Original research article

Laparoscopic Cholecystectomy with and without Drainage: A Randomised Clinical Trial

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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, Anugrah Narayan Magadh Medical College, Gaya, Bihar, India. 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: Patients with cholelithiasis were divided into two groups: those who had a drain and those who did not. Patients with acute cholecystitis were 27 percent more likely to have a drain than they were to be without one, while patients with chronic cholecystitis were 31 percent more likely to have a drain than they were to be without one. There was no statistically significant difference between the two groups. Patients with drains received a G4 (49 percent), followed by a G3 (47 percent), and finally a G2 (22 percent) (5 percent). Patients who did not have a drain had a VAS grade of G2 (49 percent), followed by G3 (30 percent), and then G1 (15 percent). There was a statistically significant difference between the two groups when the p-value was less than 0.05. Wound infection was observed in 12 (12 percent) of the patients with drains and 1 (1 percent) of the patients without drains, resulting in a p value of 0.006. Consequently, the researchers discovered a statistically significant difference between the two study groups. The mean length of stay in the hospital for patients with drains was 9.152.03 days, while the mean length of stay in the hospital for patients without drains was 4.111.36 days. There was a statistically significant difference between the two study groups, as indicated by a p-value of 0.05. The presence of nausea and vomiting was observed in 45 (45 percent) of the patients with drains and 3 (3 percent) of the patients without drains, resulting in a p value less than 0.05.

Conclusions: Uncomplicated gallstone disease can be treated by laparoscopic cholecystectomy without the need for a drain with tolerable safety if performed by an experienced surgeon with the appropriate training and equipment.

Keywords: laparoscopic, cholecystectomy, drain

Introduction

The gallbladder is a pear-shaped reservoir of bile that is located on the inferior surface of the liver and is partially covered by the peritoneum. It is responsible for the production of bile. After the appendix, the gall bladder is the most frequently surgically intervened-on component of the gastrointestinal system because of its physical location at the doorway to the liver's hilum and because of its embryological development, which includes its various variants. Gallstone
disease, one of the most frequent bile system ailments known since antiquity, requires surgical intervention to be completely cured, according to current research. Gallstones are the most prevalent and expensive digestive ailment in India, and they are also a major cause of hospitalisation. For more than a century, conventional cholecystectomy has been the treatment of choice for cholelithiasis. However, with the development of minimally invasive procedures such as mini-cholecystectomy and laparoscopic cholecystectomy, the surgical community's preference for conventional cholecystectomy has been steadily declining.

On September 12, 1985, Dr. Med Erich Mühe of Böblingen, Germany, performed the world's first laparoscopic cholecystectomy (LC) procedure.

A consensus statement issued by the National Institutes of Health (NIH) in 1992 said that LC is a safe and effective treatment for the majority of people with symptomatic gallstones, and that it has since become the treatment of choice for many patients. Treatment for symptomatic cholelithiasis has garnered practically universal support, and it is currently regarded the gold standard for the treatment of the condition.

In reality, laparoscopic cholecystectomy, one of the most significant surgical breakthroughs of the twentieth century, has completely transformed the treatment of gallstone disease. It has advanced to the status of gold standard treatment for cholelithiasis.

It is the most often performed laparoscopic operation in the world, and it is the second most frequently performed operation in gastrointestinal surgery after appendectomy.

It is a safe and successful treatment option for individuals with gallstones since it lessen postoperative pain while leaving a practically inconspicuous scar, as well as providing a shorter hospital stay and allowing patients to return to work sooner.

Laparoscopic cholecystectomy is associated with a number of consequences, which can range from moderate to significant and even life threatening at times. As with any surgical procedures, there are risks and benefits to consider.

The most prevalent complaints following laparoscopic cholecystectomy include shoulder tip pain, back pain, and nausea/vomiting, which were absent with conventional laparotomy. Routine drainage was introduced into laparoscopic cholecystectomy procedures in order to avoid such complications.

Surgeons have frequently drained after performing a laparoscopic cholecystectomy because they are concerned about the possibility of collecting bile or blood, which would need open procedures. Additionally, draining allows carbon dioxide that was insufflated during laparoscopy to escape through the drain site, thereby alleviating shoulder pain. Drainage, on the other hand, may exacerbate infective problems and cause discharge to be delayed. In addition, a higher proportion of patients reported nausea and vomiting than previously. According to studies, the drain group has a greater likelihood of wound infection and requires a longer hospital stay.

As a result, there has been some criticism around this procedure in elective traditional Cholecystectomies. According to a recent Cochrane Database Systematic Review, drains have
typically been utilised for the early diagnosis of bile leaks and any unsuspected haemorrhage, as well as for the evacuation of abdominal fluid accumulation, without the necessity for more invasive procedures such as laparoscopy.

