ORIGINAL ARTICLE ASIAN JOURNAL OF MEDICAL SCIENCES

A comparative study of laparoscopic cholecystectomy with and without abdominal drain

Soubhik Sarkar[1], Shib Shankar Kuiri[2], Yadhu Rajan[3], Kanchan Kundu[4]

[1,3,4]Senior Resident, Department of General Surgery, Bankura Sammilani Medical College, Bankura, [2]Associate Professor, Department of General Surgery, Jhargram Government Medical College, Jhargram, West Bengal, India

Submission: 03-12-2022 Revision: 02-02-2023 Publication: 01-03-2023

ABSTRACT

Background: Laparoscopic cholecystectomy (LC) has been considered the Gold-standard for the management of benign gallbladder disease. With increasing surgeon experience and advancement of instrumentations and equipment, LC is approaching continuously toward a more safe and less invasive technique. There is a consensus that drainage should not be considered mandatory or standard after elective LC. **Aims and Objectives:** The aims of this study were to assess the effectiveness of the LC without abdominal drain over sub hepatic drainage and to compare the post-operative outcome between two groups. **Materials and Methods:** A descriptive observational comparison study has been carried out in the department of General Surgery BSMCH, from September 1, to December 1, in 130 patients undergoing elective LC. Patients have been divided into two groups: Comparison group and study group after proper matching. Data have been collected via interview, clinical examination, and scrutinizing relevant medical records. Each patient has been followed up after operation. Data have been summarized for estimating various parameters such as mean duration of surgery and hospital stay between the groups and proportion of patient complaining of pain 24 h after surgery. **Results:** The mean duration of surgery in drainage group is 108 min which is significantly more than the non-drainage group 88 min. In this present study, the patients with abdominal drain are showing more incidence of post-operative nausea and vomiting (PONV) 21.53% compared to no-drain group 6.15%. In this study, 35.38% of patients with subhepatic drain developed pain after surgery, whereas only 12.3% of the patients with no drain experienced the same. Overall six patients from the drain group still had significant subhepatic collection and eight patients with no drain have the same. The mean duration of stay in hospital of the drain group is 4.06 days, whereas, in no-drain group, it is 2.26. **Conclusion**: An uncomplicated gallstone disease can be treated by LC without need for drain with reasonable safety by an experienced surgeon. Hence, no use of drain scores over use of drain in terms of PONV, post-operative pain, and therefore, there is less use of analgesics and also short duration of hospital stay. When a dry operative field is achieved during LC the drain insertion may be avoided.

Key words: Gallstone disease; Laparoscopic cholecystectomy; Subhepatic drain; Post-operative outcome

Access this article online

Website: http://nepjol.info/index.php/AJMS

DOI: 10.3126/ajms.v14i3.49975

E-ISSN: 2091-0576

P-ISSN: 2467-9100

INTRODUCTION

Laparoscopic cholecystectomy (LC) has been considered the Gold-standard for the management of benign gallbladder disease since 1985. With increasing surgeon experience and advancement of instrumentations and equipment, LC is approaching toward more minimally invasive way such as smaller ports, mini ports, and reduced ports and it is developing continuously toward a more safe and less invasive technique.[1]

Address for Correspondence:
Dr. Kanchan Kundu, Senior Resident, Department of General Surgery, Bankura Sammilani Medical College, P.O-Kenduadihi, Bankura - 722 102, West Bengal, India. **Mobile:** +91-9153832572. **E-mail:** kanchankundubsmc@gmail.com

With the advent of LC, the use of abdominal drains may be justified because of the increased incidence of biliary injury and, consequently, bile leakage. The use of prophylactic drainage in LC to avoid bile and blood collection requiring subsequent treatment is largely in lack of clarity.[2]

Cholecystectomy without abdominal drainage was first described in 1913, and since then, it is questionable whether to use it as a routine drainage or not in uncomplicated cases. A group of surgeons continue to use routine sub hepatic drain as there may be bile leak and bleeding. Such complications invariably occurred in spite of sub hepatic drainage.[3]

Drains are commonly used after surgical procedures and can be classified as either active or passive. Active drains use negative pressure to remove accumulated fluid from a wound. Passive drains depend on the higher pressure inside the wound added with capillary action and gravity to draw fluid out of a wound. Closed suction drains are routinely used to drain potential collections after surgery or after bowel anastomosis. In laparoscopic surgery, most commonly used drain is passive drain. Most of the surgeons are performing LC in their practice.

