Section: General Surgery

Original Research Article

# TO COMPARE EFFICACY OF LAPAROSCOPIC CHOLECYSTOSTOMY AND INTERVAL CHOLECYSTECTOMY VERSUS OPEN CHOLECYSTECTOMY IN CASES OF DIFFICULT GALLBLADDER

***Krishna Chowdary Amirineni[1], Niharika Adusumilli[2], Rao Haneesha[3], Kola Praveen kumar[4], S B J L Harshini[5], R Indu[6]***

*[1,2]Assistant Professor, Department of General Surgery, Kamineni Academy of Medical Sciences& Research Centre, LB Nagar, Hyderabad, Telangana, India.*
*[3,4]Postgraduate, Department of General Surgery, Kamineni Academy of Medical Sciences & Research Centre, LB Nagar, Hyderabad, Telangana, India.*
*[5,6]Postgraduate, Department of General Surgery, Kamineni Academy of Medical Sciences & Research Centre, LB Nagar, Hyderabad, Telangana, India.*

***Received*** *: 16/01/2024*
***Received in revised form*** *: 22/03/2024*
***Accepted*** *: 07/04/2024*

**Corresponding Author:**
**Dr. Niharika Adusumilli**
Assistant Professor, Department of General Surgery, Kamineni Academy of Medical Sciences& Research Centre, LB Nagar, Hyderabad, Telangana, India.
Email: niharikaadusumilli@gmail.com

**DOI:** 10.5530/ijmedph.2024.2.14

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

**Int J Med Pub Health**
2024; 14 (2); 70-75

**ABSTRACT**

**Background:** To evaluate and compare efficacy of laparoscopic cholecystostomy and interval cholecystectomy versus open cholecystectomy in cases of difficult gallbladder.

**Materials and Methods:** This study will be conducted in Department of General surgery, Kamineni Hospital, Hyderabad between October 2012 to December 2014. The facilities, expertise and the necessary Infrastructure are available in this hospital. A comparative observational study, which included 40 patients of difficult gallbladder who needs cholecystectomy. Ethics committee's permission has been taken.

**Results:** In the present study, there were difficulties associated with Laparoscopic cholecystostomy like subjecting the patient to a second surgery, carrying a drain, longer hospital stay and increased expenditure. Laparoscopic cholecystostomy followed by Interval chole- cystectomy was safe with less postoperative morbidity associated with faster patient recovery and satisfaction as documented by less postoperative pain, earlier resumption of oral feeds, earlier full mobilization and discharge home, as well as lesser complication rate with least possible scar.

**Conclusion:** In conclusion, the study supports the view that laparoscopic cholecystostomy followed by interval cholecystectomy is safer and efficacious and offers definitive advantages over open conversion and should be an available option for all patients requiring emergency cholecystectomy.

**Keywords:** Cholecystectomy, Laproscopic, Gall Bladder, VAS, Postoperative.

## INTRODUCTION

Medicine is an ever-changing art and needs to be shared with the progeny. Since the advent of laparoscopy, a new beginning started in the art of surgical craft. Many innovations and technical modifications are on the way for the satisfaction of the patient and the surgeon dealing with minimal access procedures. Laparoscopic cholecystectomy has revolutionized the whole globe and does not need any special mention. At the beginning surgeons would feel comfortable dealing with simple gallbladders but with the increase in expertise and introduction of newer armamentarium, difficult gallbladders are being subsequently dealt with.[1-4]

We strongly believe, from the experience we carry in dealing with these inflamed gallbladders, that every gallbladder is a book in itself, which needs to be read time and again for a better, and a safe outcome. Looking at the literature, the difficult thing to

understand is to define the word 'difficult gallbladder.' However, we believe difficulty is a relative term and there are certain general principles that need to be followed before embarking on laparoscopic cholecystectomy.[5-7]

The aim of the operating surgeon should not only be giving the benefits of minimal access surgery but also avoiding the operative complications and lessen the postoperative morbidity.[1]

In our experience of 15 years we have seen a good number of cases of difficult gallbladder where laparoscopic cholecystectomy could not be performed and they were converted to open cholecystectomy. We also have the experience of laparoscopic cholecystostomy being performed followed by interval cholecystectomy after 12 weeks but we did not compare the outcome and effectiveness. So, we have opted to do a scientific study to compare the effectiveness of both the procedures.

