

Comparative Study of Safety and Efficacy of Laparoscopic Cholecystectomy in Patients of Cholelithiasis by Comparing with Mini Laparotomy

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Abstract

Background: Gallstones are common in Indian population, and its treatment has shown a decisive shift from open to minimally invasive route. There is no doubt that laparoscopy requires longer and steeper learning curve and higher cost, especially in the absence of health insurance to the majority of suburban and rural Indian population. However, preferences of patients are changing rapidly due to better level of awareness and availability of healthcare facility. Aims were to study the safety and efficacy of laparoscopic cholecystectomy in patients of cholelithiasis by comparing with results of mini-laparotomy cholecystectomy by comparing the use of post-operative analgesia, operative time, post-operative hospital stay, morbidity, and mortality.

Methods: It is a prospective randomized study of 100 patients of cholelithiasis aged between 25 and 65 years operated during 2016–2017 at Maheswara Medical College, Hyderabad. They were divided into mini-laparotomy and laparoscopic cholecystectomy group by drawing a lot method. Patient's written valid informed consent for the particular procedure was obtained, and the pros and cons of both the procedure were explained in detail to the patient. This study was done after due clearance of the Ethical Committee.

Results: The median (range) operation time for laparoscopic cholecystectomy was 45–60 min (mean = 50 min) and 75–90 min (mean = 80 min) for mini-laparotomy cholecystectomy ($P < 0.001$). During the study period, operation time for laparoscopic cholecystectomy showed a tendency to become shorter. The use of injectable analgesics in case of laparoscopic cholecystectomy (mean number of days = 1.5) is considerably less than mini-laparotomy cholecystectomy (mean number of days = 3.36). The conversion rate in literature in laparoscopic cholecystectomy ranges from 3% to 15% in well-trained hands. In our series, it is 6% in spite of being a teaching and training institution.

Conclusions: Minimally invasive surgery is better than mini-laparotomy cholecystectomy in terms of post-operative pain, analgesic requirement, and early return to work. However, mini-laparotomy cholecystectomy is preferred method for surgeons in the beginning of their career and in case of difficult cholecystectomy.

Key words: Cholecystitis, Cholelithiasis, Laparoscopic cholecystectomy, Laparotomy cholecystectomy, Mini bile duct injury, Minimally invasive surgery

INTRODUCTION

Gallstones (GS) are a common occurrence in India. As many as 16% and 29% of women above the age

of 40–49 years and 50–59 years, respectively, had GS.^[1] For every patient with symptomatic gallstone disease, there are many more with asymptomatic GS. Various studies performed on mortals suggest that most of the GS are asymptomatic. In a study of 9332 post-mortem reports performed over 10 years, only 14% of those with GS had undergone cholecystectomy, indicating that up to 86% were asymptomatic. Karl Langenbuch in 1882 quoted that “The gallbladder should be removed, not because it contains stones, but because it forms them.”^[2,3] Many alternative methods for treatment of GS have been developed, but these have not been satisfactory so far.

Access this article online



www.surgeryijss.com

Month of Submission : 09-2016
Month of Peer Review: 10-2017
Month of Acceptance : 11-2017
Month of Publishing : 12-2017

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Since ages, cholecystectomy has been the gold standard surgical treatment of cholelithiasis. With the advent of laparoscopic cholecystectomy, the scenario of surgical management of cholelithiasis has changed drastically. It has opened new horizons in the management of GS. Theoretical benefits of laparoscopic approach include reduced hospitalization and cost, decreased pain, avoidance of large incision with improved cosmesis, and reduced post-operative recovery time with an early return to work. Although it showed early promising results, recent trials show an increase in the incidence of operative complications, especially common bile duct injury.^[4]

Expensive instruments, specialized training, and long learning curve also limit the use of laparoscopy. This has led to a lot of soul searching and numerous attempts at comparing the merits and demerits of laparoscopic *vis-a-vis* mini-laparotomy cholecystectomy. The recent upsurge in practice of laparoscopic surgery and other form of minimal access surgery have ushered a new era of surgical treatment which is having a profound effect on surgical management. Minimal access surgery has touched every field of surgical speciality.^[5] The non-operative methods for the treatment of cholelithiasis in the form oral bile acid (chenodeoxycholic acid and ursodeoxycholic acid) and extracorporeal shock wave lithotripsy have not shown promising results.^[6-8]

Aims and Objective

The objective is to study the safety and efficacy of laparoscopic cholecystectomy in patients of cholelithiasis by comparing with results of mini-laparotomy cholecystectomy by comparing the use of post-operative analgesia, operative time, post-operative hospital stays, morbidity, and mortality.