Several trials have shown that drains were of no benefit after elective LC for uncomplicated cholecystitis.[4,5]

It seems that drainage does not prevent post-operative complication. Instead, drainage-related complications such as fever, wound infection, wound hernia, or hemorrhage may cause unnecessary discomfort to patients.[6-8]

There is census that drainage should not be considered mandatory or standard after elective LC. Therefore, we hypothesized that the use of drain during LC for uncomplicated cholecystitis patients is not beneficial and that the routine drainage of gallbladder bed after LC may not be justified. To test this hypothesis, we conducted this study in a population of uncomplicated cholecystitis patients undergoing LC comparing the outcomes, between those received drainage and those without drainage.

Aims and objectives

The aims of this study were as follows:

General

- To assess the effectiveness of the LC without abdominal drain over subhepatic drainage and to compare the post-operative outcome between two groups.

Specific

- To estimate the duration of surgery between LC without drainage and with subhepatic drain
- To compare the effectiveness and post-operative outcome between two groups
- To measure the length of stay in hospital between two groups of the patients.

MATERIALS AND METHODS

A descriptive follow-up comparison has been carried out in the department of general surgery among all patients admitted for elective LC in the department of surgery, BSMCH, Bankura for a period of 1 year and 3 months, that is, from September 1, to November 31, 2021, after the Institutional Ethical Committee Clearance. Patients have been divided into two groups: Comparison group and study group after proper matching.

Study group

This study was LC without abdominal drain.

Comparison group

This study was LC with abdominal drain.

Estimated sample size for this study would be=133.

It is rounded off to 130. Therefore, study subjects are 130.

For the present study, consecutive cases are included for a period of 12 months. Hence, approximately 65 cases went for LC with abdominal drain and another 65 cases went LC without abdominal drain for uncomplicated cholelithiasis.

Inclusion criteria

The following criteria were included in the study:

1. Age group 18–80 years
2. Uncomplicated chronic calculus cholecystitis
3. Patients undergoing elective LC for other etiology.

Exclusion criteria

The following criteria were excluded from the study:

1. Obstructive jaundice
2. Conversion to open surgery
3. Intraoperative hemorrhage
4. Intraoperative biliary tract injury
5. Intraoperative cholangiogram required
6. Performance of any additional procedure
7. Choledocholithiasis.

Data have been collected through interview, clinical examination, and scrutinizing relevant medical records. A predesigned and pre-tested questionnaire is used for data collection. Informed consent has been sought from each patient before collecting data. Each patient has been followed up after operation. Data have been summarized for estimating various parameters such as mean duration of

surgery and hospital stay between the groups and proportion of patient complaining of pain 24 h after surgery. Various parameters are compared between two groups of patients.

RESULTS

A descriptive observational comparison study has been carried out in the department of General Surgery BSMCH, from September 1, to December 1, in 130 patients undergoing elective LC. Patients belong to various surgical units in BSMCH. Complete observational and analysis of all the parameters studies are as follows.

In Group A, 27 patients are in between 18 and 30 years age, 14 patients in 31–40 years age, 9 patients are 41–50 years of age, 12 patients are in 51–60 years of age, and three patients are in 61–70 years of age.

In Group B, 45 patients are in between 18 and 30 years of age, nine patients in 31–40 years of age, eight patients in 41–50 years of age, and three patients belong to 51–60 years of age.

In both the groups, most of the patients belong to age interval of 18–30 years.

