

A Comparative Study of Laparoscopic vs. Open Cholecystectomy in a Suburban Teaching Hospital

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Received date: Oct 8, 2015, Accepted date: Dec 1, 2015, Published date: Dec 8, 2015

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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 require longer and steeper learning curve and incur higher cost, especially in the absence of health insurance to 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. The guidelines issued by Medical Council of India on laparoscopic training for postgraduate surgical residents has shown favorable results for patients, junior faculties and residents.

Aims: To study safety and efficacy of laparoscopic cholecystectomy in patients of cholelithiasis by comparing with results of open cholecystectomy by comparing use of Post-operative analgesia, Operative Time, Post-operative hospital stay, morbidity and mortality.

Material and Method: It is a prospective randomized study of 100 Patients of cholelithiasis aged between 25 years to 65 years operated during 2011-2012 at a suburban teaching hospital. They were divided into open and laparoscopic cholecystectomy group by draw a lot method. Patient's written valid informed consent for the particular procedure was taken and the pros and cons of both the procedure were explained in detail to the patient. This study was done after due clearance of Ethical committee.

Results: The median (range) operation time for laparoscopic cholecystectomy was 50-175 min (mean=103.98 min) and 35-95 min (mean=70 min) for open 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 no. of days=1.5) is considerably less than open cholecystectomy (Mean no. of days=3.36). 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.

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

Keywords: Cholelithiasis; Cholecystitis; Minimally invasive surgery; Laparoscopic cholecystectomy; Open cholecystectomy; Bile duct injury

Introduction

Gallstones (GS) are a common occurrence in northern India. However, this trend is now showing pan India presence probably because of migration and blending of cultures and lifestyle. As many as 16% and 29% of women above the age of 40-49 years and 50-59 years, respectively, had gall stones [1]. For every patient with symptomatic gallstone disease (GSD) there are many more with asymptomatic gallstones. Various studies performed on mortals suggest that most of the gallstones are asymptomatic. In a study of 9,332 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. "The gallbladder should be removed, not because it contains stones, but because it forms them" [2,3]. Many alternative methods for treatment of gallstones have been developed but these have not been satisfactory so far. 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 gallstones. 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 open cholecystectomy. Recent upsurge in practice of laparoscopic surgery and other form of minimal access surgery has ushered a new era of surgical treatment which is having profound effect on surgical management. Minimal access surgery has touched every field of surgical specialty [5]. The non-operative methods for the treatment of cholelithiasis in the form oral bile acid

(Chenodexychoic acid and Ursodexychoic acid) and Extracorporeal Shock Wave Lithotripsy (ESWL) have not shown promising results [6-8].

Aims and Objective

To study safety and efficacy of laparoscopic cholecystectomy in patients of cholelithiasis by comparing with results of open cholecystectomy by comparing use of Post-operative analgesia, Operative Time, Post-operative hospital stay, morbidity and mortality.

Materials and Methods

Our study is a prospective randomized study included 100 patients with gall stones which were admitted to a suburban teaching hospital of India. Randomization was done by draw of lots. The selection of procedure of open cholecystectomy or laparoscopic was decided depending up 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. The study was approved by IEC. Patients between 25 years to 65 years with acute cholecystitis, or chronic cholecystitis and gall stones without pain abdomen including those with diabetes, hemolytic anemia etc., were included in the study. Patient's written valid informed consent for the particular procedure was taken. Patients less than 25 years and more than 65 years or those with Gall bladder cancer and Choledocholithiasis were excluded. This study involved preoperative assessment, intraoperative practice and post-operative management and follow up till 3 months. All the patients were studied with reference to duration of surgery, post-operative analgesic, post-operative stay, intra operative and post-operative complications.

