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A COMPARATIVE STUDY TO ASSESS THE POST-OPERATIVE MORBIDITY PARAMETERS IN PATIENTS UNDERGOING UNCOMPLICATED LAPAROSCOPIC CHOLECYSTECTOMY WITH PLACEMENT OF SUB-HEPATIC DRAIN VERSUS WITHOUT SUB-HEPATIC DRAIN – A ONE YEAR RANDOMISED CONTROLLED TRIAL.

General Surgery

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ABSTRACT

Background And Objectives Laparoscopic cholecystectomy has become the treatment of choice for symptomatic gallstones. However the routine use of drains in laparoscopic cholecystectomy has become debatable and remains controversial. The present study was done to assess the post-operative morbidity in patients with placement of sub-hepatic drain versus without drain following uncomplicated laparoscopic cholecystectomy. **Methodology** The present study is a one year hospital based randomised controlled trial done between January 2021 and December 2021 at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, on 62 patients randomised into two groups – Drain Group and Non Drain Group. **Results** Among the two groups, around 52% were males in whom drains were placed as compared to females who comprised 48.3% (p=0.307). Patient who underwent drain placement belonged to age group of 40-49 years which accounted to approximately 26% of the total study population. All 3 patients of 70-80 years of age group had drain placement with non significant p value. Patients who underwent LC without placement of intra-abdominal drainage had a significant amount of collection than in patients who underwent drain insertion. Approximately 80.65% of patients were found to have collection of atleast 30ml in the subhepatic space (p = 0.0079). Port site infections were more significant in patients who had drain insertion. However no patients in Non Drain Group developed surgical site or port site infection. 14 out of 31 patients in the drain group developed surgical and port site infections. The mean hospital stay in the drain group was 5.71 ± 1.74 days which is higher as compared to 2.74 ± 1.03 days in the Non Drain group. **Conclusion** Placement of sub-hepatic drain following LC had a mixed outcome. The advantages of intra-abdominal drainage is to prevent accumulation of bile or blood in the sub-hepatic space, thereby preventing complications such as postoperative pyrexia, biliary peritonitis, peritoneal irritation, postoperative Shoulder tip pain and nausea and vomiting. It is also associated with post-operative morbidity such as increased rates of SSI(s) and longer hospital stays.

KEYWORDS

INTRODUCTION

Laparoscopic cholecystectomy currently is the treatment modality of choice for symptomatic gallbladder disease. Gallstone sufferers can benefit from laparoscopic cholecystectomy since it lessens post-operative pain, leaves an almost cosmetic scar, requires minimal hospital time, and enables for an earlier return to work. Laparoscopic cholecystectomies accounts for around 80% of all procedures, is the gold standard treatement. After a laparoscopic cholecystectomy, some surgeons regularly drain the peritoneal cavity out of concern that blood or bile may accumulate and may necessitates another exploration.

Drains are indicated for postoperative problems such nausea and vomiting, shoulder discomfort, biliary tract injury, back pain, postoperative bleeding, sub-hepatic collections, etc. Allowing carbon dioxide that is used to create pneumoperitoneum during laparoscopy generally gets removed through the drain and thereby reducing shoulder tip pain is another reason for placement of drains. The main cause of shoulder tip discomfort is residual carbon dioxide from laparoscopic cholecystectomy that causes diaphragmatic irritation. Employing suction drains, it improves postoperative shoulder pain and nausea/vomiting by re - establishing surface tension between the visceral & parietal peritoneum. Despite being such a routine practise, placing drains after surgery has come under scrutiny and debate. Therefore, it is necessary to study if drains are favourable or not, and to assess their results and consequences.

Prevalence of cholelithiasis and gallbladder disease is high in Belgaum and henceforth there are more laparoscopic cholecystectomies performed in KLES Dr. Prabhakar Kore Hospital, Belagavi. The need of the study is therefore to assess and evaluate the merits and demerits of placing an intra-abdominal drains following a laparoscopic cholecystectomy in patients with uncomplicated gall bladder disease.