Current data indicate that biliary problems following LC occur in 0.4 percent of cases (0.1%–0.9 percent of cases). It is quite rare for postoperative hemorrhagic problems to occur, which further limits the usage of drains. An simple postoperative recovery after cholecystectomy is highly associated with the lack of sub hepatic fluid accumulation, according to research.

In some cases, the efficiency of drains in removing sub hepatic collections may be sufficient to warrant their usage in preventing postoperative problems.13

A drain put into the peritoneal cavity that contains no fluids, on the other hand, is swiftly enveloped by omentum and entirely clogged within 48 hours, according to experimental research. Bile drains, as opposed to other types of intra-abdominal collections, are thought to be significantly more efficient at emptying bile.

LC patients are more likely than the general population to have port-site infection, which occurs in 1.1–7.9 percent of cases. This problem, which is thought to be caused by the presence of a foreign body, appears to be reduced in frequency with the use of drains.

Material and methods
This randomized controlled trial single-blind study was done the Department of General Surgery, Anugrah Narayan Magadh Medical College, Gaya, Bihar, India for 12 months, after taking the approval of the protocol review committee and institutional ethics committee.

Methodology
Total 400 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

<table>
<thead>
<tr>
<th>Gender</th>
<th>With drain (group A)=200</th>
<th>Without drain (group B)=200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>90 (45)</td>
<td>80 (40)</td>
</tr>
<tr>
<td>Females</td>
<td>110 (55)</td>
<td>120 (60)</td>
</tr>
</tbody>
</table>

Table 2: Age distribution

<table>
<thead>
<tr>
<th>Age groups (years)</th>
<th>Number</th>
<th>% age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 30</td>
<td>60</td>
<td>15</td>
</tr>
<tr>
<td>30-40</td>
<td>102</td>
<td>25.5</td>
</tr>
<tr>
<td>40-50</td>
<td>86</td>
<td>21.5</td>
</tr>
<tr>
<td>50-60</td>
<td>80</td>
<td>20</td>
</tr>
<tr>
<td>Above 60</td>
<td>72</td>
<td>18</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Drain (%)</th>
<th>Without drain (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholelithiasis</td>
<td>84 (42)</td>
<td>84 (42)</td>
</tr>
<tr>
<td>Acute cholecystitis</td>
<td>54 (27)</td>
<td>22 (11)</td>
</tr>
<tr>
<td>Chronic cholecystitis</td>
<td>62 (31)</td>
<td>94 (47)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>VAS scores</th>
<th>Drain (%)</th>
<th>Without drain (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>G2</td>
<td>10</td>
<td>98</td>
</tr>
<tr>
<td>G3</td>
<td>92</td>
<td>60</td>
</tr>
<tr>
<td>G4</td>
<td>98</td>
<td>12</td>
</tr>
<tr>
<td>G5</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Post-op wound infection</th>
<th>Drain (%) (group A)</th>
<th>Without drain (%) (group B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present</td>
<td>24 (12)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Absent</td>
<td>176 (88)</td>
<td>198 (99)</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Nausea and vomiting</th>
<th>Drain (%) (group A)</th>
<th>Without drain (%) (group B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present</td>
<td>90 (45)</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Absent</td>
<td>110 (55)</td>
<td>194 (97)</td>
</tr>
</tbody>
</table>

Discussion

LC is the gold standard for the treatment of cholelithiasis. When compared to open surgery it offers various benefits like faster recovery, shorter hospital stay and better postoperative outcome and fewer complications. 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. However Hawasli et al with their team reported that no significant difference was present regarding wound infection in their trials. 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.

Another notable finding of this study was that there was a statistically significant difference in pain abdomen, as measured by VAS grade, between the two groups (p value 0.001). Tzovaras and colleagues (Tzovaras et al.) made similar discoveries.

However, according to Hawasli et al., there was a modest, but not statistically significant, difference between the two groups in terms of postoperative abdominal pain after surgery. In this study, the average length of stay in the hospital for patients with drains was 8.15 days, while the average length of stay for patients without drains was 3.11 days. Statistically, there was a significant difference (p value less than 0.05). Satinsky et al. reported findings that were similar to those reported by Guruswamy et al.

Consequently, the benefits of not inserting a drain include a reduction in hospital stay, improved patient comfort, and a lower incidence of postoperative problems. A higher incidence of wound infection and a longer hospital stay are associated with drainage, on the other hand. In the case of acute cholecystitis, the data did not support the hypothesis that the drain had any influence on either abdominal or shoulder tip discomfort.

Conclusion

Uncomplicated gallstone disease can be treated by laparoscopic cholecystectomy without the need for a drain with tolerable safety if performed by an experienced surgeon with the appropriate training and equipment. It is substantially less painful after surgery, requires fewer analgesics, and requires less time in the hospital when there is no use of a drain.
Reference

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