'Safety saves' is a golden principle in handling any surgical or operative procedure. Till date literature review did not reveal study done to see the effectiveness of laparoscopic cholecystostomy and delayed cholecystectomy versus open cholecystectomy in cases of difficult gallbladder

So, present study is aimed at comparing effectiveness of laparoscopic cholecystostomy and delayed cholecystectomy versus open cholecystectomy in cases of difficult gallbladder.

**Aims and Objectives**

To evaluate and compare efficacy of laparoscopic cholecystostomy and interval cholecystectomy versus open cholecystectomy in cases of difficult gallbladder.

## MATERIAL AND METHODS

This study will be conducted in Department of General surgery, Kamineni Hospital,

Hyderabad between October 2012 to December 2014. The facilities, expertise and the necessary Infrastructure are available in this hospital

A comparative observational study, that included 40 patients of difficult gallbladder who needs cholecystectomy.

Ethics committee's permission has been taken.

For all patients presenting with cholecystitis requiring laparoscopic cholecystectomy, an informed consent is obtained from the patient and their relatives after explaining the possibility of encountering a difficult Gall Bladder and possibilities of converting the procedure to either laparoscopic cholecystostomy or open cholecystectomy depending on the clinical judgement of the surgeon. Initially patients are subjected to an diagnostic laparoscopy and the findings were noted down. When the following criteria are encountered it is defined as a Difficult Gallbladder

1. Gall Bladder showing Acute Inflammation i.e
   a. Thickened, edematous GB wall
   b. Vascular adhesions
   c. Thickened, Hyperemic and edematous peritoneum over calots triangle
2. Empyema Gall Bladder identified by pus on aspiration of an acutely inflamed gallbladder
3. Inflamed Gallbladder with Pericholecystic Collections
4. Acute Gangrenous Cholecystitis
5. At that time the operating Surgeon decides whether to perform laparoscopic cholecystostomy or open cholecystectomy and the results of the two groups were compared.

Group A–Open Cholecystectomy

Group B –Cholecystostomy Followed by Interval Cholecystectomy.

The study was to compare effectiveness of laparoscopic cholecystostomy and delayed cholecystectomy versus open cholecystectomy in cases of difficult gallbladder.

The follow up of the patient is for a period of 3 months after cholecystectomy

**Inclusion criteria of patients for study**

Patients of all age groups and both sexes are included in the study with

1. GallBladder showing Acute Inflammation i.e
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   c. Thickened, Hyperemic and edematous peritoneum over calots triangle
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4. Acute Gangrenous Cholecystitis

**Exclusion Criteria**

1. Patients with severe or uncontrolled systemic disease, metabolic disorders, neurological, congenital or cardiovascular diseases are excluded from this study.
2. Mass lesion of gall bladder (suspected malignancy)
3. Patients not fit for general anesthesia

**Population**

The study population includes 2groups of 20 patients each undergoing surgery for difficult gallbladder surgery at Kamineni Hospital, Lb nagar, Hyderabad.

**Duration**

FromOctober2012 to October2014

**PARAMETERS OBSERVED**

1) Duration of hospital stay
2) Vital parameters like-pulse rate, blood pressure, respiratory rate, SPO2
3) Complications

- Injury to common bile duct
- Postoperative incisional hernia
- Peritonitis
- Bleed from gall bladder bed

Hospitals, LB nagar Hyderabad. No Hypothesis is being tested in the study. Therefore no sample size has been calculated.

Based on the admissions in the past 4 years it is noted that 92 cases who fulfill the inclusion criteria get admitted. Based on this it is anticipated that during the study period approximately 40 patients will be enrolled in the study (at proposal stage) At the final submission stage this can be modified suitably to make it in past tense.

**Study Design**

A Prospective Observational Study

Number of cases to be recruited: 40 cases of difficult gallbladder seen at Kamineni hospital.

**Sample Size**

This is a non-randomized, comparative study. The primary purpose of this study is to Understand the effects of Laparoscopic cholecystostomy with Interval cholecystectomy as compared to Open cholecystectomy when a difficult Gall bladder has been encountered in patients presenting with Cholecystitis to Kamineni.

## RESULTS

**Case Distribution**

All the patients are divided in to 2 groups of 20 each, one group undergoing Laparoscopic cholecystostomy with delayed laparoscopic cholecystectomy and the other group undergoing Open conversion when a difficult Gall bladder was encountered. [Table 1]

**Gender Distribution**

16 were male and 24 were female.

