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Study of utility of sub-hepatic drain in laproscopic Cholecystectomy: A Randomized Control Trial

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Abstract: Laparoscopic Cholecystectomy has proved to be a boon for thousands of cholelithiasis patients. One of the most common surgery performed, it proves to be comfortable and safe. The use of subhepatic drain has been a matter of debate since its advent. This randomized control study was done to study the utility of sub-hepatic drain in laparoscopic Cholecystectomy. A total of 50 patients were enrolled for the study, 25 underwent drain placement while in 25 patients, a placebo drain was entwined in the dressing. Operative parameters and outcomes were compared. There was no significant difference in post-operative fluid collection in peritoneal cavity assessed by USG at 24 hours. The group without drain has significantly less post-operative pain and thus decreased demand of analgesics. Also the hospital stay was less in the group without drain, the difference being statistically significant. So, the present study shows that the sub-hepatic drain can be safely omitted in an uncomplicated laparoscopic Cholecystectomy and will result in better patient comfort with earlier discharge.
Keywords: Laparoscopic Cholecystectomy, sub-hepatic drain, cholelithiasis, gall stones.

INTRODUCTION

Cholecystectomy is the second most frequently performed abdominal surgery after appendectomy [1]. It is being preferred over the world with good results. After the advent of ultrasonography in the diagnosis of biliary lithiasis, the incidence of cholecystectomy has sharply escalated.

Initially the sub-hepatic drain was put in almost every case, but with better skill and expertise [2, 3], tubeless cholecystectomy has become the preferred choice. But the issue of draining the sub-hepatic area [4] post-operatively still remains unresolved. The merits of drains derive from the notion that they allow the aggress of bile leaking from the Gall Bladder bed [5-8], Cystic duct stump or from an damaged common bile duct, as well as the duct or exudates resulting from surgical trauma. On the contrary it was observed that small amounts of fluid were reabsorbed by the peritoneum.

The concept of prophylactic drain thought to be a necessity earlier, has been losing its importance because of gradual acceptance of the procedure and increasing experience. In early years of laparoscopic cholecystectomy, most surgeons usually retained a drain in subhepatic space [9]. As these patients used to have complaints of abdominal pain, shoulder tip pain and nausea or vomiting, post-operatively. High pressure pneumoperitoneum using carbon dioxide gas was accused for these complications. The result of recent systemic reviews [10] show no benefit with the routine use of intra-abdominal drains after both open, as well as, laparoscopic cholecystectomy, with the use of drain was found to be associated with increased rate of wound infection [11-15].

Therefore, this study was designed to assess the value of drain in elective laparoscopic Cholecystectomy, based on post-operative Gall Bladder fossa fluid collection, intensity of pain, morbidity and mortality.

MATERIALS AND METHODS

This study was a hospital based prospective observational comparative study and was conducted in Department of General Surgery, National Institute of Medical Sciences and Research, Jaipur. The study period was from November 2015 to April 2017.

50 cases of Elective Laparoscopic Cholecystectomy. (Sample size has been calculated at 95% confidence level of seed article according to the formula; $N = 4Pq/e^2$; where N = sample size, P = Prevalence, q = 100 – P and e = Error.) which was subdivide equally 25 cases with and without drain.

Patients were selected as per the before mentioned Selection criteria and after having taken consent, were randomized by chit in Box method before surgical procedure into 2 groups, Group A: Drainage group (25 patients) and Group B: Non-Drainage group (25 patients)

