ISSN: 0975-1556

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2021; 13(3); 218-223
Original Research Article

Randomized Controlled trial Comparing Laparoscopic Cholecystectomy with and without Drains

Arvind Kumar[1], Ashok Kumar Sharma[2]

[1]Senior Resident, Department of General Surgery, V.M.M.C and Safdarjung Hospital, New Delhi, India.

[2]Associate Professor, Department of General Surgery, V.M.M.C and Safdarjung Hospital, New Delhi, India.

Received: 01-06-2021 / Revised: 04-07-2021 / Accepted: 23-07-2021
Corresponding author: Dr. Arvind Kumar
Conflict of interest: Nil

Abstract

Aim: The aim of this study to compare the laparoscopic cholecystectomy with and without drains. **Methods:** This randomized controlled trial single-blind study was done the Department of General Surgery, VMMC and Safdarjung Hospital, New Delhi from January 2019 to December 2019. 200 patients were included in this study. Patients were divided into 2 groups; A with drain and B without drain. A complete history, physical evaluation, the relevant investigations were done, and the post-operative period and complications were assessed. Patients were grouped by simple random sampling. **Results:** Amongst cholelithiasis patients 42% had drain and 42% without drain. Amongst acute cholecystitis patients, 27% had drain and 11% without drain and amongst chronic cholecystitis patients, 31% had drain and 47% without drain. The difference was not statistically significant. VAS (Visual analogue scale) grade in patients with drain was G4 (49%), G3 (47%) then G2 (5%). VAS grade in patients without drain was G2 (49%) followed by G3 (30%) then G1 (15%). $P<0.05$, there was statistically significant difference observed between the two groups. Wound infection is noted in 12(12%) with drain and 1 (1%) without drain group, hence p value was 0.006. So, there was statistically significant difference noted between the two study groups. Mean hospital stay in patients with drain was 9.15±2.03 days and a patient without drain was 4.11±1.36 days. $P<0.05$, there was statistically significant difference noted between two study groups. Nausea and vomiting were noted in 45 (45%) with drain and 3 (3%) without drain group, hence p value was less than 0.05. **Conclusions:** An uncomplicated gall stone disease can be treated by laparoscopic cholecystectomy without need for drain with reasonable safety by an experienced surgeon. With no usage of drain, it is significantly advantageous in terms of post-operative pain, use of analgesics and hospital stay.

Keywords: laparoscopic cholecystectomy, drain

Introduction

The gallbladder is a pear-shaped reservoir of bile situated on the inferior surface of the liver, partially covered by peritoneum.[1] Gall bladder, by virtue of its anatomical position at the gateway to the hilum of the liver and by virtue of its embryological development including its numerous variations is the commonest component of gastrointestinal system after the appendix requiring surgical intervention. Gallstone disease, one of the commonest biliary tract disorders known since ages requires surgical intervention for total cure. In India gallstones are most common and costly digestive disease and are a major cause of hospitalization.[2-4]

Conventional cholecystectomy have enjoyed unchallenged supremacy as treatment of choice for cholelithiasis for more than 100 years but its preference in the surgical fraternity is slowly and steadily decreasing after the invent of minimally invasive surgery like mini-cholecystectomy and laparoscopic cholecystectomy.[5,6] Dr. Med Erich Mühe of Böblingen, Germany, performed the first laparoscopic cholecystectomy (LC) on September 12, 1985. A National Institutes of Health (NIH) consensus statement in 1992 stated that LC provides a safe and effective treatment for most patients with symptomatic gallstones and has become the treatment of choice for many patients. LC has received nearly universal acceptance and is currently considered the criterion standard for the treatment of symptomatic cholelithiasis.[7] Infact laparoscopic cholecystectomy has revolutionised the treatment of gallstone disease, being the most remarkable surgical innovations of 20th century. It has become gold standard for the treatment of cholelithiasis.[8,9] It is the commonest laparoscopic operation performed worldwide and is the second most commonly performed operation in GI surgery after appendectomy.[10] Laparoscopic cholecystectomy provides a safe and effective treatment for patients with gallstones as it reduces postoperative pain with almost inadvisable scar, short hospital stay and earlier return to work.[11]

As all other surgical interventions laproscopic cholecystectomy is also associated with number of complications, which may range from mild to serious and even life threatening at times. Shoulder tip pain, back pain, and nausea/vomiting, absent in the conventional laparotomy, are the common complaints in laparoscopic cholecystectomy. To prevent such complications routine drainage was adopted in laparoscopic cholecystectomy[12] Surgeons have routinely drained after laparoscopic cholecystectomy because of the fear of collection of bile or blood requiring open procedures. Another reason for draining is to allow Carbondioxide insufflated during laparoscopy to escape via the drain site, thereby decreasing the shoulder pain. On the other hand, drain use may increase infective complications and delay discharge. A higher proportion of patients with nausea and vomiting have also been noted. Studies have shown higher wound infection rate and longer hospital stay in the drain group.[12] Therefore, controversy has surrounded this practice in elective conventional Cholecystectomies. The recent Cochrane Database Systematic Review shows that traditionally, drains were used for the early detection of bile leaks and any unsuspected hemorrhage and to evacuate abdominal fluid collections without the need for more invasive procedures. At present, the rate of biliary complications after LC is 0.4 % (range, 0.1–0.9 %). Postoperative hemorrhagic complications are very rare which further limit the use of drains. The absence of sub hepatic fluid collections after cholecystectomy is strongly associated with an uncomplicated postoperative recovery. The efficacy of drains to evacuate sub hepatic collections may justify their use to prevent postoperative complications.[13] However, experimental studies showed that, when a drain is inserted in the peritoneal cavity that contains no fluids, it is quickly surrounded by omentum and completely occluded within 48 hours. Drains are supposed to be much more