Both Cholecystostomy group and open cholecystectomy group had 40% (8/20) females and 60% (12/20) males.

COMORBIDITIES:

More number of patients with diabetes mellitus, Hypertension are present in cholecystostomy group. Open cholecystectomy group contained more number of hypertensive patients than suction dressing group. [Table 2]

DURATION OF SURGERY

Duration of surgery for both the groups was measured in minutes and was calculated from the time of starting incision to skin closure.

As the cholecystostomy group contained 2 surgeries laparoscopic cholecystostomy and interval laparoscopic cholecystectomy for caluculation the duration of both the surgeries were added up and compared with duration of the Open cholecystectomy group.

Duration of surgery in cholecystostomy group is 136+/- 24 minutes and that in open group is 123+/- 33 minutes (P value 0.2). Student's t test was done to the above variables, which showed no significant difference in the duration of surgery between the two groups. [Table 3]

HOSPITAL STAY:

Hospital stay for both the groups was measured in days and was calculated from the time of admission to discharge.

As the cholecystostomy group contained 2 surgeries laparoscopic cholecystostomy and interval laparoscopic cholecystectomy for caluculation the hospital stay for both the surgeries were added up and compared with hospital stay of the Open cholecystectomy group.

Hospital stay in cholecystostomy group is10.3+/- 2.1days and that in open group is 7.3+/-1.3 days (P value 0.04)

Student's t test was done to the above variables, which showed hospital stay was significantly more in cholecystostomy group compared to open group. [Table 4]

RETURN TO WORK

Return to work after surgery in both the groups was measured in weeks and was calculated from the date of surgery to the time getting back to his routine activity

As the cholecystostomy group contained 2 surgeries laparoscopic cholecystostomy and interval laparoscopic cholecystectomy for caluculation the return to work of both the surgeries were added up and compared with return to work of the Open cholecystectomy group.

Return to work in cholecystostomy group is3.2+/- 0.9 weeks and that in open group is 2.9 +/-1.9 weeks (P value0.5)

Student's t test was done to the above variables, which showed no significant difference in the return to work between the two groups. [Table 5]

POSTOPERATIVE PAINS CORE:

Post-operative pain score after surgery in both the groups was measured using visual analogue scale fixed time intervals at 0,6,12,24,48 and 72 hours for all the 3 surgeries.

The two surgeries of Laparoscopic cholecystostomy group had almost similar pain scores after surgery and graphs overlapped and as small pain suffered twice cannot be added up so we had tabulated the highest pain suffered in two surgeries of same group at each time and compared with the open group. Serial measures of Pain scoring between 2 groups measured with fixed time intervals were analysed using repeated measures Analysis of variance (ANOVA). P value was caluculated as $p<0001$ (Significant). Pain was significantly lower in laparoscopic group compared to open cholecystectomy group. [Table 6]

**Complications**

Respiratory and wound complications were higher in Open cholecystectomy group compared to laparoscopic group.

5 of 20 patients developed respiratory complications in open cholecystectomy group compared to none in laparoscopic group.

5of 20 patients developed wound complications (seroma/Abscess) in open cholecystectomy group compared to none in laparoscopic group 1 patient in laparoscopic group developed bile leak

which was managed conservatively and none had it in open group.

Postoperative bleeding and Incisional hernia was not observed in both the groups in 3 month follow up period.

**Cost of the procedure** Cost of the procedure was significantly higher with laparoscopy group as it contained two surgeries and laparoscopic instruments compared to open group which was conventional and involved single surgery. Indirect cost with respect to loss of wages was comparable in the both the groups as the return to work was similar in both the groups. [Table 7]

**Table 1: Case Distribution**

| Cholecystostomy Group | Open Conversion Group |
|---|---|
| 20(50%) | 20(50%) |

**Table 2: Gender Distribution**

| Sex | Cholecystostomy group (50%) | Open conversion group (50%) |
|---|---|---|
| Male | 8(40%) | 8(40%) |
| Female | 12(60%) | 12(60%) |
| | | |

**Table 3: Comorbidities**

| | Diabetes mellitus | Hypertension | RVD | Smoking | Alcoholism |
|---|---|---|---|---|---|
| Cholecystostomy group | 4 | 3 | 1 | 4 | 4 |
| Open group | 5 | 5 | 0 | 3 | 1 |