Written informed consent was taken from all patients and the trial protocol was approved by the Scientific and Ethical Committee. Surgery was done using a conventional 4 port method: 2 midline- one at the umbilicus and one below the xiphoid process, 10 mm each and two lateral – one below the costal margin and other in right lumbar region, 5 mm each. After the completion of cholecystectomy, the subhepatic drain was put strictly on a random basis by opening the sealed envelopes in the operation theatre. In group A, a polyethylene 18 g multiparous Ryle's tube was inserted through the most lateral 5 mm trocar. In group B, a shortened tube was fixed to the skin with a tape after blocking the tip with a bead. All drains, in both groups, were connected to a collection bag. Thus, the operator, the patients, and the assessors were all blinded to the intervention. All the patients were given antibiotic prophylaxis (in the form of a single intravenous shot of 1 gm Ceftriaxone). Post-operative pain assessment was performed using a Visual Analogue Scale (VAS), using which the severity of pain for each patient was noted on a linear scale from 0 to 10. Assessment of Drainage was done on the basis of quantity and quality of the drainage. Presence and quantity of subhepatic fluid collection from 12 to 48 hours after surgery was assessed by abdominal ultrasonography. Any Post-operative complication was noted.

The hospital stay of all patients was noted in days, along with the reason for longer hospital stay (more than 2 days). The drain was removed after 48 hours, unless it contained bile of any amount or blood > 100 ml in a period of 24 hours. In case of bile in the drainage, the drain was not removed unless the bile leak had completely ceased. In case of excessive (> 100 ml) bleed, the drain was removed when the amount of drainage was < 100 ml in 24 hours and the patient was hemodynamically stable with stable values of Hemoglobin. Follow-up examination was done at 1 week post-operatively by the assessors who were unaware of patients' group allocation. The examination was done clinically and by an abdominal ultrasonography.

Statistical analysis was performed with the SPSS, Trial version 23 for Windows statistical software package (SPSS inc., Chicago, il, USA) and Primer for the generation of descriptive and inferential statistics. The Categorical data were presented as numbers (percent) and were compared among groups using Chi square test. The quantitative data were presented as mean and standard deviation and were compared using by students t-test Probability P value <0.05 was considered statistically significant.

RESULTS

In a period of one year, two groups of 25 cases each were studied. Both the groups had no differences in terms of age, sex or complaints.

However, Significant difference was observed of the Operative Time (min) among the groups , more mean Operative Time (min) 45 ±3.15 was observed in patients with drain as compared to cases without drain 39.92 ±2.72 . The difference was statistically significant with the 'P' value being <.01

Table 1: Duration of Surgery /Operative Time (min)

	Drain		No Drain		Total	
Operative Time (min)	No	%	No	%	No	%
36 to 40	2	8	17	68	19	38
41 to 45	14	56	8	32	22	44
46 to 50	7	28	0	0	7	14
51 to 60	2	8	0	0	2	4
Total	25	100	25	100	50	100
Mean ±SD	45 ±3.15		39.92 ±2.72			

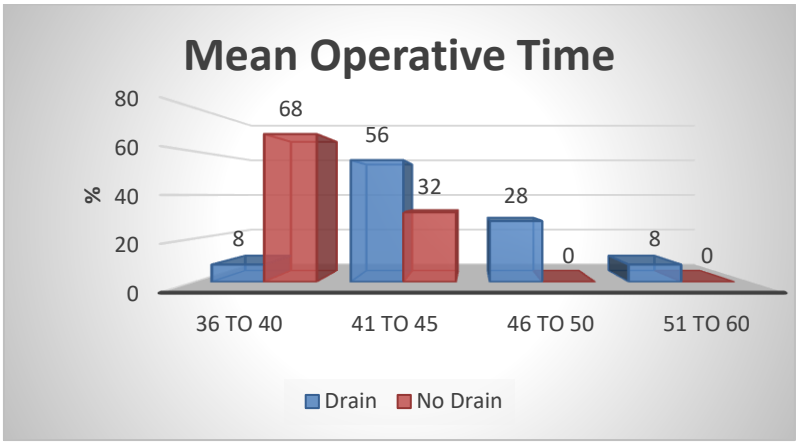

Fig-1: Mean Operative Time

No significant difference was observed according to diagnosis i.e. Groups were similar according to diagnosis. The most common diagnosis was Cholelithiasis (86%) followed by Chronic Cholecystitis (12%) than Gallbladder Polyp (2%). Similar pattern was observed among both the groups. Also, there was no difference between the 2 groups in terms of intra-operative bile spillage.

