method of establishing pneumoperitoneum in laparoscopic cholecystectomy was equally safe in terms of major complications. Closed/Veress method gave faster access to the abdomen as compared to the open method, (Gr-A- 5.36 ± 1.33 minutes and Gr. B- 7.91 ± 1.46 minutes, respectively, p value <0.0001). Open/Hasson's method was associated with more primary port site complications (4/50 vs. 1/50, p value 0.029) and troublesome intraoperative gas leaks (6/50 vs. 1/50, p value <0.001). Open technique for primary peritoneal access port for laparoscopic cholecystectomy did not impart any additional benefits in terms of safety and morbidity profile in patients undergoing LC.
Conclusion: Open technique for pneumoperitoneum was as safe and effective as the closed technique.

Keywords: Pneumoperitoneum, Veress needle, Hasson's method, Laparoscopy, Cholecystectomy.

Introduction:

Laparoscopy is currently widely used in the practice of medicine, for both diagnostic and therapeutic purposes. The minimally invasive approach has become the method of choice for treating most benign abdominal diseases that require surgery. However, it is obvious that laparoscopic procedures are not risk free. Laparoscopic surgery involves insuffiation of gas into the peritoneal cavity, producing pneumoperitoneum to clearly visualize the abdominal contents using an illuminated telescope field [1]. Laparoscopy has been reported to have some complications; however, these are rare and should be considered when performing the procedure. Complications such as vascular injury, omental injury, port site hernia, port site infection, port site hematoma, and gas leakage have been reported [2-4]. It has been reported that the incidence of vascular injury during laparoscopy is 2 per 10,000 cases, and also per 100,000 cases, 3.3 cases of mortality-associated major complications have been reported [5,6]. Two main methods of laparoscopy for pneumoperitoneum creation have been widely used for many years: the classic closed method (Verres method, where Verres needle is used) and open method (Hasson method, where Hasson's cannula is used) [7-9]. It has not yet been established in the literature that this method has an optimal value over the others. Using a method with the least complications and short access time for pneumoperitoneum is crucial for patients undergoing cholecystectomy. Previous studies have reported the use of open versus closed methods to create pneumoperitoneum during laparoscopic cholecystectomy [10-13]. Studies have reported conflicting results regarding access time for creating pneumoperitoneum, closure time, and complications, such as vascular injury, omental injury, portsite hernia, portsite infection, portsite hematoma, and gas leakage.
Laparoscopic entry is a blind procedure, and it represents a problem for all the related complications. Complications arising from laparoscopic surgery are rare and commonly occur when attempting to gain access to the peritoneal cavity [14]. Creating a pneumoperitoneum is the most important step of laparoscopic surgery procedure (LS) because that access is associated with injuries to the gastrointestinal tract and major blood vessels and at least 50% of these major complications occurs prior to commencement of the intended surgery. Laparoscopy is preferred to laparotomy wherever feasible because of its advantages like decreased postoperative hospitalisation, less postoperative pain, faster improvements in quality of life, better cosmetic results, and smaller scars[15,16]. This procedure consists of creating a pneumoperitoneum therefore, distending the abdominal cavity, primary and secondary port placements, and different port closure techniques. There are five basic ways available at present to create pneumoperitoneum - blind Veress needle insertion, direct trocar insertion, optical trocar insertion, open method, and modified open method, out of which direct Veress needle insertion is the most commonly used [17].

The most significant risks for laparoscopy consist of trocar injuries during insertion into the abdominal cavity, port site complications like port site infection, port site oedema, port site haematoma, and port site pain, and a greater risk of hypothermia and peritoneal trauma due to increased exposure to cold and dry gases during insufflation[18]. The risk of such injuries, especially those during trocar entry, is increased in patients who have low body mass index or have a history of prior abdominal surgery [15,16]. However, the overall incidence of complications in laparoscopic surgery is still less compared to open surgery. Past studies indicate that the open method is better than closed method in terms of duration of the surgery and frequency and severity of complications, especially in patients with low BMI, scars of previous surgery, abdominal tuberculosis, and pelvic inflammatory disease[17-20]. The safety and efficacy of a laparoscopic approach over open surgery has been well established during the past few decades[21]. This is associated with a reduction in post-operative pain, shortened hospital stay and an early return to work[22]. Some studies have reported the optimal benefit of the closed method compared to the open method, whereas others have reported the optimal benefit of the open method compared to the closed method.[4,10-13, 14, 23-25].
Owing to these conflicting results this study was aimed to establish which procedure (open or closed) has the optimal benefit in terms of the efficacy, safety and outcomes.