efficient in draining bile than other types of intra-abdominal collections. Port-site infection is a minor complication that affects 1.1–7.9 % of patients after LC. The use of drains seems to improve the incidence of this complication, possibly related to the presence of a foreign body.

Material and Methods

This randomized controlled trial single-blind study was done the Department of General Surgery, v.m.m.c and Safdarjung Hospital, New Delhi, India from January 2019 to December 2019 after taking the approval of the protocol review committee and institutional ethics committee. After taking informed consent detailed history was taken from the patient or relatives.

Methodology

Total 200 patients were included in this study. Patients were divided into 2 groups; A with drain and B without drain. A complete history, physical evaluation, the relevant investigations were done and the post-operative period and complications were assessed. Patients were grouped by simple random sampling.

Patients of all ages, sex or occupation who are diagnosed to have cholelithiasis or cholecystitis were included for this study.

Patients with following criteria were excluded- (a) other pathologies like CBD stones, cholangitis, pancreatic duct obstruction; (b) with biliary malignancy; and (c) pediatric age group were excluded from this study.

Statistical analysis

After the data collection, the results were tabulated and statistically analysed. Descriptive statistics and Chi square test were used to obtain the results. SPPS version 20 was used to analyze data.

Results

In the drain group, 45% were males and 55% were females whereas in without drain group, 40% were males and 60% were females (Table 1). The difference was not statistically significant. Most of the patients in the study were between the age group of 31-40 years (Table 2).

Table 1: Sex distribution

Gender	With drain (group A)=100	Without drain (group B)=100
Males	45 (45)	40 (40)
Females	55 (55)	60 (60)

Table 2: Age distribution

Age groups (years)	Number	%age
Below 30	30	15
30-40	51	25.5
40-50	43	21.5
50-60	40	20
Above 60	36	18

Amongst cholelithiasis patients 42% had drain and 42% without drain. Amongst acute cholecystitis patients, 27% had drain and 11% without drain and amongst chronic cholecystitis patients, 31% had drain and 47% without drain (Table 3). The difference was not statistically significant.

Table 3: With or without drain

Diagnosis	Drain (%)	Without drain (%)
Cholelithiasis	42 (42)	42 (42)
Acute cholecystitis	27(27)	11 (11)
Chronic cholecystitis	31 (31)	47 (47)

VAS grade in patients with drain was G4 (49%), G3 (47%) then G2 (5%). VAS grade in patients without drain was G2 (49%) followed by G3 (30%) then G1 (15%) (Table 4). P<0.05, there was statistically significant difference observed between the two groups.

Table 4: Post-operative pain

VAS scores	Drain (%)	Without drain (%)
G1	0	15
G2	5	49
G3	46	30
G4	49	6
G5	0	0

Wound infection is noted in 12(12%) with drain and 1 (1%) without drain group (Table 5), hence p value was 0.006. So there was statistically significant difference noted between the two study groups.

Table 5: Post-operative wound infection.

Post-op wound infection	Drain (%) (group A)	Without drain (%) (group B)
Present	12 (12)	1 (1)
Absent	88(88)	99 (99)

Mean hospital stay in patients with drain was 9.15±2.03 days and patients without drain was 4.11±1.36 days. P<0.05, there was statistically significant difference noted between two study groups. Nausea and vomiting was noted in 45 (45%) with drain and 3 (3%) without drain group (Table 6), hence p value was less than 0.05. So, there was statistically significant difference noted between the two study groups.

Table 6: Nausea and vomiting

Nausea and vomiting	Drain (%) (group A)	Without drain (%) (group B)
Present	45 (45)	3 (3)
Absent	55 (55)	97 (97)

Discussion

LC is the gold standard for the treatment of cholelithiasis.[14] When compared to open surgery it offers various benefits like faster recovery, shorter hospital stay and better postoperative outcome and fewer complications.[15] The present study reported a significant difference in the rate of wound infection in group A (12%) as compared to group B (1%).