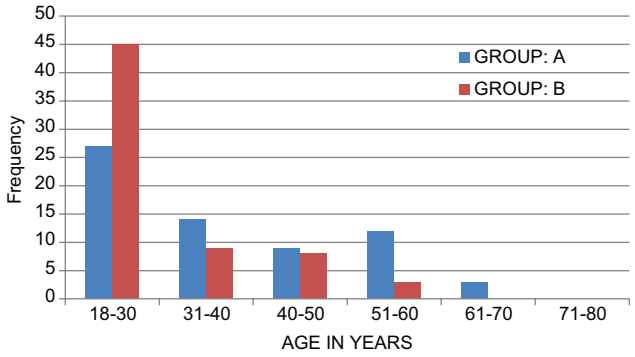
The mean age of the study population is 34.16 and a standard deviation of 12.58 [Diagram 1].

Total 72 patients are in the age between 18 and 30 years comprising 55.38% of the study population.

Diagram 1

Distribution of age interval in study population

AGE	GROUP: A	GROUP: B	Total	%
18-30	27	45	72	55.38
31-40	14	9	23	17.69
40-50	9	8	17	13.07
51-60	12	3	15	11.53
61-70	3	0	3	2.30
71-80	0	0	0	0
Total	65	65	130	100
Mean:	34.16			
SD	12.58			



The incidence of administration of intra-abdominal drain is significantly more in the higher age interval of 31–40 years, 41–50 years, and 51–60 years [Diagram 2].

In this present study, there are 98 females among 130 patients comprises 75% of total patients. Group A consists 19 male and 46 female patients, whereas 13 male and 52 female patients are present in Group B.

The mean duration of surgery in drain group is 108 min which is significantly more than the no-drain group 88 min.

There is more number of patients without abdominal drain whose operative time is <70 min.

The drain group patients are more in numbers whose operative time is more than 70 min compared to the no-drain group (Table 1).

In this present study, the patients with abdominal drain are showing more incidence of post-operative nausea

Diagram 2

Age Interval	Drain Insertion	Total study population	%
18-30	27	72	37.5
31-40	11	23	47.82609
41-50	12	17	70.58824
51-60	12	15	80

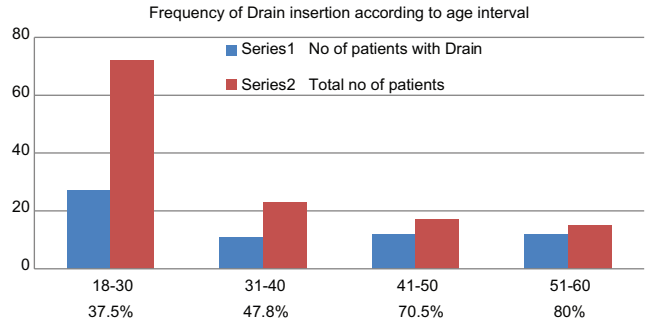
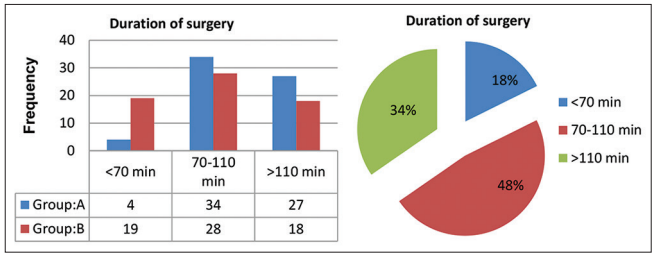


Table 1: Distribution of duration of surgery (in minutes) among study population

Operative time	Group A	Group B
<70 min	4	19
70–110 min	34	28
>110 min	27	18
Mean	108 min	88 min



and vomiting (PONV) 21.53% compared to no-drain group 6.15% (Table 2).

Patients with subhepatic drain are more frequently experienced pain (after 24 h of surgery) compared to those with no subhepatic drain.