METHODOLOGY

MATERIALS AND METHODS

This study was done in Department of General Surgery, KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi over a duration of one year from January 2021 to December 2021. It is a randomised controlled trial study done on a total 62 patients randomly assigned into two groups – Drain and Non Drain group comprising of 31 patients each. The randomisation group was mentioned on paper and sealed in an envelope using the SNOSE method. A number was assigned to the envelope. Once the patient has agreed to participate in the study, he or she was asked to select one sealed envelope from a box and will then be assigned to a treatment/study group. Patient(s) who give consent for the study, age group ranging between ≥ 18 years and ≤ 80 years of either gender, acute and chronic cholecystitis, interval cholecystectomies, uncomplicated calculous cholecystitis undergoing laparoscopic cholecystectomy and patients with previous abdominal surgeries were included in the study. Patients with co-morbidities, immunocompromised patients and subjects on anti-platelets and anti-coagulants, patients who require conversion to open cholecystectomies, CBD exploration, subjects with underlying chronic liver disease and malignancies were excluded from the study.

Statistical Analysis

The research focuses on the comparison of two groups. Mean and standard deviation were calculated for continuous quantitative variables. The intergroup continuous variables were compared using appropriate statistical tools such as the unpaired student's t test. The student's paired t test were used to compare two quantitative variables within a group. Rates, ratios, and percentages were used to express categorical data. The Chi-square test or Fisher's exact test was used to test the relationship between the outcome, clinical, and demographic characteristics. The median were used to represent discrete variables. For comparing discrete variables, nonparametric tests were used. The comparison were depicted using appropriate graphs. The value of p for all tests was less than 5%. (0.05) is considered significant.

RESULTS

1. Collection In Sub-hepatic Space

Table – 1: Table representing collection in the sub-hepatic fossa in the two groups.

		DRAIN GROUP	NON DRAIN GROUP				
COLLECTION IN SUBHEPATIC SPACE	NUMBER OF PATIENTS	%	NUMBER OF PATIENTS	%	TOTAL	p VALUE	INFERENCE
PRESENT	15	48.39	25	80.65	40	0.0079	VS

ABSENT	16	51.61	6	19.35	22		
TOTAL	31	100.00	31	100.00	62		

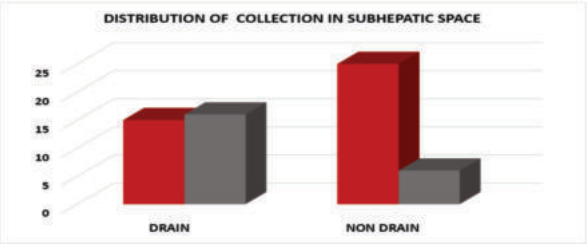

FIG – 1: Bar diagram representing sub-hepatic collection in drain & non-drain groups.

Patients who had to undergo LC without placement of intra-abdominal drainage had a significant amount of collection than in patients who underwent drain insertion.

Approximately 80% of patients were found to have collection of atleast 20ml in the subhepatic space.

2. Drain Site Infection

Table– 2: Comparison of Drain site and port site infection in the two groups.

		DRAIN	NON DRAIN				
DRAIN SITE INFECTION	NUMBER	%	NUMBER	%	TOTAL	P VALUE	INFERENCE
YES	14	45.16	0	0.00	14	< 0.0001	VS
NO	17	54.84	31	100.00	48		
TOTAL	31	100.00	31	100.00	62		

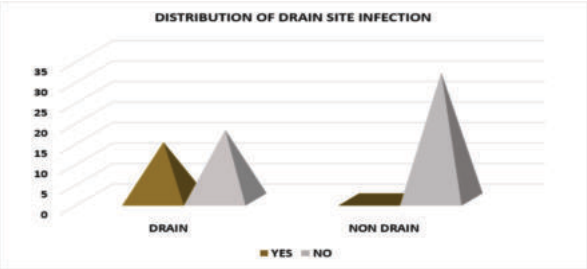

FIG – 2: Distribution of Drain and Port site infections among the drain and non drain groups.