Materials and Methods:

This was a prospective comparative and randomized study. The study was conducted at the Department of Surgery, DR KNSMIMS, GADIA, BARABANKI,UP, INDIA., from June 2024 to May 2025. A total of 100 patients, aged 18 to 70 years, both sexes with cholelithiasis who were advised and consented to laparoscopic cholecystectomy in the general surgery department during this study period. Cases in which pneumoperitoneum was created by closed technique were grouped as group A (n=50), and those by open technique as group B (n=50).

Inclusion Criteria:
The inclusion criteria were as follows:
All patients undergoing routine LC
Patients aged 18 to 70 years
Diagnosed to be calculous cholecystitis on ultrasound

Exclusion Criteria
The exclusion criteria were as follows:
Those unwilling to consent
LC on pregnant women
LC for indications other than calculous cholecystitis
LC along with laparoscopic CBD exploration
Previous abdominal operations

Methods:
The patients divided into two groups i.e. open or Hasson's method (group B) (n=50) and closed or Veress method (group A) (n=50) groups using the envelope method of randomisation. After obtaining a written informed consent subsequently obtained the following data on a printed proforma such as history: name, age, gender, religion, education, occupation, residential address, chief complaints, past history, family history, diet, bowel and bladder habits, addiction, etc., detailed clinical examination: general, per abdominal, and per rectal examination, routine investigations: haemoglobin, total count, urine albumin, urine sugar, blood sugar, blood grouping, X-ray chest, and ultrasonography (abdomen and pelvis) and specific investigations: serum creatinine, electrolytes, bilirubin, bleeding and clotting time, computed tomography (abdomen), etc.
Before the operation, shaving and cleaning of local parts, antibiotic prophylaxis, and catheterisation was carried out. The laparoscopic procedure was conducted under general anaesthesia in sterile conditions. In closed technique (Veress technique), it was created a sub-umbilical longitudinal skin incision of 2-3 mm through which Verres needle was inserted in the midline in sagittal plane at a 45 degree angle to the spine to avoid injury to major vessels especially in thin and lean patients. Confirmation of the entry of Verres needle into the peritoneum was done by saline drop test and initial intra- peritoneal pressure of less than 10mm Hg in order to prevent extra-peritoneal insufflation.
In case of open technique (Hasson technique), it was created a small longitudinal sub-umbilical transverse skin incision of 1.3-1.5 cm which was followed by opening of the rectus sheath with a triangular knife (size 11) in the same direction and separating it and the rectus muscle with straight artery forceps both transversely and longitudinally. The peritoneum was picked with artery forceps and a nick was made with a triangular knife to open the peritoneal cavity. After opening the peritoneal cavity, inserted the cannula or laparoscopic sheath without the trocar followed by CO2 insufflation maintained at a flow rate of 2 l/min and at 12 mm Hg pressure. The abdominal cavity was thoroughly inspected after creation of the pneumoperitoneum for complications before the intended procedure and complications were divided into major (emphysema extending up to the neck causing dyspnoea, bowel perforation, bladder perforation, and mesenteric vascular injury) and minor (abdominal bruise, localised emphysema, small haematoma, omental injury, bowel serosa injury, and gas leak) depending upon the nature and severity of injuries. The operative procedure was carried out and excised organs were removed from the umbilical port. All patients were given Injection Cefosulbactum (1.5 gm IV 12 hourly) for a period of 3 days with the first dose given 3 hours prior to induction. Inj. diclofenac

(50 mg diluted in 100 ml normal saline IV 12 hourly) for 3 days followed by tablet diclofenac (50 mg BD) for post-op pain. Patients were kept nil-by- mouth till bowel sounds were heard. Their dressing was done on alternate days and sutures were removed on the 12th post-operative day. Post-operative local examination done to check for signs of infection by looking for tenderness over suture line, colour change and discharge while the presence of haematoma was checked by the presence of swelling over suture line. A detailed systemic examination to assess the abdomen, respiratory, cardiovascular, and central nervous systems was carried out.

Statistical Analysis:

Statistical analysis was carried out using statistical packages for SPSS Inc. SPSS for Windows, Version 26.1. Chicago, SPSS Inc. Continuous and categorical variables were expressed as mean ± SD and frequency (percentages). Student's t-test was applied to compare the two groups. Two-sided p-values are considered statistically significant at $p<0.05$. Microsoft Word and Excel have been used for data entry.