The amplitude of pain experienced by the study population is measured by VAS (visual analog scale) and those with score more than five (out of ten) are considered as "presence of pain" in this study.

About 35.38% of patients with subhepatic drain developed pain after surgery, whereas only 12.3% of the patients with no drain experienced the same (Table 3).

Table 2: Distribution of post-operative nausea and vomiting among study population

Post-operative nausea and vomiting	Present	Absent	%
Group A	14	51	21.53
Group B	4	61	6.15

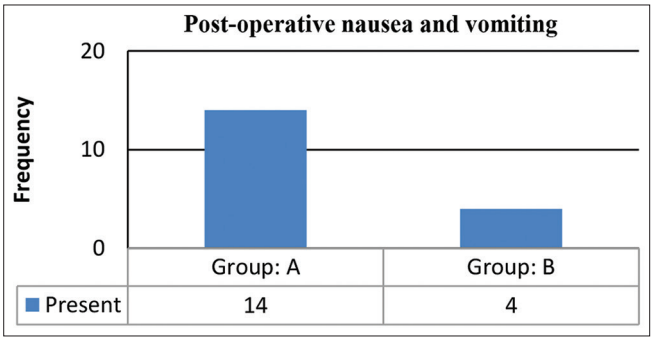
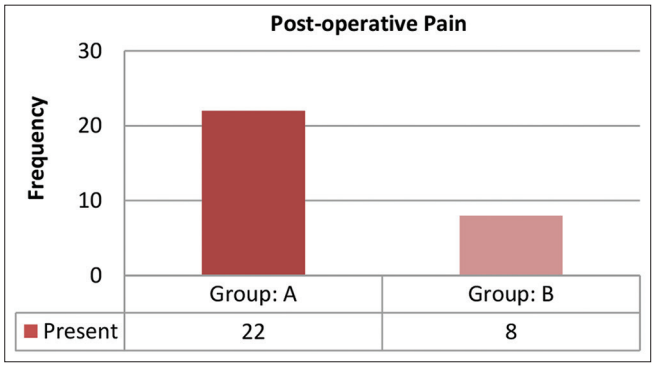


Table 3: Distribution of post-operative pain after 24 h between two groups

Post-operative pain	Group A	Group B
Present	22	8
Absent	43	57
Total	65	65
%	35.38	12.3



24 h after surgery all patients had undergone abdominal ultrasound and the amount of subhepatic fluid was calculated.

The amount exceeding 25 ml is considered as presence of significant subhepatic collection and was documented.

Six patients from the drain group still had significant subhepatic collection and eight patients with no drain had the same (Table 4).

Only one patient had developed surgical site infection among all study population. The patient belonged to drain group.

No other patients of no-drain group showed surgical site infection (Table 5).

No patients in drain group were discharged before 3 days from hospital. No patients in no-drain group had more than 5 days of hospital stay.

Table 4: Distribution of patients according to post-operative subhepatic collection at 24 h

Subhepatic collection (@24 h)	Group A	Group B
Present	6	8
Absent	59	57
Total	65	65
%	9.23	12.3

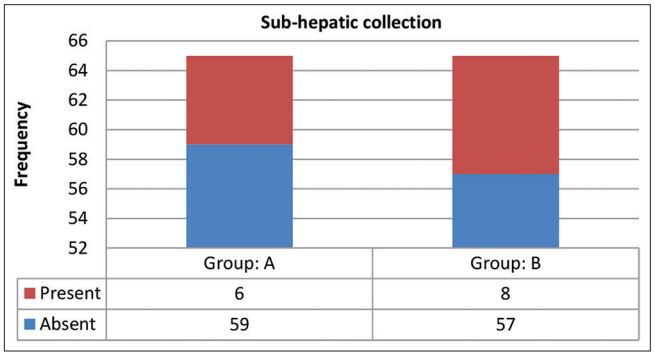
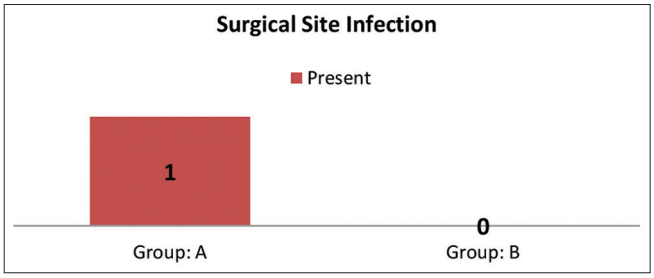