**Table 4: Duration of Surgery**

| | Open | Lap | P Value |
|---|---|---|---|
| Duration of Surgery | 123+/-24 | 136+/-33 | 0.2 |

**Table 5: Hospital Stay**

| | Open | Lap | PValue |
|---|---|---|---|
| Duration of Surgery | 7.3+/-1.3days | 10.3+/-2.1 | 0.04 |

**Table 6: Return to work**

| | Open | Lap | P value |
|---|---|---|---|
| Duration of Surgery | 2.9+/-1.9wks | 3.2+/-0.9 | 0.5 |

**Table 7: Complications**

| Complications | Open Group | Cholecystostomy group |
|---|---|---|
| Respiratory | 5 | 0 |
| wound | 5 | 0 |
| BileLeak | 0 | 1 |
| Bleeding | 0 | 0 |
| IncisionalHernia | 0 | 0 |

## DISCUSSION

Cholelithiasis is a common disease entity. Frequent occurrence and serious complications of cholelithiasis have made this one of the most important surgically correctable diseases.

Laparoscopic cholecystectomy has significantly changed the treatment of gallstone disease. Although this technique has been adopted by many practicing surgeons, concern about its use in Acute calculus Cholecystitis and the incidence of major complications still exists in the setting of encountering a difficult Gall bladder. The morbidity and mortality associated with laparoscopic cholecystectomy is lesser compared to open cholecystectomy. Several large published series have reported their experience with laparoscopic cholecystectomy.

There is increasing evidence proving the role of Laparoscopic cholecystectomy in Acute Calculus Cholecystitis. But every surgeon experiences a stage where he starts thinking this may not be the right time to enter and proceed to open conversion to complete. Open conversion is associated with increased risk of complications.

It has been the need of the hour to identify and rationalize the alternative methods to open conversion when a difficult gall bladder is encountered when cholecystectomy is attempted for Acute Cholecystitis.

Increasing evidence is available in support of Laparoscopic cholecystostomy as an alternative to open conversion when the gall bladder is not amenable for safe removal.

There were few case reports mentioning cholecystostomy as an alternative to open conversion and a safe interval cholecystectomy later

on but there was no study as such to compare the effectiveness of both the procedures.

In the comparative study by Jatzkoet al, open operation was associated with a 7.7% morbidity rate, compared with 1.9% for LC, and a 5% mortality rate vs 1% for LC.[7]

This was a observational comparative clinical study consisting of 40 patients of difficult gall bladder who needs cholecystectomy presented to Kamineni Hospital, Hyderabad between October 2012 and October 2014.

For all patients presented with cholecystitis requiring laparoscopic cholecystectomy, an informed consent is obtained from the patient and their relatives after explaining the possibility of encountering a difficult Gall Bladder and possibilities of converting the procedure to either laparoscopic cholecystectomy or open cholecystectomy depending on the clinical judgement of the surgeon. Initially patients are subjected to an diagnostic laparoscopy and the findings were noted down. When the following criteria are encountered it is defined as a Difficult Gallbladder.

**Age and sex**

The main sufferers of gallbladder disease in our study were females as compared to males. Out of total 40 cases,16 cases were males, which are very much similar to those observed by Fraze and others8and U. Berggren and others.[9] Most of the males affected were in the 5th and 6th decades of life whereas females were in the 4th and 5th decades of life. The reason for the high incidence among females could be that pregnancy and child birth have a definitive influence on biliary tract disease, acting by causal stasis as well as weight gain and consequent hypercholesterolemia. Another reason could be the effect of female hormones i.e estrogen and progesterone, especially progesterone acting on the gallbladder and reducing motility, causing stasis and thereby promoting gallstone formation.

Duration of surgery, return to work, operative time, Complications in our present study could not be compared with any previous studies as there was no similar study available and further more present study was done on difficult Gallbladder and cholecystectomy and hence complications, operative time will be comparatively higher than that of normal cholectectomy either laparoscopic or open.

**Duration of surgery**

Duration of surgery in cholecystostomy group is 136+/- 24 minutes and that in open group is 123+/-33 minutes. The duration of surgery was lesser in the lap group but as this was an additive time of two surgeries together it was almost comparable to open group as it was longer.

