Addis Ababa University, College of Health Sciences, Tikur Anbessa Specialized Hospital

Mini-cholecystectomy

A 5-year retrospective cross-sectional study

By: Solomon Bekele, MD, 4th year General Surgery Resident

Advisor: Girmaye Tamirat: MD, Consultant General and EndocrineSurgeon

Ass. Professor of Surgery, CHS, AAUand

Prof. Tessema Ersumo: Professor of Surgery.

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1. Abstract

Background: Gallstone disease is one of the most common surgical pathology. cholecystectomy is main mode of management for gallstones. Laparoscopic cholecystectomy, open cholecystectomy, and mini cholecystectomy are options for surgical removal of the gallbladder.Several studies showed that minicholecystectomy offers minimal trauma to the patient with similar complication rate.

Objectives: This study is aimed to determine and analyze the outcomes of Mini-Cholecystectomy performed at Betezatha General Hospital from January 1, 2014 to December 31, 2019.

Patients and Methods: A 5-Year retrospective cross-sectional study ofall patients who underwent mini-cholecystectomies from January 1, 2014 through December 31, 2019 at Betezatha General Hospital.

Results: A total of 206 patients underwent mini-cholecystectomy. With a male to female ratio of 1:6. Most patients (57%) presented with RUQ pain. Almost 70% of patients were found to have at least one comorbidity along with gallstone disease. The average operation time was 35minutes. Patients with chronic contracted cholecystitis were found to have difficult mini-cholecystectomy. Conversion rate to standard cholecystectomy was 2.9%. Bile duct injury occurred in 1 patient (0.45%). Almost all patients (98%) had hospital stay of less than 72hrs.

Conclusions: Mini-cholecystectomy is a safe method of cholecystectomy which can be practiced in a resource limited setting without undue complications.

2. Introduction

2.1. Background

Gallstone disease is one of the most common surgical diseases encountered in most parts of the world and Ethiopia(2,3). Patients with symptomatic gallstones are eligible for cholecystectomy. Gallstones are becoming increasingly common; they are seen in all age groups, but the incidence increases with age; (4) and about a quarter of women over 60 years will develop them (5). In most cases they do not cause symptoms, and only 10% and 20% will eventually become symptomatic within 5 years and 20 years of diagnosis (4,5).Thus the average risk of developing symptomatic disease is low, and approaches 2.0-2.6%/year (6).

Three different operative techniques are practiced for the removal of gallbladder: the classical open cholecystectomy, laparoscopic cholecystectomy and minicholecystectomy. Laparoscopic cholecystectomy is the current gold standard surgical technique (7). Classical open cholecystectomy is most commonly performed procedure in our setup. Mini-cholecystectomy is an alternative minimally invasive surgical option, practiced by few surgeons with probably comparable outcomes with laparoscopic cholecystectomy. Mini-cholecystectomy or small incision cholecystectomy is when the length of incision is less than 5cm. incision length above this is considered conversion to or classical open cholecystectomy.

Single blind randomized controlled trials have indicated that convalescence differences between minicholecystectomy and laparoscopic cholecystectomy are small(8). From another report, no significant differences were observed between minicholecystectomy and laproscopic cholecystectomy in terms of patient's opinion of general well-being, abdominal pain and scarring, one year after surgery(9). Health care costs are lower after minicholecystectomy than after laparoscopic cholecystectomy(8,9).

Even though laparoscopic cholecystectomy is the gold standard for surgical treatment of cholelithiasis, classical open cholecystectomy is widely practiced in Ethiopia for reasons including lack of skilled manpower and appropriate setup.

Differences in primary outcomes like mortality and complication, particularly bile duct injuries are important reasons to choose one of the operative techniques. When these primary outcomes show no significant difference, then secondary outcomes like non-severe complications, pulmonary outcomes, differences in health status related quality-of-life, hospital stay, and differences in cost-effectiveness analysis should help decide which technique is superior.

2.2. Statement of the problem

2.2 Significance of the study

- There are no studies so far in Ethiopia determining outcomes of mini-cholecystectomy.
- The aim of this study is to determine the outcomes of mini-cholecystectomy performed at Betezatha general Hospital in the years 2014 to 2019.

3 Objectives

3.1 General objectives

- To Determine analyze outcomes of mini-cholecystectomy.

3.2 Specific Objectives

- To determine and Analyze the rate of complication of mini-cholecystectomy with open and laparoscopic cholecystectomy with literature review
- To determine the operation time, post-operative complications, postoperative hospital stays, and rate of conversion of mini-cholecystectomy.