Table 5: Distribution of patients according to surgical site infection

Surgical site infection	Group A	Group B
Present	1	0
Absent	64	65
%	1.53	0



The mean duration of stay in hospital of the drain group is 4.06 days, whereas, in non-drain group, it is 2.26 (Table 6).

DISCUSSION

Cholelithiasis is a very common disease entity. Complications of cholelithiasis are frequent and often serious and this has made this disease as one of the most important surgically correctable diseases.

Open cholecystectomy has been the gold standard treatment for gallbladder diseases for more than 100 years since Carel Johann Langenbuch performed the first open cholecystectomy in 1882.[9]

The first LC was performed in human in 1987 by Dr. Philip Mouret. It has become the new gold standard treatment and almost replaced open cholecystectomy for the treatment of gallstone disease.[9]

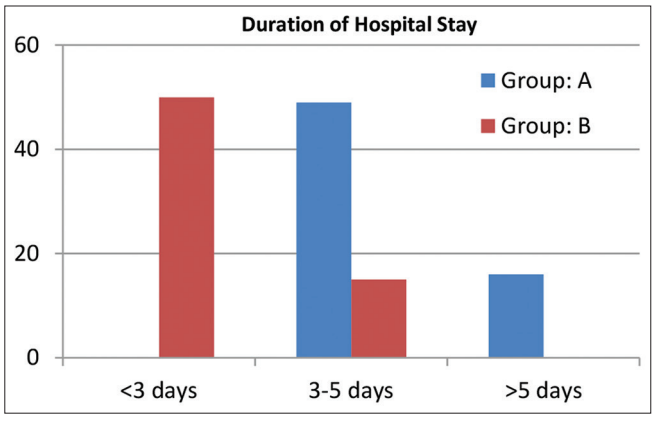
The first LC was performed in India at the JJ Hospital, Mumbai in 1990, followed by few months later in Pune by Dr. Jyotsna Kulkarni.[10]

The main reason to use prophylactic drainage in LC is to reduce complications such as intra-abdominal collections that require treatment and to detect bile leak, thereby decreasing the overall mortality and morbidity rates.

It is said that cholelithiasis can affect all age; however, they were more common in 2nd, 3rd, and 4th decade of life as 86% of the cases in this study belonged to these age groups.

Table 6: Distribution of patients according to duration of hospital stay

Duration of hospital stay	Group A	Group B	Total
<3 days	0	50	50
3–5 days	49	15	64
>5 days	16	0	16
Mean duration (days)	4.06	2.26	



Maximum incidence is seen in 18–30 years of age group which is 55% and the followed by 30–40 years of age group containing 18%.

Total 130 patients were selected for this study and were divided in Groups A and B. Group A patients have intra-abdominal drain and Group B patients do not. The maximum incidence in both groups belongs to 18–30 years which is 27 patients (41%) in Group A and 45 patients (69%) in Group B. However, peak incidence in the 4th and 5th decade has been reported by workers such as Hugh[11] and Schmitz et al.[12]

The maximum incidence of gallstone disease in this study was female as compared to males. Out of 130 patients, 32 patients (25%) were male and 98 patients (75%) were female. In Group A, `19 patients (30%) were male and 46 patients (70%) were female. In Group B, 13 patients (20%) were male and rest 52 patients (80%) were female. The mentioned parameters are very much similar to the study observed by Frazee et al.,[13] and Berggren et al.[14]

The average duration of the surgery in total study population is 98 min and SD of 31.33. The average duration of surgery in drain group (Group A) is 108 min and in no-drain group (Group B) is 88 min. The average duration of surgery in other studies is as follows.