METHODS

Our study is a prospective randomized study included 100 patients with GS which were admitted to Maheswara Medical College, Hyderabad. Randomization was done by drawing of lots. The selection of procedure of mini-laparotomy cholecystectomy or laparoscopic was decided depending on the inclusion and exclusion criteria, exception when patient consent was not given for a particular procedure. Information was collected from the patients after a written valid informed consent from them. Patients between 25 and 65 years with acute cholecystitis or chronic cholecystitis and GS without pain abdomen including those with diabetes and hemolytic anemia were included in the study. Patients written valid informed consent for the particular procedure was obtained. Patients <25 years and more than 65 years or those with gallbladder cancer and choledocholithiasis were excluded from the study. This study involved pre-operative assessment, intraoperative practice, and post-operative management and follow-up till 3 months.

All the patients were studied with reference to the duration of surgery, post-operative analgesic, post-operative stay, intraoperative, and post-operative complications. Patients were admitted a day before surgery in case of elective cholecystectomy from OPD after complete investigations performed required for general anesthesia. Some patients were admitted from the emergency department of hospital as they had presented with acute abdominal pain. These patients were investigated for the same.

Investigations performed in these patients include hemogram, blood sugar level, urine examination, liver function test, blood urea and serum creatinine level, chest X-ray, electrocardiogram, and ultrasonography of the abdomen. The patient was studied with respect to their clinical presentation and was grouped as patients with asymptomatic GS, acute calculus cholecystitis, and chronic calculus cholecystitis. After complete investigations and after satisfying the inclusion and exclusion criteria for our study, patients were subjected to either mini-laparotomy or laparoscopic cholecystectomy depending on draw of lots. The first dose of antibiotics administered to the patient just before incision, immediately after intubation. Nasogastric tube is inserted routinely irrespective of the nature of operation.

General anesthesia was administered to all the patients. Foleys catheterization and Ryle's tube insertion were done in all patients. Post-operative management included nil by mouth till bowel sounds are heard. Intravenous fluids in the form of crystalloids, broad-spectrum antibiotics (injection cefotaxim). Injection amikacin and injection metronidazole were added in cases of bile leak. Analgesics in the form of injection tramadol were given. Top-up analgesia in the form of intramuscular injection diclofenac sodium was given, whenever it was required. Discharge after the start of oral diet and without any signs of post-operative wound infection after first dressing change. If the sign of wound infection was present, then pus from wound was taken and sent for microbiological culture and sensitivity testing.

Appropriate antibiotics started after reports and wound care taken accordingly. Follow-up in OPD for stitch removal after 7 days, if operative wound is healthy. All laparoscopic cholecystectomies converted to mini-laparotomy cholecystectomy were considered as difficult laparoscopic cholecystectomy for evaluation of data.

RESULTS

Of 100 patients included in the study, 70 patients did not presented with pain abdomen and had been diagnosed on ultrasonography for vague abdominal symptoms, such as epigastric fullness and early satiety. 16 patients had presented with features suggestive of acute cholecystitis, and 14 had already been diagnosed earlier and had

few episodes of acute cholecystitis in the past. The mean operation time for laparoscopic cholecystectomy was significantly longer than for mini-laparotomy cholecystectomy [Figures 1 and 2].

The median (range) operation time for laparoscopic cholecystectomy was 45–60 min (mean = 50 min) and 75–90 min (mean = 80 min) for mini-laparotomy cholecystectomy ($P < 0.001$). During the study period, operation time for laparoscopic cholecystectomy showed a tendency to become shorter. Therefore, mini-laparotomy cholecystectomy group has significantly less operation time than laparoscopic cholecystectomy group ($t [98] = 6.1746$, $P < 0.001$) we are 99% confident that the mean difference lies between 1.6669 and 66.2931, suggesting that the association between the due variable is not due to chance.

Laparoscopic cholecystectomy 1–4 days. Mini-laparotomy cholecystectomy 2–8 days. Pain duration is more in mini-laparotomy and less in laparoscopic cholecystectomy. The mean post-operative hospital stay was 3.7 days after laparoscopic cholecystectomy and 5.46 days after mini-laparotomy cholecystectomy. Conversion of laparoscopic to mini-laparotomy cholecystectomy occurred in 3 of the 50 patients, i.e., 6% of initially scheduled to undergo laparoscopic cholecystectomy. Two cases of laparoscopic cholecystectomy were converted to open surgery due to common bile duct injury and one due to intraoperative hemorrhage.