Results:

All the 100 patients that participated in this study were belonged to the age group of 18-70 years out of which majority were 21-45 years old which is the period of maximum physical activity (Table 1).

Table-1: Age group for open and closed method

Age group	LC-Closed (group A)	Open (group B)
18-20 years	1	1
21-40	23	25
41-50	22	19
51-70	4	5
Total	50	50

Table-1 illustrated, most number of patients were belonging to 21-40 year age group with frequency 48 (48%) followed by 41-50 year age group, frequency 41 (41%), 51-70 years with 9 (9%) and least number of patients were from 18-20 group with frequency of 2%. There were 37% male and 63% females in the current study (Table-2).

Table-2: Sex distribution.

Sex	LC -Closed (group A)	Open (group B)
Male	18	19
Female	32	31
Total	50	50

Table-3: Operative time for open and closed method

Operative time	LC-Closed (group A)	Open (group B)
Less than 40 mins	3	-
41-50 mins	38	-
51-60 mins	9	13
61-70 mins	-	21
71-80 mins	-	16

The patients who had undergone Laparoscopic cholecystectomy experienced relief from pain earlier than those who underwent Open cholecystectomy. It was observed that mean duration of post-operative pain was 19.1 hrs in group A as compared to mean duration of 28.9 hrs in group B patients. The time period of post-operative hospital stay was shorter in group A than in group B. The mean

period of post-operative hospital stay was 1.6 days in group A and 3.9 days in group B. (Table-4 and figure-1).

Table-4: Duration of hospital stay after surgery in two groups.

Days	LC-Closed (group A)	Open (groupB)
<2 days	38	0
2-3 days	11	6
3-4 days	1	18
4-5 days	0	22
>5 days	0	4

Figure-1: Duration of hospital stay after surgery in two groups.

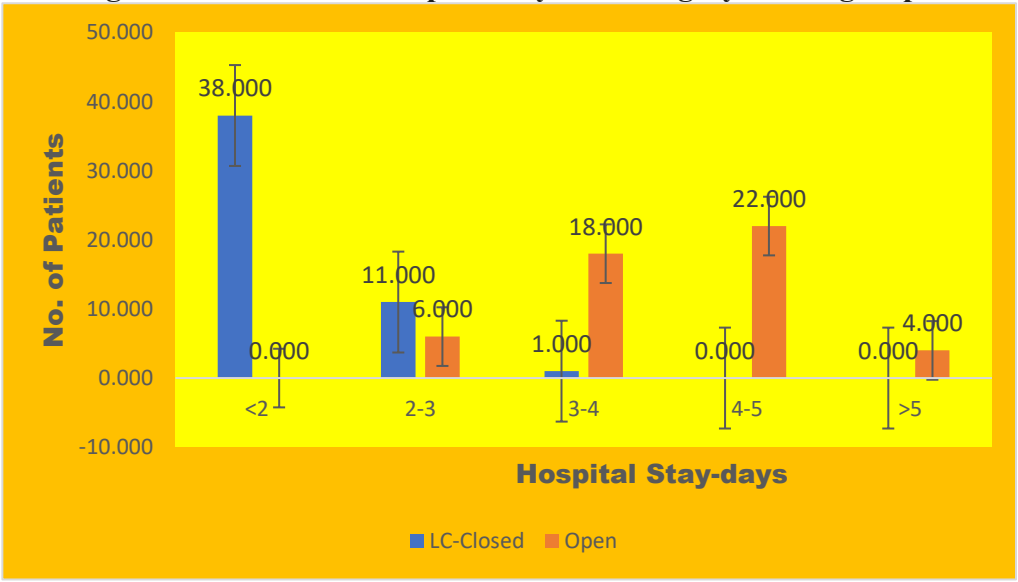
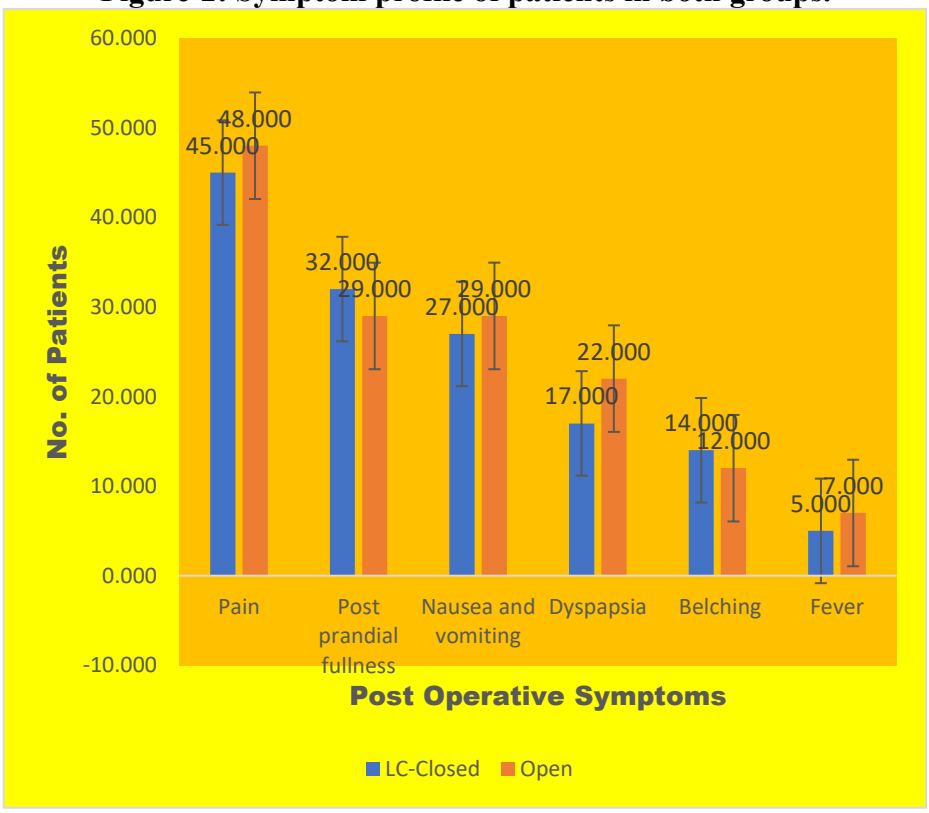