Series	Duration of surgery
Karayiannakis et al.[15]	105 min
Ravimohan et al.[16]	46.8 min
Rademaker et al.[17]	78 min
Soper et al.[18]	95 min
Ros et al.[19]	93 min

In this study, Group A (with intra-abdominal drain) took comparatively more time than Group B (with-out intra-abdominal drain) which is statistically significant (P=0.00032). Total 18 out of 130 patients had PONV. Among them, 14 patients (21.5%) belong to Group A (patients with intra-abdominal drain), and rest four patients (6.15%) from Group B (patients without intra-abdominal drain).

PONV has statistically significant association with Group A, that is, patients with intra-abdominal drain with P=0.011.

There is no general consensus on the use of only one scale for measuring pain. This study has analyzed depending only on the studies using a validated scale.[20] Moreover, here, it is reported post-operative pain at a fixed time: 24 h after surgery.

In this study, 22 out of 65 patients (34%) in the drain group experienced pain after surgery, while eight out of

65 patients (12%) experienced pain after surgery in no-drain group. It is evident from the study that there is statistically significant difference in presence of pain between two groups with P=0.0038.

Six patients (9.23%) with subhepatic drain had collection after 24 h of surgery and eight patients (12.3%) of no-drain group had subhepatic collection. There is no statistically significant difference of incidence of subhepatic collection between two groups with P=0.571.

Only one patient (1.53%) in drain group has got port site infection at the drain site.

In this study, it has been found that post-operative hospital stay in Group A is more compared to Group B. The mean duration of post-operative stay in hospital for Group A is 4 days, where, in Group B, it is 2.26 days.

Forty-nine out of 65 patients in Group A had mean duration of post-operative stay which is between 3 and 5 days. All patients of Group A had duration of post-operative stay in hospital more than 3 days. No patients in Group B stayed in hospital more than 5 days. Most of the patients (50 patients) in Group B have post-operative hospital stay <3 days.

SUMMARY

The main reason to use prophylactic drainage in LC is to reduce complications such as intra-abdominal collections that require treatment and to detect bile leak, thereby decreasing the overall mortality and morbidity rates. At present, the rate of biliary complications after LC is 0.4% (range, 0.1–0.9%)[22] and post-operative hemorrhagic complications are similarly very rare.

- Maximum incidence is seen in 18–30 years of age group which is 55% and the followed by 30–40 years of age group containing 18%
- The main sufferers of gallstone disease in this study were female as compared to males. Out of 130 patients 32 patients (25%) were male and 98 patients (75%) were female
- The average duration of the surgery in total study population is 98 min and SD of 31.33
- Total 18 out of 130 patients had PONV. PONV has statistically significant association with Group A that is patients with intra-abdominal drain with P=0.011
- The use of drains seems to improve the incidence of this complication, possibly related to the presence of a foreign body.[23] Reducing the permanence of the drain after surgery is a valid method to decrease wound infection rates. Prevention of intra-abdominal collections after LC is the main reason of drainage. The peritoneal cavity usually absorbs serous fluids rapidly, but blood and bile are absorbed more slowly.[24] Post cholecystectomy collections in the subhepatic space as a whole is small, rapidly reabsorbed, and essentially similar in frequency whether a drain is used or not
- However, only some clinically significant abdominal collections may need intervention, while other abdominal collections may not be clinically significant. The only patient requiring intervention in the two trials mentioning treatment of the abdominal collections was in the drain group. The drain may also give false sense of security as it may get blocked and the patient continue to bleed internally and later presenting with signs of shock, as reported in one study
- Another study reported laparotomy for post cholecystectomy bile peritonitis in patients who had drains placed, suggesting that drain placement does not guarantee prevention of this complication. It is assumed that the use of a drain might be helpful for early detection of post-operative bleeding. However, significant bleeding can also be easily detected by clinical and ultrasonographic signs of intra-abdominal hemorrhage if there is no drain.[25]

Limitations of the study

In-spite of the best and sincere effort this study has some limitations:

1. The study has been carried out in a single centre.
2. The study would have been better if the study population was more.
3. There is a possibility of subjective bias in pain score as it was measured in VAS (Visual Analogue Scale).