Similarly, the 2 groups did not show any statistically significant difference with respect to abdominal sonography at 24 hours for any subhepatic collection, with mild collection only in 3 patients in group A and 5 in group B. Similar results were obtained in abdominal sonography at 1 week, with no patient showing any subhepatic collection.

A significant difference was found when comparing the 2 groups with respect to post-operative pain. The post-operative pain was assessed using the Visual Analogue Scale (VAS), and the mean score at 12 hours post-operatively was 2.8 in group A and 1.24 in group B, with the 'P' value being <0.001, thus being statistically significant.

Table-2: Comparison of Pain Scores

	Drain		No Drain		Total	
	No	%	No	%	No	%
VAS at 12 hours	3	12	5	20	8	16
Mean ±SD	2.80	1.32	1.24	0.66		P<0.001S
VAS at 24 hours	22	88	20	80	42	84
Mean ±SD	1.20	0.65	1.08	0.70		P=0.55NS

Chi-square = 0.403 with 1 degree of freedom; P = 0.526NS

However, at 24 hours post-operatively, the difference was not significant (group A = 1.20, group B = 1.08, 'P' = 0.53).

With regards to Post-operative analgesic requirements, the difference was statistically significant (group A = 2.12 doses, group B = 1.36 doses, 'P' = 0.007S).

Table-3: Analgesic requirement Comparison

	Drain		No Drain		Total	
Analgesic required (no. Of doses)	No	%	No	%	No	%
1	6	24	16	64	22	44
2	11	44	9	36	20	40
3	7	28	0	0	7	14
4	1	4	0	0	1	2
Mean ±SD	2.12±0.83		1.36±0.49			

Chi-square = 12.745 with 3 degrees of freedom; P = 0.007S

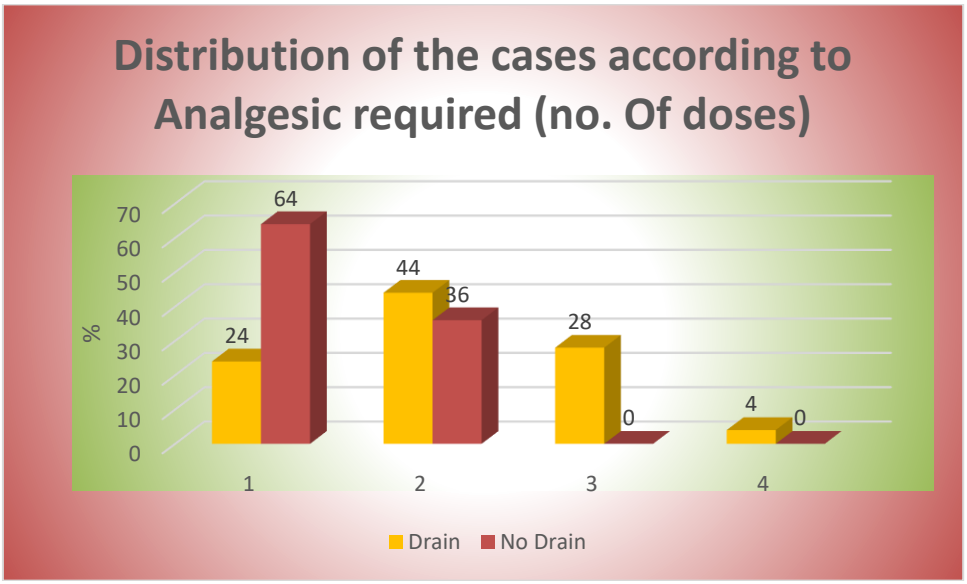

Fig-2: Analgesic requirement Comparison

The incidence of post-operative nausea and vomiting was comparable between the two groups, wound infection was seen in 2 patients in the drain group and no cases were in No drain group. Still, the difference was not statistically significant.

A total of 6 (24%) patients in Group A showed a post-operative increase in body temperature, while a total of 1(4%) patients in Group B showed fever.

