Postoperative Evaluation of Patients of Laparoscopy Cholecystectomy with and without Drain with the Help of Ultrasonography

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ABSTRACT

Introduction: Most common complaints after laparoscopic cholecystectomy are abdominal pain, shoulder tip pain, and nausea, vomiting in the post-operative period. These have been attributed to high pressure pneumoperitoneum using carbon dioxide gas causing irritation of the diaphragm and other abdominal viscera. Thus, a drainage tube is inserted to decrease the intra-abdominal pressure to mitigate these symptoms. However, the role of routine drainage after laparoscopic cholecystectomy is still controversial. Several studies including some meta-analysis performed to assess the role of drains in reducing complications in laparoscopic cholecystectomy could not definitively establish the same. The surgical community is divided on this issue due to the lack of evidence on usefulness of drain. Therefore, we planned a controlled randomized comparative study to assess the value of drain in uncomplicated laparoscopic cholecystectomy.

Material and Methods: The study was conducted in department of General surgery Maharishi Markendeshwar Medical college and Hospital, Kumarhatti, Solan, Himachal Pradesh, India from July 2018 to June 2019. During a period of one year, 50 patients (group A) were randomized to have a drain placed, with No. 14 Ryles tube, kept in sub hepatic space after laparoscopic surgery, whereas the other 50 patients (group B) did not have any drain in the subhepatic space. These patients were evaluated regarding any differences in morbidity, postoperative pain, wound infection and hospital stay between the two groups.

Result and Conclusions: The present study was unable to substantiate the utility of subhepatic drain following the elective laparoscopic cholecystectomy procedure.

Keywords: Cholecystectomy, Laparoscopy Drainage, Sub Hepatic Space

INTRODUCTION

Prophylactic drains in abdominal surgery are widely used either to detect early complications, such as postoperative hemorrhage or leakage, or to remove collections that might be toxic, such as bile, and become infected. Drain is a tube that is left inside the abdomen to allow drainage of fluids to outside the abdomen. Some surgeons routinely put a subhepatic drain after laparoscopic cholecystectomy because of the fear of collection of bile or blood requiring re-exploration. As the name indicates, it helps to drain out these collections to the exterior, thereby minimizing the chances of re-exploration. But the routine use of drains may either require the overnight stay or removal after discharge. This leads to increased resource utilisation and precious time in this era of day care surgery, where patients are admitted and discharged on the same day of surgery. However, evidence-based data does not support the use of prophylactic drainage in the majority of abdominal surgical procedures. In the era of open cholecystectomy, a meta-analysis showed that drains increased morbidity without providing any additional benefit for patients. At present, laparoscopic cholecystectomy (LC) is the preferred method for either elective cholecystectomy or emergent cholecystectomy. The role of prophylactic drainage in LC to avoid bile and blood collection requiring subsequent treatment is largely not defined but this has helped in preventing the blood collection requiring intervention after LC and allows drainage of CO2, used for in sufflation during laparoscopy, to escape via the drain site, thereby decreasing the shoulder pain. The surgical community is divided on this issue due to the lack of evidence on usefulness of drain. Therefore, we planned a controlled randomized comparative study to assess the value of drain in uncomplicated laparoscopic cholecystectomy.

MATERIAL AND METHODS

The study was conducted in department of General surgery Maharishi Markendeshwar Medical College and Hospital, Kumarhatti, Solan, Himachal Pradesh, India from July 2018 to June 2019. During a period of one year, 50 patients (group A) were randomized to have a drain placed, with No. 14 Ryle’s tube, with and without drain with the help of ultrasonography.

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tube, kept in sub hepatic space after laparoscopic surgery, whereas the other 50 patients (group B) did not have any drain in the subhepatic space. In group A, patients drain was kept for 48 hrs and removed after USG abdomen. In group A, patients 8 were male and 42 were females whereas in group B, 6 male and 44 females took part in this study. End points of this study were to detect any differences in morbidity, postoperative pain, wound infection and hospital stay between the two groups. The study was approved by the ethical committee of the institute.

**Inclusion criteria**
- Age group 18-75 years
- Symptomatic cholelithiasis
- Patients undergoing elective laparoscopic cholecystectomy

**Exclusion Criteria**
- Obstructive Jaundice
- Conversion to open surgery
- Cholecdocholithiasis
- Acute cholecystitis
- Pancreatitis

Written informed consent was obtained in all the cases. Hemogram, liver-function tests, urine analysis, pre-operative chest x-ray, ECG and ultra-sonography of intra and extrahepatic biliary tract was done in all cases. All patients underwent Laparoscopic cholecystectomy under general anaesthesia using four port techniques. In group A patients (n=50), sub-hepatic space was drained by a ryles tube drain, brought out through mid-axillary line, whereas, no port was used in group B. All the patients, in both Study and control group, were evaluated for abdominal pain (Visual Analogue Scale), Shoulder pain, Drain site infection, Wound infection, Fever, Duration of post-operative hospital stay, Nausea, Vomiting, Haemorrhage post-operatively. Postoperative pain was assessed on day 0, 1, 2, 3 after operation by using Visual Analogue scale. On day 0, all patients were administered analgesics at 1hr, 6hrs and 8 hrs of extubation. On days 1, 2 and 3, the patients were given analgesics as and when required, based on the severity of pain. The wound infection was recorded by examination of wound daily for any discharge and/or redness.