CONCLUSION

An uncomplicated gallstone disease can be treated by LC without need for drain with reasonable safety by an experienced surgeon. With no usage of drain, it is significantly advantageous in terms of PONV, post-operative pain thus use of analgesics and hospital stay. This study was unable to prove that drains were useful in reducing complications in LC. However, it is reasonable to avoid drain insertion when a dry operatory field is obtained at the end of the procedure.

ACKNOWLEDGMENT

It is my proud privilege to express my deep sense of gratitude to principal sir, HOD sir, all my teachers and colleagues, my guide, institutional ethical committee, dept of community medicine for their intense help to conduct the study. I would like to thank all my patients and their

family members without whom the study was impossible to conducted. I would like to thank my parents for their constant support. Above all, it is the blessings of Almighty God that made the whole work possible.

REFERENCES

1. Litynski GS. Highlights in the History of Laparoscopy. Frankfurt, Germany: Barbara Bernert Verlag; 1996. p. 165-168.
2. Askew J. A survey of the current surgical treatment of gallstones in Queensland. ANZ J Surg. 2005;75(12):1086-1089. https://doi.org/10.1111/j.1445-2197.2005.03617.x
3. Mellor SG, Thomas MH and Donnellan BS. Cholecystectomy: Safe or not safe to drain? J R Soc Med. 1988;81(10):566-568. https://doi.org/10.1177/014107688808101005
4. Tacchino R, Greco F and Matera D. Single-incision laparoscopic cholecystectomy: Surgery without a visible scar. Surg Endosc. 2009;23(4):896-899. https://doi.org/10.1007/s00464-008-0147-y
5. Philipp SR, Miedema BW and Thaler K. Single-incision laparoscopic cholecystectomy using conventional instruments: Early experience in comparison with the gold standard. J Am Coll Surg. 2009;209(5):632-637. https://doi.org/10.1016/j.jamcollsurg.2009.07.020
6. Pai D, Sharma A, Kanungo R, Jagdish S and Gupta A. Role of abdominal drains in perforated duodenal ulcer patients: A prospective controlled study. Aust N Z J Surg. 1999;69(3):210-213. https://doi.org/10.1046/j.1440-1622.1999.01524.x
7. Kumar M, Yang SB, Jaiswal VK, Shah JN, Shreshtha M and Gongal R. Is prophylactic placement of drains necessary after subtotal gastrectomy? World J Gastroenterol. 2007;13(27):3738-3741. https://doi.org/10.3748/wjg.v13.i27.3738
8. Merad F, Yahchouchi E, Hay JM, Fingerhut A, Laborde Y and Langlois-Zantain O. Prophylactic abdominal drainage after elective colonic resection and suprapromontory anastomosis: A multicenter study controlled by randomization. French associations for surgical research. Arch Surg. 1998;133(3):309-314. https://doi.org/10.1001/archsurg.133.3.309
9. Singh K and Ohri A. Journal of minimal access. Surg. 2005;1:59-61.
10. Udwadia TE. Laparoscopy in India-a personal perspective. J Minim Access Surg. 2005;1(2):51-52. https://doi.org/10.4103/0972-9941.16526
11. Hugh TB. New strategies to prevent laparoscopic bile duct injury--surgeons can learn from pilots. Surgery. 2002;132(5):826-835. https://doi.org/10.1067/msy.2002.127681
12. Schmitz R, Rohde V, Treckmann J and Shah S. Randomized clinical trial of conventional cholecystectomy versus minicholecystectomy. Br J Surg. 1997;84(12):1683-1686. https://doi.org/10.1046/j.1365-2168.1997.02814.x