Complications mini-laparotomy cholecystectomy/ laparoscopic cholecystectomy wound infection 9/3 (difficult laparoscopic cholecystectomy cases). Intraoperative bleeding 0/1, wound dehiscence 1/0, abdominal infection 2/0, bile duct injury 0/2, pancreatitis 0/0, postoperative ileus 5/3, pulmonary problems 1/2, cardiac problems 0/0, death 0/0. In our study, the duration of operative time for laparoscopic cholecystectomy is considerably longer than duration of mini-laparotomy cholecystectomy. This significant difference could be due to long learning curve for laparoscopic surgery. It is interesting to note that the indications for analgesia in both procedures were different, whereas in mini-laparotomy cholecystectomy group, this was due to wound pain, the patients in the laparoscopic group required post-operative analgesia for relief of shoulder tip pain secondary to diaphragmatic irritation due to CO₂ pneumoperitoneum.

Wound infection in mini-laparotomy procedure is 3 times the laparoscopic procedures. Jatzko *et al.* in their study observed that Grade I complications rate is lower in laparoscopic cholecystectomy group (0.3%) as compared to open cholecystectomy group (5.1%). Barkun *et al.* in Toronto group study also observed that a number of complications in laparoscopic cholecystectomy were significantly less than number of complication in open

cholecystectomy. Siddiqui *et al.*, in their study, observed that frequency of wound infection was 3 times common in mini-laparotomy cholecystectomy as compared to laparoscopic cholecystectomy in acute cholecystitis.

For elderly patients, many of whom have limited cardiopulmonary reserves, laparoscopic surgery could increase the morbidity and mortality of surgery. Laparoscopic surgery has been theoretically associated with compounding cardiac problems because the intra-abdominal pressure coupled with head up position results in pooling of blood in legs, reduced venous return, hypotension, and increased tendency to develop venous thrombosis. Pressure effects of carbon dioxide gas insufflated may have effect on venous return, the heart rate and rhythm, basal lung expansion, carbon dioxide retention, and acidosis. One of the possible disadvantages of laparoscopic cholecystectomy in acute cholecystitis is longer operating time when compared with mini-laparotomy cholecystectomy.

DISCUSSION

In the history of surgery, very few operations have changed the thinking and operating habits of surgeons as quickly and on such broad scale as laparoscopic cholecystectomy. This technique of small incision for cholecystectomy has shown good result in terms of reducing pain and morbidity and paved the way for the use of minimal access surgery.^[9,10] Laparoscopic cholecystectomy was first performed in Lyon, France, in March 1987 by Philippe Mouret, a general surgeon, who already had vast experience in gynecological surgery and consequently was knowledgeable in the use of laparoscope. The extent to which the surgical incision contributes to morbidity and mortality is well established. Sufficient time has elapsed since the first laparoscopic cholecystectomy was performed. Indeed, explosive growth of minimally invasive surgery of which laparoscopic cholecystectomy is prototype mandates the need for comparisons with respect to morbidity and mortality. Most surgeons have passed through the learning curve phase of their experience and have now settled into established patterns of activity.^[11,12]

There has been a lot of debate whether to operate asymptomatic GS or not. A century ago, in 1904, Mayo wrote “there is no innocent gallstone,” but today we know that there are plenty of evidences to support that not only there are asymptomatic GS but also most of these incidentally found stones remain asymptomatic throughout life and do not require treatment. GS disease is a benign condition because 70–90% of patients remain asymptomatic. Several studies have shown that the natural history of incidentally discovered gallstone is not only benign but also even when they do develop complications it is usually preceded by at least one episode of biliary pain.