Figure-2: Symptom profile of patients in both groups.



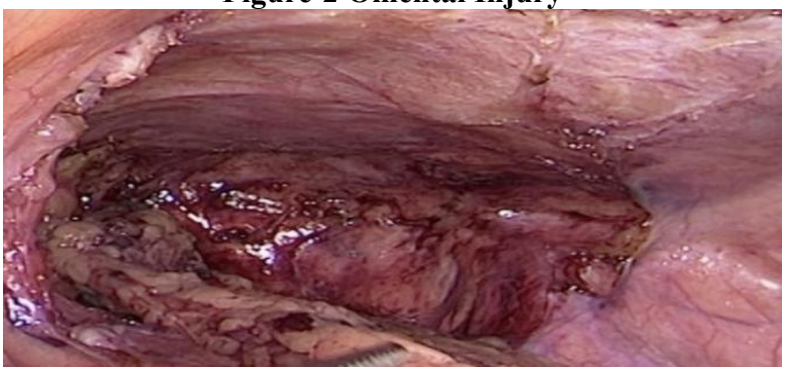
According to Figure 2, port site pain at discharge, port side wound infection, dyspapsia, belching, fever and vomiting were noticed .
Early resumption of diet was seen in those patients who were in the laparoscopic cholecystectomy group. In group A post-operative resumption of normal diet was possible within 2 days (mean 1.2 days) while group B required longer time (mean 2.5 days). Apart from surgical site infection no other surgery related complications were seen in either of the two groups. In fact, infection rate in group B patients was almost double than that observed in group A patients. The rate of surgical site infection was 3.7% in Open and 2.4% in LC-Closed respectively.

Table-5: Comparison of complications in both the study groups

Complication	Group A	Group B	P value
	N (%)	N (%)	
Port Site Gas Leakage	8(16)	2(4)	0.752
Extra- Peritoneal Insufflations	4(8)	2(4)	0.027
Loss Of Space	5(10)	3(6)	0.025
Entry in Wrong Plane	7(14)	2(4)	0.010
Omental Injury	3(6)	2(4)	0.021

Table-5 shown, there were many entry complications noticed during closed method. Among all the entry complications in closed methods, port site gas leakage, entry in wrong plane, loss of space, extra peritoneal insufflations, abdominal wall hemorrhage and omental injury were noticed with frequency of 8 (16%), 7 (14%), 5 (10%), 4 (8%), 3 (6%) respectively.