13. Frazee RC, Roberts JW, Symmonds R, Snyder SK, Hendricks J, Smith R, et al. What are the contraindications for laparoscopic cholecystectomy? Am J Surg. 1992;164(5):491-494; discussion 494-5. https://doi.org/10.1016/s0002-9610(05)81187-0
14. Berggren U, Gordh T, Grama D, Haglund U, Rastad J and Arvidsson D. Laparoscopic versus open cholecystectomy: Hospitalization, sick leave, analgesia and trauma responses. Br J Surg. 1994;81(9):1362-1365. https://doi.org/10.1002/bjs.1800810936
15. Karayiannakis AJ, Makri GG, Mantzioka A, Karousos D and Karatzas G. Systemic stress response after laparoscopic or open cholecystectomy: A randomized trial. Br J Surg. 1997;84(4):467-471. https://doi.org/10.1046/j.1365-2168.1997.02622.x
16. Ravimohan SM, Kaman L, Jindal R, Singh R and Jindal SK. Postoperative pulmonary function in laparoscopic versus open cholecystectomy: A prospective, comparative study. Indian J Gastroenterol. 2005;24(1):6-8.
17. Rademaker BM, Ringers J, Odoom JA, de Wit LT, Kalkman CJ and Oosting J. Pulmonary function and stress response after laparoscopic cholecystectomy: Comparison with subcostal incision and influence of thoracic epidural analgesia. Anaesth Analg. 1992;75(3):381-385. https://doi.org/10.1213/00000539-199209000-00011
18. Soper NJ, Barteau JA, Clayman RV, Ashley SW and Dunnegan DL. Comparison of early postoperative results for laparoscopic versus standard open cholecystectomy. Surg Gynecol Obstet. 1992;174(2):114-118.
19. Ros A, Gustafsson L, Krook H, Nordgren CE, Thorell A, Wallin G, et al. Laparoscopic cholecystectomy versus mini-laparotomy cholecystectomy: A prospective, randomized, single-blind study. Ann Surg. 2001;234(6):741-749. https://doi.org/10.1097/00000658-200112000-00005
20. Huskisson EC. Measurement of pain. Lancet. 1974;2(7889):1127-1131. https://doi.org/10.1016/s0140-6736(74)90884-8
21. Thiebe U and Eggert A. Drainage after laparoscopic cholecystectomy. Minim Invasive Chir. 1994;3:90-92.
22. Chiche L and Letoublon C. Traitment des complications de la cholecystctomie. In: EMC, Techniques Chirurgicales-appareil Digestif. Paris: Elsevier Masson SAS; 2010. p. 40-960.
23. Gurusamy KS, Samraj K, Mullerat P and Davidson BR. Cochrane Database Syst Rev. 2007;3:CD006004. https://doi.org/10.1002/14651858.CD006004.pub2
24. Najmaldin A and Guillou P. A Guide to Laparoscopic Surgery. New Jersey, United States: Wiley-Blackwell; 1998. p. 22-39.
25. Fisher RS, Rock E and Malmud LS. Gallbladder emptying response to sham feeding in humans. Gastroenterology. 1986;90(6):1854-1857. https://doi.org/10.1016/0016-5085(86)90252-0

Authors' Contributions:
SS- Manuscript preparation, data collection and literature search; **SSK**- Conceptualised the study, literature search, data analysis and interpretation; **YR**- Literature search and Prepare first draft; **KK**-Concept and design of study, review the Literature and Revision of manuscript.

Work attributed to:
This work is attributed to our respected teachers and our family members.

ORCID ID:
Dr. Soubhik Sarkar- https://orcid.org/0000-0002-9199-0833
Dr. Shib Shankar Kuiri- https://orcid.org/0000-0003-2212-6571
Dr. Yadhu Rajan- https://orcid.org/0000-0001-6339-4690
Dr. Kanchan Kundu- https://orcid.org/0000-0002-6300-600X

Source of Funding: Nil, **Conflicts of Interest:** None declared.