4 Patients and Methods

4.1 Study area:

The study was conducted in United Vision and Betezatha Hospitals, both of which are located in Addis Ababa, capital city of Ethiopia. Both are among known private hospital setups in the city where many types of surgical procedures are addressed. Patients in this study had their preoperative evaluation at United Vision and referred to Bethzatha for surgery. Post-operative follow up is done at United Vision.

4.2 Study design:

Comparative retrospective cross-sectional study was conducted to determine the outcomes of mini-cholecystectomy in Betezatha Hospital from January 2014 – December 2019.

4.3 Study population:

All patients who underwent mini-cholecystectomy in Betezatha General Hospital in the years Jan. 2014 – Dec. 2019 for symptomatic cholelithiasis.

5 Operation:

A personal standardized technique for mini-cholecystectomy was established after more than 10-year experience of performing the operation in patients with acute and/or cholecystitis. The incision was started approximately 3 cm to the right of the midline and ran obliquely parallel to and 3 cm below the right costal margin. The initial length of the incision was 3-5cm, depending on the size of the patient and the degree of gallbladder distension; it was extended if necessary. Extensions beyond 5cm are not considered as mini-cholecystectomy. The rectus muscle was split or divided. In a patient with a markedly distended gallbladder, decompression of the gallbladder was the first step after entering the abdominal cavity. Most patients underwent retrograde cholecystectomy. The stumps of the cystic duct and cystic artery were ligated with delayed absorbable suture material. The term ‘operative time’ was defined as the period starting at ‘knife to skin’ and finishing at ‘last stitch’. Mini-cholecystectomy was defined difficult when the surgeon finds a chronic contracted or empyema gallbladder and when faced with

significant, dense adhesions. Anesthesia time was timed from time of induction to extubation.

6 Inclusion/Exclusion criteria:

6.1.1 Inclusion criteria:

- All patients who underwent mini-cholecystectomy in the study period were be included.

6.1.2 Exclusion criteria:

- All patients who underwent conventional cholecystectomy.
- Patients who had undergone cholecystectomy for indications other than cholelithiasis were excluded from the study.
- Patients for whom cholecystectomy was done for acute cholecystitis.

7 Sample size determination

As this study used non-convenience take all sampling method, the number of patients included in this study were all patients who underwent mini-cholecystectomy in the study period in Betezatha General hospital.

8 Sampling technique/procedure

All patients who underwent minicholecystectomy in Betezatha hospital from Jan. 2014 – Dec. 2019 for gallstone disease are included in the study.

9 Data collection and analysis

The chart of patients who have undergone mini-cholecystectomy in Betezatha General hospital from January 2014 – December 2019 was obtained from the registry book of the operating roomand personal medical charts of patients. Data needed for this research was collected by reviewing the charts of patients who have underwent cholecystectomy during the study period using a questioner developed for this study. The questioner consisted of demographic data of patients, presenting symptoms, Preoperative labs and ultrasound features, procedure details, complications and follow-up status.

9.1 Data processing and management

Collected data was entered into a computer and analyzed using SPSS 20 (statistical Packages for social sciences). Statistical comparison was made using t test. Considering 95% CI, P-value of <0.05 was considered significant in all statistical comparisons.

10 Dissemination of Findings

After completion, the research is to be submitted to the department of surgery, results and recommendations to be considered. Final paper will be submitted to convenient publishing journal at the end.

11 Variables

11.1 Independent variables

- Age
- Sex
- Religion
- Comorbidities
- Family history of gallstone disease
- Main Presenting symptom and associated symptoms
- Duration of illness

11.2 Dependent variables

- Operative diagnosis
- Operation time
- Conversion to classical cholecystectomy
- Post-operative hospital stay
- Scar length
- Post-operative complications (biliary leak, Obstructive jaundice, SSI)
- Re-laparotomy
- Death

12 Operational definitions

- Cholecystectomy: removal of gallbladder regardless of surgical technique used.
  - Mini-cholecystectomy: surgical removal of the gallbladder using <5cm right subcostal incision.
  - Classical open cholecystectomy: surgical removal of gallbladder using incisions > 5cm.
- The procedures were labeled difficult if the surgeon operated on either a contracted gallbladder with or without empyema and faced significant adhesions.
- Complications of cholecystectomy: any complication of cholecystectomy including intra-operative and post-operative period as defined by the modified Clavien-Dindo classification of post op complications.

13 Ethical Consideration

- Data collection was started after the study was approved by the Institutional Ethics Review Committee of the College of Health Sciences of Addis Ababa University and secured a permission letter from Betezatha General Hospital. Confidentiality of the records was maintained throughout the study period. Reports did not include names and identifiers of patient.