Similar findings were reported by Halim et al and it advised not to place drain after elective LC.[16] However Hawasli et al with their team reported that no significant difference was present regarding wound infection in their trials.[17] Another finding in this study was that the incidence of nausea and vomiting was slightly higher among group A (45%) as compared to group B (3%) and the difference was statistically significant (p value<0.05). Similar findings were reported by Satinsky et al which stated that there was statistically significant difference in the incidence of nausea, vomiting among the 2 groups.[18]

Another major finding of this study was that there was a significant difference in pain abdomen as assessed by VAS grade in both groups (p value<0.001). Similar findings were also reported by Tzovaras et al.[19] However Hawasli et al found that there was a minor, but not a statistically significant difference between 2 groups in postoperative pain abdomen. In this study mean hospital stay in patients with drain was 9.15±2.03 days and a patient without drain was 4.11±1.36 days. There was a significant difference with a p value<0.05. Similar findings were given by Guruswamy et al and Satinsky et al.[20]

Thus, the advantages of not inserting a drain are reduction of hospital stay, patient comfort, and lower incidence of postoperative complications. On the other hand, drainage results in a higher wound infection rate and longer hospital stay. Data was unable to prove that the drain has any effect on either abdominal or shoulder tip pain in the setting of acute cholecystitis.

Conclusions

An uncomplicated gall stone disease can be treated by laparoscopic cholecystectomy without need for drain with reasonable safety by an experienced surgeon. With no usage of drain, it is significantly advantageous in terms of post-operative pain, use of analgesics and hospital stay.

Reference

1. Danny A Sherwinter “Laparoscopic Cholecystectomy” assessed at https://profreg.medscape.com/px/getpractice profile
2. Wani NA, Khan ZA.Experience with biliary tract surgery. Ind J Surg. 1995; 62:181-186.
3. Hussain A, Ahmed N, Zarger HU.Gall Stones: A chemical study in Kashmir.Ind J Surg. 1984:156-160.
4. William TL. Clinical manifestations and impact of gallstone disease.Am J Surg. 1993:165:405-408.
5. Goco IR, Luciola G, Chamber RN. Mini-cholecystectomy and operative cholangiography: A means of cost containment. Am Surg. 1983; 49:143-5.
6. Mouret P. From the first laparoscopic cholecystectomy to the frontier of laparoscopic surgery; the future prospective. Dig Surg. 1991; 8:124-25.
7. SherwinteDanny A, Kurt E Roberts. Laparoscopic Cholecystectomy. Assessed at http://emedicine.medscape.com/article/1582292-overview#a30
8. Bruce DS, Stephen BE. Laparoscopic cholecystectomy: Treatment of choice for symptomatic cholelithiasis. Ann Surg. 1991; 213:665-77.
9. Soper NJ, Stockmann PT. Laparoscopic cholecystectomy: The new gold standard. Arch Surg. 1992; 127:917-23.
10. Mufti TS, Ahmad S, Naveed D, Akbar M, Zafar A. Laparoscopic cholecystectomy: An early experience at Ayub Teaching Hospital Abbotabad. J Ayub Med Coll Abbottabad. 2007; 19:42-44.
11. Gouda El-labban, Emad Hokkam, Mohamed El-labban, Ali Saber, Khaled Heissam, Soliman El-Kammash. Laparoscopic elective cholecystectomy with and without drain: A controlled randomised trial. J Minim Access Surg. 2012; 8:90–92.
12. Gurusamy KS, Samraj K, Mullerat P, Davidson BR. Routine abdominal drainage for uncomplicated laparoscopic cholecystectomy. Cochrane Database of Systematic Reviews 2007, Issue 4. Art. No.: CD006004.
13. Chiche L, Letoublon C (2010). Traitment des complications de la chole´cystctomie. In: EMC, Techniques chirurgicales- Appareil digestif, pp. 40–960. Elsevier Masson SAS, Paris.
14. Koti RS, Davidson CJ, Davidson BR. Surgical management of acute cholecystitis. Langenbecks Arch Surg. 2015;400(4):403-19.
15. Shamim M. Routine Subhepatic Drainage versus No Drainage after Laparoscopic Cholecystectomy: Open, Randomized, Clinical Trial. Indian J Surg. 2013;75(1):22-7.

16. Halim A, Ahmad I, Iqbal J, Khan Z. Role of drain in laparoscopic cholecystectomy. J Med Sci. 2011;19: 49-53.
17. Hawasli A, Brown E. The effect of drains in laparoscopic cholecystectomy. J Laparoendosc Surg. 1994;4(6):393-8.
18. Satinsky I, Mittak M, Foltys A, Dostalik J. Subhepatic drainage in laparoscopic cholecystectomy-a necessity or an overused tradition?. RozhlChir. 2003; 82:427-31.
19. Tzovaras G, Liakou P, Fafoulakis F, Baloyiannis I, Zacharoulis D, Hatzitheofilou C. Is there a role for drain use in elective laparoscopic cholecystectomy? A controlled randomized trial. Am J Surg. 2009;197(6):759-63
20. Gurusamy KS, Samraj K, Mullerat P, Davidson BR. Routine abdominal drainage for uncomplicated laparoscopic cholecystectomy. Cochrane Database Syst Rev. 2007;(4): 6004