The patients in Group B (No Drainage) had a lower mean duration of hospital stay (2.08±0.28 days) as compared to Group A (Drainage) (2.52±0.65 days). The difference was statistically significant with the 'P' value of 0.013S.

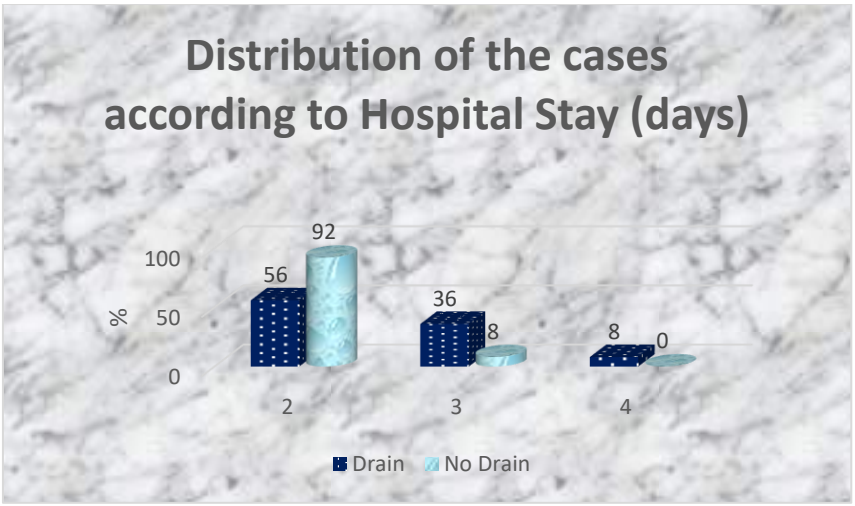

Fig-3: Distribution of the cases according to Hospital Stay (days)

Most of the patients were discharged on the 2nd Post-operative day, however 2 patients in Group A and no patients in Group B required a longer hospital stay.

Thus, a significant difference was observed of the hospital stay among the groups, more days of stay were observed in patients with drain as compared to cases without drain.

DISCUSSION

Laparoscopic Cholecystectomy is one of the [16] most common elective surgeries in the modern surgical practice all over the world. The revolution that has been brought on by this procedure has been unprecedented in its scale [17]. Traditionally, a sub-hepatic drain has always been placed at the end of the procedure, especially so if there is a concern of bile leak, or hemorrhage from the area after laparoscopic cholecystectomy. Although, it has been long known that a small amount of fluid is effectively reabsorbed by the peritoneum [18], and a clinically significant, large

amount of collection often leads to blockage of the drain, may be due to omental plug or a blood clot, and thus, in 1991, the 'Ideal Cholecystectomy' [23] was described in Germany as one without the use of sub-hepatic drain, as it was associated with easier convalescence, a shorter hospital stay, and lesser chances of complications. Still, surgeons have long been taught in the past that it is safer to put a sub-hepatic drain. In a number of studies, the drains have been held responsible for a number of post-operative complications such as post-operative infection by converting a sterile fluid collection into an infected one; increased secretion of serous fluid; and, rarely, formation of an intestinal fistula. Even today, many surgeons routinely place a sub-hepatic drain after a simple, elective cholecystectomy.

A number of different randomized, control trial have been done regarding prophylactic drainage using a sub-hepatic drain after laparoscopic cholecystectomy, all over the world [30].

Petrowsky *et al*. [26] performed a review of multiple such trials and failed to demonstrate any advantage or disadvantage of routine drainage on post-operative complications. On the other hand, numerous such studies conducted have repeatedly shown that avoiding a sub-hepatic drain post-operatively results in reduced operative time, lower incidence of wound infection, pyrexia, reduced hospital stay, and even reduced morbidity. Review of medical literature finds no evidence that supports a routine use of drainage after every uncomplicated, elective, laparoscopic cholecystectomy and hence, should not be used in routine practice.