Figure-2 Omental Injury



Laparoscopic view of omentum with diffuse oozing of blood.
It has also been observed that open method has shown less complication during operative procedure as well as after operation, while closed method shown higher rate of complication, but all parameters were not significant statistically.

Discussion:

In the present study demographic data was found statistically insignificant. Female dominance was seen in this study, 64% of patients of the close entry group and 62% patients of the open entry group were female. A previous study also mentioned that the presence of gallstones was two to three times higher among women than men[23]. The present results were accordant with the study of others [24-26].
Time of access in the close entry group was the time calculated from insertion of the veress needle to insertion of the first port. In the open entry group, it was the time taken from the skin incision to trocar entry. Time of access was significantly lower in open entry group compared to close entry group. Mean access time was 5.62±2.19 minutes in the close entry group and 4.55±1.76min in the open entry group. Maximum patients of close entry group had 6-12 min access time; in open entry group 66.7%

patients had 1-7 min access time. The study results were statistically significant and comparable with other studies[27, 28-31, 40,41].
In contrast, A study revealed that 127/200 patients had 1-5 min access time with close entry technique (veress needle) and with open method (Hasson cannula) 144/200 patients with is maximum had 6-10 min access time. Mean access time was 5.62 ± 2.23 and 7.18 ± 2.52 respectively[32].
A previous study also revealed in their study the mean time taken for access 4.78 ±11.43 and 6.11±4.12 and close and open entry group which was also contrary with the present study results. After the analysis between the two groups, it was found that the access time, using the open entry technique to access the abdomen was significantly quicker than the close entry technique. At the time of discharge from hospital 5(10%) and 2(4%)patients had no pain in group A and group B respectively. 28 (56%) patients in close entry group and 29(58%) patients have moderate pain. In both the groups' improvement in pain was observed fast. The same results were also reported in a previous study [29], which advocated that, a total of 37 patients of veress needle group had severe pain and 24 patients had moderate pain on 1st post-operative day. 33 patients had no pain and 20 had mild pain on the day of discharge. 43 patients in open method group had severe pain and 53 patients had moderate pain on 1st post-operative day. 52 patients had no pain and 45 had mild pain on discharge. Post op pain is similar between two groups of patients with on the day of discharge.

In the present study 8(16%) patients in close entry and 2(4%) patients in open entry group were having port site gas leakage. This observation was concordant with other studies [33-37]. Entry in Wrong Plane were observed in 7(14%) patients of close entry group and 4% patients of open entry group and loss of space were seen in 5(10%) patients of close entry group and 6% patients of open entry group which was statistically significant. Extra- Peritoneal Insufflations were seen in 4(8%) patients of close entry group. No complications like vascular injury, bowel injury and gas embolism were noted in both the groups of this study. This was also comparable with previous studies study [27, 34-39].

There was no statistically significant difference in the pain score or length of hospital stay in the two groups. Various other studies which measured pain score have also reported no significant difference in closed-LC and open approaches in relation to postoperative pain[28].

Conclusion:
Cholelithiasis is a very common problem in India and hence an effective management for this is very essential. Open and closed laparoscopic cholecystectomy are two modalities of treatment offered to patients suffering from symptomatic gall stones. The present study was conducted with the aim of comparison of perioperative complications done in the research, after comparing and completing the study. It was concluded that open method shown less complication during operative procedure as well as after operation, while closed method shown slight higher rate of complication. Overall, open technique was as good as closed technique and was a good substitute to closed technique for pneumoperitoneum creation in laparoscopic cholecystectomy.

The closed/Veress method of establishing pneumoperitoneum in laparoscopic cholecystectomy was equally safe in terms of major complications and gives quicker access to the abdomen as compared to the open/Hasson's method. The open/Hasson's method was associated with more port site complications and troublesome intraoperative gas leaks. Thus, the open technique for primary peritoneal access port for laparoscopic cholecystectomy does not impart any additional benefits in terms of safety and morbidity profile of patients. But open method was merely safer than closed technique. Correlation of comparative study between both methods was 0.063 (p=0.063), which was not significant. Due to small number of patients have taken into study as well as study time period was short. Final judgment for the research, multicentric trials in different institutions are required for the initial, crucial, and technically challenging step of newly emerging field of surgery.

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