Patients were admitted a day prior to surgery in case of elective cholecystectomy from OPD after complete investigations performed required for general anesthesia. Some patients were admitted from 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 Haemogram, Blood sugar level, Urine examination, Liver function test, Blood urea and serum creatinine level, Chest x-ray, ECG and Ultrasonography of abdomen. The patient were studied with respect to their clinical presentation and were grouped as patients with asymptomatic Gall stones, 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 open or laparoscopic cholecystectomy depending upon draw of lots. First dose of antibiotics administered to the patient just prior to 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 was 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 (Inj cefotaxim). Injection amikacin and Injection Metronidazole were added in cases of bile leak. Analgesics in the form of Injection Tramadol was given. Top-up analgesia in the form of intramuscular Injection Diclofenac Sodium was given, whenever it was required. Discharge after start of oral diet and without any signs of postoperative wound infection after first

dressing change. If sign of wound infection were 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 cholecystectomy converted to open cholecystectomy were considered as difficult laparoscopic cholecystectomy for evaluation of data.

Results

Out 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, like 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 Open cholecystectomy. The median (range) operation time for laparoscopic cholecystectomy was 50-175 min (mean=103.98 min) and 35-95 min (mean=70 min) for open cholecystectomy ($p<0.001$). During the study period operation time for laparoscopic cholecystectomy showed a tendency to become shorter (Table 1). The following table depicts the operation duration of both the groups. The independent sample 't' test applied to duration of surgery in minutes v/s type of surgery shows highly significant association, sample size of each group (n) is 50. The independent sample t test results t statistics 6.1746 degree of freedom 98 critical value 2.6259 99% confidence interval [1.6669 66.2931] Therefore Open 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, suggest that the association between the due variable is not due to chance.

Nature of operation	Range of operation time (Min)	Mean operation time (Min)	Standard deviation
Laparoscopic cholecystectomy	50-175 min	103.98 min	34.8756
Open cholecystectomy	35-95 min	70 min	17.2615

Table 1: Operating time (in minutes).

It has been observed that duration of post-operative pain and analgesia required were significantly less in laparoscopic cholecystectomy group than open cholecystectomy group (Table 2) The independent samples 't' test applied to pain duration in days to type of surgery (mean difference lies between -0.2354 and 3.9554, P value <0.001). The sample size (n) is equal i.e 50, t statistics -5.212 degree of freedom 98 critical value 2.6259 99% confidence interval [-0.2354 3.9554]. The independent samples't' test applied to no of days (duration) analgesia required to type of surgery. The sample size (n) is equal i.e 50. t statistics -5.212 degree of freedom 98 critical value 2.6259 99% confidence interval [-0.2354 3.9554] Result - Reject the null hypothesis. We are 99% confident that the mean difference lies between -0.2354 and 3.9554, Suggesting that the association between the two variables is not due to chance.

Nature of operation	Range of pain duration in days	Pain duration in days (mean)	Standard deviation
Laparoscopic cholecystectomy	1-4 days	1.5 days	1.4743
Open cholecystectomy	2-8 days	3.36 days	2.048

Table 2: Pain duration for both open and laparoscopic cholecystectomy groups are as follows.

The mean post-operative hospital stay was 3.7 days after laparoscopic cholecystectomy and 5.46 days after open cholecystectomy. The independent samples 't' test applied to number of days (duration) of post-operative hospital stay required to type of surgery. {The sample size (n) is equal i.e. 50. Independent sample t test: t statistics -3.3142 degree of freedom 98 critical value 2.6259 99% confidence interval (-1.3581 4.8781)} Result shows rejection of null hypothesis. Therefore, Open cholecystectomy group had significantly less hospital stay than laparoscopic cholecystectomy group (t

(98)=-3.3142, p<0.001) and had the mean difference lies between -1.3581 and 4.8781.

Conversion of laparoscopic to open cholecystectomy occurred in three (3) of the fifty (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 intra operative hemorrhage.

Complications	Open cholecystectomy	Laparoscopic cholecystectomy
Wound infection	9	3 (Difficult laparoscopic cholecystectomy cases).
Intra operative 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

Table 3: Complications of open and laparoscopic surgery.