Though many surgeons are worried about post-operative abdominal collections, which they think can cause havoc. While it may be true theoretically, it is not always true in practical life [18]. It is also to be noted that the nature of the fluid collection is also equally important. Intra-peritoneal blood collection can cause post-operative pyrexia, increase the risk of wound infection and sepsis [19], and prolong the duration of hospital stay; while the presence of bile in the sub-hepatic region produces peritoneal irritation. However, some abdominal collections may not require any intervention, with only some being clinically significant. It is also often seen that a drain may get blocked, may be due to a blood clot or an omental patch, and provide the surgeon with a wrong sense of security, while the patient may continue to bleed internally and later, present with symptoms and signs of shock. A similar case was reported in one study [25].

In another study, a case was reported in which laparotomy was required for post-cholecystectomy bile peritonitis despite having a drain placed post-operatively, thus proving that sub-hepatic drain placement does not guarantee prevention of this complication in all cases.

While it is thought that a drain may provide us with a clue regarding early detection of post-operative hemorrhage, the same can also be diagnosed by clinical and ultrasonographic signs of intra- abdominal hemorrhage even if no drain is placed. Even if there is persistent doubt, the ultrasonography can be repeated. While an enlarging collection associated with worsening pain or persistent fever might suggest an abscess, the possibility persists that the formation of this fluid was in fact stimulated by the drain itself, which acted as a foreign body, thus stimulating the secretion of the fluid.

The drain may also prove to be harmful, when, after a simple cholecystectomy, an infection introduced because of the drain alongit, may render an otherwise harmless collection of bile a cause of peritonitis.
A drain may also become walled off rapidly, and then stimulates an exudate in response to its very own presence.
Even if complications do occur in cases where a drain was not placed, using minimally invasive techniques and principles, such as percutaneous aspiration and/or endoscopic techniques may be used to effectively cope with these complications.

Insertion of a drain may negate one of the most important benefits of a laparoscopic cholecystectomy i.e. less pain. The term 'drain fever syndrome' after Cholecystectomy was described by Myers in 1962 [27]. In this condition, right upper quadrant pain and fever develops if a drain is placed for longer than 48 hours. The pain and fever disappeared spontaneously within 1-3 days and occurred n 4% cases of the non-drain group and in 23% cases in the drain group. The difference may be due to the following reasons:

- A foreign body reaction caused by the drain itself.
- Formation of a connection between the skin and the peritoneal cavity.
- The feeling of pain and discomfort caused by the pain prevents the patients from coughing.

The drain may itself cause pain at the site of insertion as well as pain during its removal, thus precipitating the need for increased analgesic requirement.

Port-site infection is a minor complication that affects 1.1-7.9% of patients after a laparoscopic cholecystectomy. The use of a drain increases the incidence of this complication. This may be due to the drain, probably allowing the bacteria to gain access to the gallbladder bed or the abdominal wall or the peritoneal cavity that predisposes to and increases the chances of contamination and infection [20,21].

According to recent studies, infection renders mucosal barriers more sensitive to bile [22]. Patients who have sustained closed intra-peritoneal rupture may remain relatively well for a long period of time. This is in significant contrast to those who develop biliary peritonitis after cholecystectomy where the clinical course is rapidly fatal if not effectively treated. It has thus been suggested that drains may introduce infection along them, rendering a harmless collection, into a cause of peritonitis. An open drain also becomes rapidly walled off, as demonstrated by Yates [20] more than 80 years ago, and then provokes exudates in response to its own presence.

In the study conducted by Syed Fahad *et al* [28], incidence of wound infection was less in the non-drain group (1, 1.66%) as compared to the same in the drain group (8, 13.3%). Similar results were observed in the studies conducted by Satinsky and Uchiyama [5, 23].

El-Labban G *et al*. [29] and Marcello *et al*. [24] also showed similar results, with the incidence of wound site infection being 5 times more in the Drain group than that in the non-drain group in their study population.

CONCLUSION

Thus it can be safely inferred that routine use of sub-hepatic drain in an uncomplicated laparoscopic Cholecystectomy is not only useless, it can sometime be a cause of various complications such as pain, fever and infection. The drain may increase the hospital stay and overall cost of the procedure.

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