Port site infections were more significant in patients who had drain insertion. However no patients in Non Drain Group developed surgical site or port site infection.

3. Operated Site Infection

Table – 3: Comparison of the two groups in terms of higher rate of surgical site infection.

		DRAIN	NON DRAIN				
OPERATED SITE INFECTION	NUMBER	%	NUMBER	%	TOTAL	P VALUE	INFERENCE
YES	5	16.13	7	22.58	12	0.5203	NS
NO	26	83.87	24	77.42	50		
TOTAL	31	100.00	31	100.00	62		

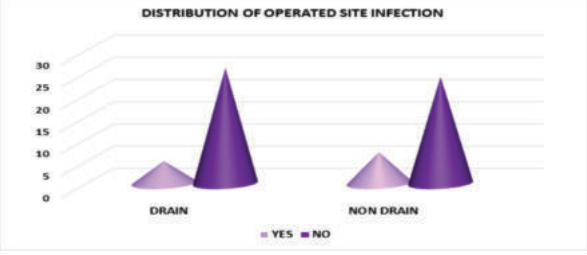

FIG – 3: Diagram showing the distribution of surgical site infection among the two groups.

It was found that the incidences of surgical site infection among the drain and non-drain group was not significant.

4. Nausea And Vomitting

TABLE – 4: Shows distribution of patients in two groups having postoperative Nausea and vomiting.

		DRAIN	NON DRAIN				
NAUSEA AND VOMITTING	NUMBER	%	NUMBER	%	TOTAL	P VALUE	INFERENCE
YES	15	48.39	12	38.71	27	0.4422	NS
NO	16	51.61	19	61.29	35		
TOTAL	31	100.00	31	100.00	62		

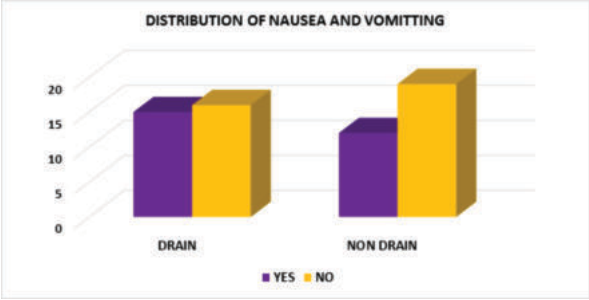

FIG – 4: Bar diagram representating higher incidences of postoperative nausea and vomiting in the drain group.

From our randomised controlled trial study it was found that the cases of nausea and vomitting are proportionately higher in the drain group when compared to non-drain group.

5. Operative Time

In the following tables p values are calculated using student's unpaired t test

OPERATIVE TIME									
DRAIN GROUP				NON DRAIN GROUP					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	P VALUE	INFERENCE
92.32	11.45	75	120	68.35	8.09	54	93	<0.0001	HS

Table – 7: Table showing the comparison of the operative time taken among both the groups.

LENGTH OF HOSPITAL STAY									
DRAIN GROUP				NON DRAIN GROUP					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	P VALUE	INFERENCE
5.71	1.74	3	10	2.74	1.03	1	5	<0.0001	HS

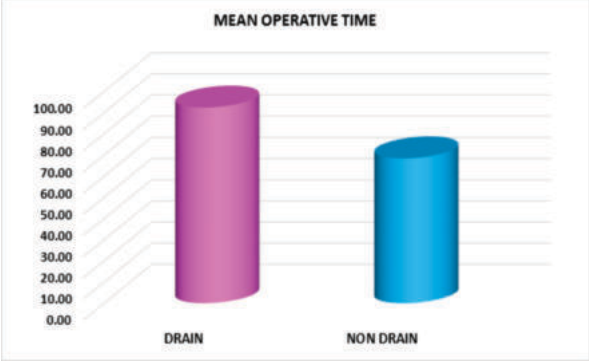

FIG – 5: Pictorial Representation of the total operation time taken in the two groups.

From this study, we found that the patient who underwent LC with drain placement had an mean operative time of 92 mins when compared to the other group.