**The duration of surgery is lesser in the LAP group when compared to the OPEN group for the following reasons**

1. **Ease of access –** laparoscopic cholecystectomy requires the creation of few small port sites in the abdomen for insertion of the instruments hence, the time taken to open the abdomen by dissecting the muscles and fascia is minimized when compared to the open procedure and conversely closure of the port sites is faster when compared to closing a large abdominal incision.
2. **Better visualization** of the anatomy using during laparoscopy aided by the better light sources and lens systems which magnify the view thereby facilitating easy dissection and avoidance of complications.
3. **Laparoscopic cholecystectomy** is performed under general anaesthesia, hence the anaesthetic time is also minimized, thereby minimizing total procedure time.

**Complications**

The overall rates of complications were more in the open group. The most common complications found were wound and chest infection (seen almost exclusively in open group). These findings can be explained on the basis of a large sub costal incision used in the open group. The presence of such a large incision and the associated pain inhibits respiratory movements, thereby leading to at elect as is and pulmonary infection

The large wound hematoma associated with a large incision can act as a nidus for infection thereby leading to wound infection and its associated complications like delayed wound healing, wound dehiscence, incisional hernia etc

Bile Leak was observed in only one patient of cholecystostomy group and was resolved with **ERCP +Sphincterotomy**

Other complications like bile duct injury, major bleeding, visceral injury were not encountered probably due to improved visualization afforded by the laparoscope thereby facilitating better delineation of normal anatomy and also early detection of aberrant anatomy.

**Postoperative pain**

Patients undergoing laparoscopic cholecystectomy had less pain (mild to moderate) when compared to those undergoing open cholecystectomy (moderate to severe). In a similar study conducted by Hieronymus PJD et al,[15] similar findings were seen.

This can be attributed to the fact that laparoscopic cholecystectomy uses smaller skin incisions and less dissection of muscles and fascia that is associated with a lesser degree of local inflammatory response and consequently less pain and less requirement of analgesics.

**Period of hospital stay**

The period of hospital stay was taken from day of admission to the day of discharge. The total period of Hospital stay in cholecystostomy group is 10.3+/-2.1days and that in open group is 7.3+/-1.3 days. Early discharge from the hospital has a positive influence on the patient as it decreases the convalescence period and also promotes early return to work and also prevents nosocomial infections. Early discharge also decreases hospital costs.

Studies by Jeffrey S Barkun,[16] Ahmed Assalea,[17] A W Majeed et al,[18] and Tuula Kivilvoto et al,[19] also showed a much shorter stay in both groups a postoperative hospital stay of 1.8 days & 3-5 days in the open group.

**Return to work**

Return to work after surgery in both the groups was measured in weeks and was calculated from the date of surgery to the time getting back to his routine activity

As the cholecystostomy group contained 2 surgeries laparoscopic cholecystostomy and interval laparoscopic cholecystectomy for caluculation the return to work of both the surgeries were added up and compared with return to work of the Open cholecystectomy group.

Return to work in cholecystostomy group is 3.2+/-0.9 weeks and that in open group is 2.9 +/-1.9 weeks (P value0.5).

**Table 8: Comparison of operative time**

| | GroupLap | GroupOpen |
|---|---|---|
| AJ Karayiannakis et al[10] | 105 minutes | 98 minutes |
| Ravi mohan SM et al[11] | 46.8 minutes | 44.7 minutes |
| Bart M Redemake[12] | 78 minutes | 90.5 minutes |
| Sooper et al[13] | 95 minutes | 122 minutes |
| Axe ROS et al[14] | 93 minutes | 118 minutes |

## CONCLUSION

The results support the view that laparoscopic cholecystostomy followed by interval cholecystectomy is a safe and justified alternative for open conversion when a difficult gallbladder is encountered.

In conclusion, the study supports the view that laparoscopic cholecystostomy followed by interval cholecystectomy is safer and efficacious and offers definitive advantages over open conversion and should be an available option for all patients requiring emergency cholecystectomy.

**Limitations of the Study**

1. Cost effectiveness of the two types of procedures could not be compared effectively as the cholecystostomy group involves two hospital admissions and long follow up.
2. Morbidity could not compared between the two groups.
3. Randomization could not be done due to ethical problems and lack of evidence pertaining to cholecystostomy.

**Conflict of Interest:** None

**Funding Support:** Nil

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