**RESULTS**

The general patient profile of the study and the control groups is detailed in table-1. The study group comprised of fifty patients, placed with a drain in the subhepatic space with its exit at mid axillary line. Drain was kept for 48 hrs. The mean duration of drain placement was 2.3±1.9 days. The mean duration of hospitalization was 3±2.9 days in patients with drains and 2.9±1 days in patients without drains and this was found to be statistically significant (p<0.05). The comparison of clinical features in the two groups is detailed in table -2.

In the study group (A), hepatobiliary ultrasonography on the 2nd post-operative day revealed a fluid collection in the gallbladder fossa in 18 patients (36%). The mean volume of collected fluid was 6.6±5.2 ml. The fluid collection was <10 mL in 10 patients, 10-15 mL in 8 patients. The fluid accumulation didn't have any correlation with patient age and gender, however, on detailed history taking these patients revealed history of frequent attacks of cholecystitis.

| Study Group (n=50) with drain | Control Group (n=50) without drain |
|------------------------------|-----------------------------------|
| Number of patients           | Study group (n=50)                |
| Male                         | Control group (n=50)              |
| Female                       | 50                                |
| Average age                  | 8                                 |
| Wall thickness of gall bladder| 42                                |
| Non-edematous = 42           | Edematous = 6                     |
| Edematous = 8                | Non-edematous = 44                |
| Number of calculus           | S8                                |
| S14 M36                      | Table-1: Patient Profile of the Study and Control group |

| Outcome Indicators | Study group (n=50) | Control group (n=50) | P value |
|--------------------|--------------------|----------------------|---------|
| Volume of abdominal collection | 6.6±5.2 ml | 7±3.5ml | <0.05 |
| Duration of drain placement | 2 days | NA | <0.001 |
| Previous H/O collection and cholecystitis | 8 | 6 | >0.05 |
| Duration of hospitalization | 3±2.9days | 2.9±1days | <0.05 |
| Severity of abdominal pain | 38 | 21 | <0.001 |
| Severity of drain site pain | 16 | Nil | <0.001 |
| Severity of shoulder tip pain | 18 | 12 | >0.05 |
| Nausea / vomiting | 22 | 18 | |
| Abdominal visceral injury | Nil | Nil | |
| Wound infection | Nil | Nil | |
| Fever | 3 | 3 | |
| Haemorrhage | Nil | Nil | |
| Gall bladder perforation | Nil | Nil | |
| Leakage from drain site | 4 | Nil | |

Table-2: Comparison of clinical features of the study and control groups
Of these 18 patients, 7 (14%) were male and 11 (22%) female patients (P>0.05) and 14 (28%) of them revealed a history of acute cholecystitis, whereas the other 4 didn’t have any such history in the past (P<0.05). Fourteen out of 50 (28%) patients in control group-B (without drains) had fluid collections in the post-operative phase as compared to 18 (36%) patients with drains. The volume of fluid collection between the two groups was comparable as shown in table 2. One out of these 14 patients showed fluid collection (<5ml) on repeat ultrasonography on day 30, however, none of the patients in group-A showed any collection on Day 30. Overall the post-operative pain was observed in 90 patients 6 hrs after the surgery in both the groups. Of which 38(76%) patients were in Group-A and 21(42%) patient in group B. Thus, it was significantly higher (p<0.005) in patients with a drain than in patients without drain. Wound Infection was not recorded in any of these patients in any of the groups. Post-operative pyrexia (Oral temperature>39°C) was seen in 6 patients in post operative period with equal numbers in both the groups. No injury to abdominal viscera was recorded in any of the groups.