6. Duration Of Hospital Stay

Table – 8: Shows the length of hospital stay among the two groups.

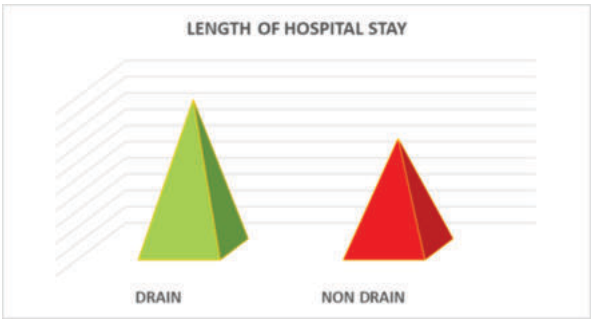

FIG – 6: Patient in whom drain were placed has a comparatively longer hospital stay than the non-drain group.

The postoperative stay in hospital was relatively longer in the drain group compared to the non-drain group.

DISCUSSION

For more than 100 years, the conventional cholecystectomy has served as the therapy of choice for cholelithiasis. However, with the introduction of laparoscopic procedures like the mini-cholecystectomy and LC, this preference is slowly and steadily waning. On September 12, 1985, Dr. Med Erich Mühe from Böblingen, Germany, carried out the first LC.[4]

One of the most typical conditions seen in the surgical outpatient department is still gallstones. Since its introduction in 1987, laparoscopic cholecystectomy (LC) has increasingly have become standard method of treating gallstones.[2] Gallstone patients gets benefited from laparoscopic cholecystectomy since it lessens postoperative pain, leaves nearly no scar, requires a shorter hospital stay, and allows for an earlier return to work.[4]

In abdominal surgery, prophylactic drains are frequently used to either wash away collections that could be harmful, such biliary that can become contaminated, or to detect early issues, like postoperative bleeding or leakage.[6] During laparoscopic cholecystectomy, the majority of surgeons used to drain the subhepatic area, primarily out of concern for bile peritonitis. However some surgeons doesn't follow the idea of the usage of drains in elective LC and hence the usage of drains in LC have become a questionable topic of debate.

Another justification for drain usage is to promote carbon dioxide that was used during laparoscopy to leave through the drain site, which lessens STP. The main cause of shoulder tip discomfort is residual carbon dioxide from laparoscopic cholecystectomy that causes diaphragmatic irritation. Post-operative nausea and vomiting are also brought on by this residual carbon dioxide. Surface tension between the liver and diaphragm, in particular, is lost as a result of residual gas. Pain in the shoulder tip is caused by the liver's dragging on its diaphragmatic attachments. Utilizing suction drains, it reduces postoperative nausea and vomiting as well as shoulder pain by returning the visceral and parietal peritoneum's surface tension to normal.[1]

At a recent Australian analysis, surgeons were divided into three groups at random: those who frequently used drains, the few who used drains, and the other group of surgeons who never used drains after LC. According to a recent and comprehensive multicenter analysis done in Brussels, Belgium, 74.9% of surgeons use an abdominal drain when considering laparoscopic surgery (LC) for acute cholecystitis.[6]

According to several studies, the placement of drains had no meaningful impact on the infection rate or the need for additional surgery. Additionally, according to some research, there was no statistically significant difference in post-laparoscopy cholecystectomy discomfort between the drain and no drain groups.[6] In light of the ongoing debate over the necessity of using drains during an uncomplicated laparoscopic cholecystectomy, a randomised study was conducted to evaluate the function of drains during LC.