Figure 1: Laparoscopic cholecystectomy

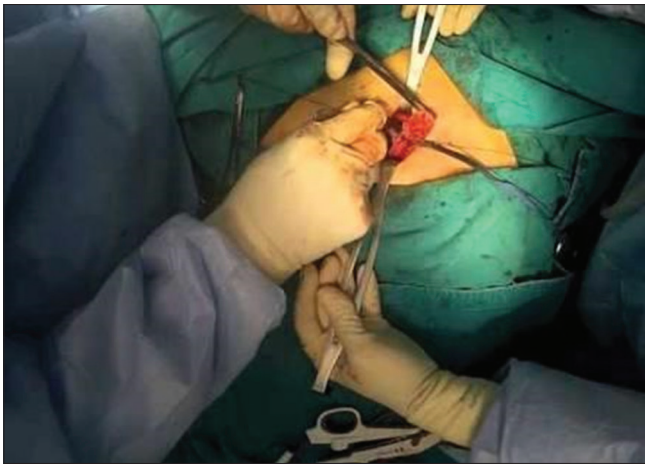


Figure 2: Mini-laparotomy

Studies on long-term follow-up of individuals with asymptomatic GS have shown that, over a 20-year period, only 20% will develop biliary pain and the mean probability of developing pain is only 2% during the 1st 5 years, 1% during the 2nd, 0.5% in the 3rd, and 0% during the 4th five years. In other words, the longer the stones remain asymptomatic, the less likely it is that complications will occur. In about 30%, patients who have had pain do not have further episodes of pain. Thus, for persons with asymptomatic GS, the natural history is so benign that not only treatment but also a regular follow-up is not recommended.^[13-16] Has laparoscopic cholecystectomy changed the view of the surgeons or physicians and the patients toward asymptomatic GS? Unfortunately, the answer is “Yes.”

After the introduction and widespread use of laparoscopic cholecystectomy, a significant change has been observed possibly due to the attitude of surgeons to relax the indication of surgery, including for asymptomatic gallstone, resulting in an increase (of up to 60%) in cholecystectomies worldwide. Laparoscopic cholecystectomy in young patients with

uncomplicated, asymptomatic GS is safe with greater patient acceptance, and this approach in early age eliminates the need for problematic surgery at a later date when the patient is older, with associated diseases or with complications.^[17,18]

The indications of surgery for asymptomatic GS are the presence of diabetes, porcelain gallbladder, and gallbladder with multiple stones and hemolytic anemia. It has been stated that diabetic patients are particularly prone to biliary complications from their stones. This led some authors to advocate prophylactic cholecystectomy in asymptomatic diabetic patient. Sometimes, consideration is given to perform an incidental cholecystectomy in addition to the planned operation in patients with asymptomatic GS. The purpose would be to prevent post-operative cholecystitis or the later development of symptoms. The chance of slipping into CBD is high, as complications such as obstructive jaundice, cholangitis, and pancreatitis are likely.^[19-23] Conversion rates in laparoscopic cholecystectomy range from 3% to 15% in well-trained hands. In our series, conversion rate is 6%; only 2 cases were converted to open because of common bile duct injury and intraoperative hemorrhage.

The frequency of bile duct injury is 0.1–0.2% for mini-laparotomy cholecystectomy and 0.3–0.6% for laparoscopic cholecystectomy. Two most common reasons for conversion are dense upper abdominal adhesions or necrotic gallbladder wall that precludes grasping and elevation with grasper. Common risk factors for conversion are male gender, obesity, cholecystitis (especially, after 48–72 h after onset of symptoms), and choledocholithiasis. Most conversions happen after a simple inspection or a minimum dissection, and the decision to convert should be considered as a sign of surgical maturity rather than a failure. Conversion should be opted for in the beginning and at the time of recognition of a difficult dissection rather than after the occurrence of complication. It is vital for the surgeons and patients to appreciate that the decision to go for conversion is not failure but rather implies safe approach and sound surgical judgment. It is therefore mandatory to explain the patients about the possibility of conversion to open technique at the time of taking consent for laparoscopic cholecystectomy.^[24,25]

CONCLUSION

Worldwide, many case series have been published regarding the comparison between laparoscopic cholecystectomy and mini-laparotomy cholecystectomy, and results are in favor of laparoscopic cholecystectomy. However, it is always better to do mini laparotomy in difficult cases, as it helps young doctors to learn

conventional technique and most importantly it reduces the complications associated with difficult laparoscopy cholecystectomy like CBD injury, Hemorrhage (primary & reactionary) where the incidence is high in untrained beginner laparoscopic surgeons.

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How to cite this article: Patil SM. Comparative Study of Safety and Efficacy of Laparoscopic Cholecystectomy in Patients of Cholelithiasis by Comparing with Mini Laparotomy. *IJSS Journal of Surgery* 2017;3(6):1-5.

Source of Support: Nil, **Conflict of Interest:** None declared.