DISCUSSION

Gall stone disease is a common problem of the hepatobiliary system and cholecystectomy has been the mainstay of treatment for symptomatic disease. Laparoscopic removal is considered to be the procedure of choice than the open approach for elective cholecystectomy. Laproscopic approach has certain definitive advantages over the open cholecystectomy in terms of less postoperative pain, better pulmonary function, better arterial oxygenation and shorter hospital stay. The incidence of Biliary complications after LC ranges from 0.2%-0.8% (25) in the post-operative period. More over the hemorrhagic complications are very rare in the laproscopic approach. The use of drains has been thought to reduce the complications as they evacuate subhepatic collections as and when they accumulate in this space. However, experimental evidence reveal that insertion of a drain in the peritoneal cavity is followed by reactionary cover by omentum and it may get completely occluded within 48 hours, if there is no active fluid collection the cavity. In order to overcome this problem, Burke GL et al included tantalum in surgery which was resistant to corrosion and infection as well as the case with other metallic drains. Tantalum is generally chemically inert but strong alkali or acid can have detrimental effect on it, however it remains largely unaffected by oxidizing agents found in living tissues. Tantalum clips has lead to a decline in the overall operative time by avoiding extra corporeal knotting. In the present study, we didn’t observe any cystic duct leakage in any of the groups. So both extra corporeal suture ligation and clip application are safe in securing the cystic duct. The utility of intra corporeal ligation of cystic duct using absorbable suture was proved by Ahmed A et al in their study that this a practical, safe and cost-effective approach. In a prospective randomized study by Leo et al showed that suture ligation of the cystic duct is safe and cost-effective alternative to the application of metal clips. Hence, they recommended suture ligation in all laparoscopic cholecystectomies, especially in difficult cases. The ease of application of metal clips help in decreasing the overall operative time and are being a preferred choice these days. However, in cases of a wide cystic duct, it is difficult to apply a metal clip, thus, ligation with extra corporeal knotting is the best approach. Therefore, the surgeon must have an expertise in applying the extra corporeal knot in such cases. In addition, clips are costlier than Mersilk ligature 1-0 hence is a cost-effective option.

Although the overall time taken for surgery is longer with extra corporeal knotting but it makes a substantial difference in the cost of the procedure (even after not considering the cost of the clip applicator) without compromising the safety and efficacy of laparoscopic cholecystectomy. In the present study, the average operative time in the drain group was 50 min and 40 min in the no drain group without any significant difference between the two. In his first cholecystectomy in 1882, Lamgenebuch placed a peritoneal drain as a part of the procedure and thereafter the routine practice of drain placement of drains became a part of this surgery for a long time. However, this practice has received criticism in elective conventional cholecystectomies in majority of the surgeons discontinuing this practice. Placement of a drain after laparoscopic cholecystectomy in view of the collection of bile or blood in the post-operative phase has been advocated by some to avoid open procedure. In addition the drain allows the easy escape of CO₂, used for in sufflation during laparoscopy, hence helps in minimizing the shoulder pain. But, our data is unable to prove the efficacy of suction drains either in minimizing the abdominal or shoulder tip pain after LC, as is in agreement with the observations of Jorgensen et al.

Nausea and vomiting was observed in 40 patients (group A =22, group B =18) in our study but these complications are less in gasless laparoscopic cholecystectomy. Similarly, studies by Gurusamy and Tarik et al didn’t reveal any significant difference in post operative nausea and vomiting between drain and no drain groups. A higher incidence of wound infection rate and longer hospital stay has been observed in patients with the drain in the post-operative period. Duration of hospital stay was considerably longer (p<0.05) in patients with sub-hepatic drains (3± 2.9days) as compared to group without any drain (2.9±1).This is due to the fact that placement of subhepatic drains requires in hospital observation of the patient at least for 48 hours. Similar observations have been reported previously by Gurusamy and Satinsky et al with significantly longer hospital stay in patients with the drains. On the contrary, Hawasi and Brown did not observe any significant difference between drain and without drain group in terms of duration of hospital
stay, abdominal and shoulder tip pain. The higher incidence and severity of pain in patients with drains is probably due to the irritation of the peritoneum and skin at the point of exit of the drains. The Visual Analogue Scale assessment of pain in the post-operative period didn’t reveal any difference between the two groups in our study. However, the evidence in the literature by Kazuhisa et al showed a significantly higher mean VAS score patients with drain than without drain at 24 and 48 hours, especially in women. Likewise, a higher incidence of pain was observed by Tzovaras et al in patients undergoing laparoscopic cholecystectomy with drain without any added benefit.

Wound infection was not observed in any of the patients in any of the groups, which is consistent with the findings of Hawashi et al and Playforth et al regarding wound infection in their trials. On the contrary, Gurusamy et al found a significant higher incidence of wound infection in patients with drain than without drain. The peritoneal cavity usually absorbs serous fluids rapidly, but blood and bile are absorbed more slowly. Subhepatic space collections in the post-operative phase are generally rapidly reabsorbed, however, their size and number are the same in patients with and without drain. The major reason for drainage is the fear of bile leakage that may lead to biliary peritonitis, which is usually due to an aberrant bile duct and not slippage of the cystic duct ligature.

CONCLUSION

The present study was unable to prove the utility of drains in reducing complications in LC. However, still there is no evidence at present to refute its utility in the setting of emergent LC. Therefore, it is reasonable to avoid drain insertion when a dry operatory field is obtained at the end of the procedure.

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