One of the commonest indications as to why surgeons prefer a drain in sub-hepatic space is for the fear of intraabdominal collection and bile leakage which can be a fatal complication. In abdominal ultrasonography done on postoperative day 2 in our study, there were 8 patients who had subhepatic collection of 30ml or more. 1 patient in the drain group had upto 60ml of localised collection in the subhepatic space. Hence in the drain group a total of 15 patients (48.3%) had collection in the subhepatic space as detected on USG. In the non drain group a total of 25 patients (80.65%) had significant collection on postoperative day 2 detected on USG, out of which 2 patients had maximum collection upto 50ml and 60ml respectively which statistically very significant (p=0.0079). A 5 year period study conducted by G Tzovaras, Fafoulakis et al(2009) on a total of 565 patients randomised into two groups of 284 and 281 patients into Drain and Non drain group respectively found that 4 patients developed a bile leak in the drain group as compared to 2 patients in the non drain group. It is assumed that use of drains might have a protective role in some where bile leak could have occurred thus avoiding the complications such as peritonitis, biloma formation, etc.[7] Another study done by Marcello Picchio et al (2012) had a significant amount of patients in the drain group in whom no subhepatic fluid collection was noted in abdominal USG done 1 week after surgery (84.9%). Following cholecystectomy, the lack of subhepatic fluid accumulation is highly correlated with a straightforward postoperative recovery. Drains' ability to effectively remove subhepatic collections may support their use in preventing surgical problems. Experimental research, however, revealed that whenever a drain is put into a peritoneal cavity that is empty of fluids, omentum quickly surrounds it and totally occludes it within 48 hours.[8]

The causes of post-LC nausea and vomiting are numerous. One of the hypothesised explanations is that inhaling CO2 increases cerebral blood flow, which in turn increases nausea and vomiting. Additionally, retained CO2 induces the production of carbonic acid, which results in peritoneal acidosis and, consequently, more nausea and vomiting. Laparoscopic cholecystectomy patients have experienced less post-operative nausea and vomiting and a quicker recovery when CO2 is eliminated via abdominal wall raising devices. Drains inserted in the subhepatic area serve as a pathway for the release of trapped CO2, lowering intraperitoneal acidosis and, consequently, nausea and vomiting.[1]

The mean postoperative hospital stay was significantly longer in patients who required placement of intraabdominal drainage i.e a mean duration of 5-6 days of hospitalisation was required in those group of patients whereas in those patients who did not undergo drain placement had a mean stay of approximately 2-3 days in the hospital and hence had a quicker recovery. The operative time in whom drains were required to be placed was also higher than those group where no drain was indicated. This is probably because of more intraoperative complications such as distorted anatomical demarcation of planes, difficulty anatomy of Calots Triangle and hemorrhagic events due to bleeding from the liver bed, etc.

But as per previous researches and studies conducted by Walter Buigantella et al (2014) suggested that the intra-abdominal drain placement is also related to increased postoperative pain: aggravates the postoperative discomfort due to the irritation of the peritoneum and skin by a foreign substance.

CONCLUSION

Laparoscopic cholecystectomy is associated with a number of complications, similar to other surgical procedures. These complications can sometimes be extreme enough to be life-threatening. Hence some surgeons prefer the usage of drains in the subhepatic space to prevent such complications. Multiple experimental studies and researches proved that there is no practical usefulness in placement of an abdominal drain after the procedure. But prophylactic drainage in certain circumstances proved to be beneficial in our study such as the significant amount of subhepatic collection as detected in the ultrasonography on postoperative day 2 could be gradually drained out via the intraabdominal drainage system. In the drain group a total of 15 patients (48.3%) had collection in the subhepatic space as detected on USG. In the non drain group a total of 25 patients (80.65%) had significant collection on postoperative day 2 detected on USG, out of which 2 patients had maximum collection upto 50ml and 60ml respectively which was statistically significant (p=0.0079). Despite having multiple morbidities such as increased postoperative pain, prolonged hospital stay, increased incidences of nausea and vomiting, etc, it helps in early detection of bile leakage and subhepatic fluid accumulation which allows us to intervene timely and prevent complications such as biliary peritonitis, haemoperitoneum from liver bed haemorrhages, sepsis secondary to intraabdominal

collection or abscess formation. Therefore drain placement was found to be useful in our study only in early detection of subhepatic fluid accumulation. Hence we can assert that routine subhepatic drainage in patients undergoing uncomplicated elective laparoscopic cholecystectomy do not always increase the postoperative outcome and must be considered only as per the need when perioperative complications arises.

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