Various series.	Mean operative time open cholecystectomy (min)/Postop hospital stay(Days)	Mean operative time laparoscopic cholecystectomy (min)/Postop hospital stay (Days)
CH Chau et al.	84.8 minutes/10.1 days	92.2 minutes/7.1 days
Lujan et al.	77 minutes/8.1 days	88 minutes/3.3 days
Gupta et al.	41.89 minutes/4 days	66.28 minutes/3 days
Our study	70 minutes/5.46 days	103.98 minutes/3.7 days

Table 4: Operative time and Post-operative stay (comparison of various study).

Rest of the laparoscopic cholecystectomies were uneventful. In open cholecystectomy group largest number of complications were due to

wound infections (Number 09) which significantly higher as compared with laparoscopic cholecystectomy (No 03). Postoperative ileus was present in 5 patients of open cholecystectomy group necessitated the need for continuation of nasogastric decompression. Four patient from open group developed chest infection post operatively (Table 3). The Post-operative pain and use of analgesics in case of laparoscopic cholecystectomy (Mean=1.5 days) is considerably less than open cholecystectomy (Mean=3.36 days) (Table 4).

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 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 lot of debate whether to operate asymptomatic gallstones or not. A century ago, in 1904, Mayo wrote 'there is no innocent gallstone', but today we know there are plenty of evidences to support that not only there are asymptomatic gallstones but most of these incidentally found stones remain asymptomatic throughout life, and do not require treatment. Gallstone 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 even when they do develop complications; it is usually preceded by at least one episode of biliary pain. Studies on long-term follow-up of individuals with asymptomatic gallstones 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 five 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 gallstones, 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 towards asymptomatic gallstones? 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 gallstones 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 gallstones are presence of diabetes, porcelain gall bladder 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 gallstones. The purpose would be to prevent postoperative cholecystitis or the later development of symptoms. Patients having multiple gallstones. The chance of slipping into CBD is high, as complications like obstructive jaundice, cholangitis and pancreatitis are likely [19-23].

Conversion rates in laparoscopic cholecystectomy ranges from 3% to 15% in well trained hands (Table 5). 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% to 0.2% for open cholecystectomy and 0.3% to 0.6% for laparoscopic cholecystectomy. Two most common reasons for conversion are dense upper abdominal adhesions or necrotic gall bladder wall that precludes grasping and elevation with grasper. Common risk factors for conversion are male gender, obesity,

cholecystitis (especially after 48 to 72 hours 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 possibility of conversion to open technique at the time of taking consent for laparoscopic cholecystectomy [24,25].

Various Study	Year	Conversion rate (%)
Vecchio et al.	1998	2.2
Butt et al.	2006	4
Guraya et al.	2004	2.9
Tarcoveanu et al.	2005	3.2
Southern surgeons club	1991	4.7
Lim et al.	2005	11.5
McGee et al.	1996	10
Our study	2012	6

Table 5: Comparison of conversion rates between various studies study.

In our study duration of operative time for laparoscopic cholecystectomy is considerably longer than duration of open 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 open 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 [26,27].

Wound infection in open 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 JS et al. in Toronto group study also observed that 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 three times common in open 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 open cholecystectomy. Post-operative hospital stay for open Cholecystectomy is more than 3 days in most

studies whereas it is 3 or less in cases of laparoscopic cholecystectomy patients [28-30].

Conclusion

Worldwide many case series have been published regarding comparison between laparoscopic cholecystectomy and open cholecystectomy and results are in favor of laparoscopic cholecystectomy. However, open cholecystectomy is preferred method for Surgeons in the beginning of their career and in cases of difficult cholecystectomy. Rate of complications doesn't show significant difference between both groups. Patients belonging to suburban population usually present late and expected to be relatively difficult to operate. Moreover, the added responsibility of training postgraduate students without compromising the safety of patients makes it even more challenging.

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