14 Results

- A total of 206 patients were operated during the study period satisfying all inclusion criteria of the study.The mean age was **44** years, with SD of 13. The minimum age was 23 years and maximum was 85 Years. Females accounted for **85.4%** of the cases and male accounted for **14.6%**. The male to female ratio was 1:6. First degree family history of gallstone disease was found in **24.8%** of patients.

14.1 Main presenting and associated symptoms

- Most common presenting symptom of the patients was right upper quadrant pain. This was followed by a combination of epigastric and RUQ pain. Asymptomatic patients constitute for about 1.5% of the presentation.

Table 1: Main presentation symptoms

Symptoms	Frequency	Percent
RUQ pain	118	57.3
Epigastric pain	26	12.6
RUQ and epigastric pain	18	8.7
Asymptomatic	3	1.5
Other Symptoms	41	19.9
Total	206	100.0

- The average time of patient presentation with main presenting symptoms is **18 months**. The time ranges from 1 week to 120months (5 years).

Table 2: Associated symptoms

Symptoms (N=206)	Frequency	Percentage %
Fat intolerance	111	53.9
Dyspepsia	78	37.9
Vomiting	69	33.5
Constipation	67	32.5
Fever	6	2.9
Jaundice	5	2.4

14.2 Comorbidities

Table3: Comorbidities found in patients operated for gallstone disease.

Comorbidity (N=206)	Frequency	Percentage %
Hypertension	33	16
Diabetes Mellitus	21	10.2
Asthma	11	5.3
Lipedema	5	2.4

o

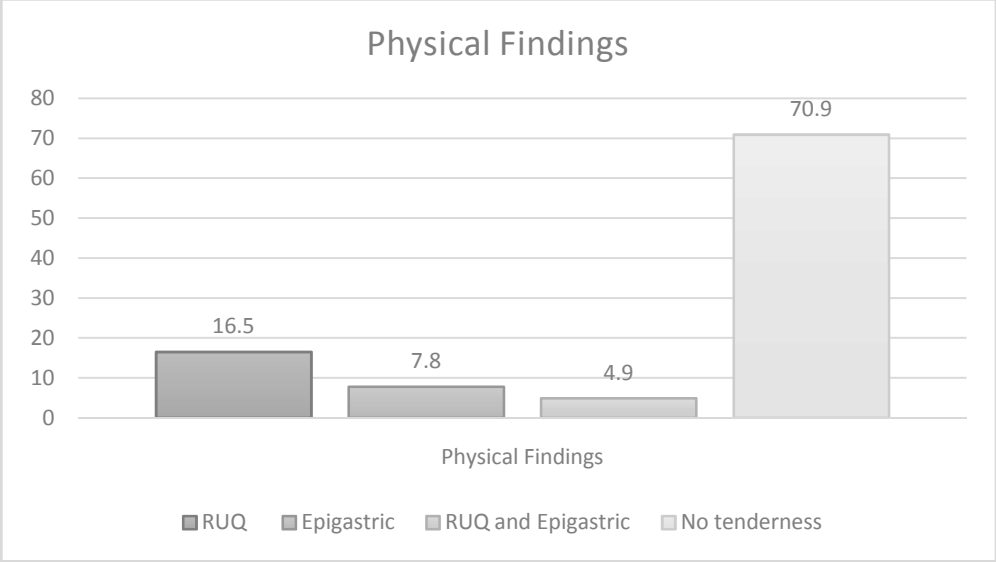
- Almost 70% of patients were found to have at least one comorbidity along with gallstone disease.

Table 4: Associations between comorbidities and operative diagnosis.

Comorbidity	Operative Diagnosis				
		Calculous shrunken or contracted cholecystitis	Calculous gallbladder empyema	Hydropic acute cholecystitis	P-Value
Hypertension	11	12	9	1	**0.017**
Diabetes Mellitus	7	10	4	0	**0.004**
Asthma	7	1	3	0	0.643
Lipedema	4	1	0	0	0.789

- Presenting signs were assessed and 16.5% patients presented with right upper quadrant tenderness and 10% of patients presented with combined right upper and epigastric tenderness. As expected, 70% of patients had no tenderness on physical examination.

Chart 1: Presenting physical findings



- Abdominal ultrasound was done in all patients and 18% of patients had solitary gallbladder stone and the rest 82% had multiple stones.Ultrasound was able to detect and document contracted gallbladder in 14.6% of patients. No patients underwent Mini-cholecystectomy with ultrasound findingof acute calculous cholecystitis. Majority, 91.1%, of patients had a pre-operative diagnosis of calculous cholecystitis. The remaining 8.9% had hydropic and/or empyema of the gallbladder.

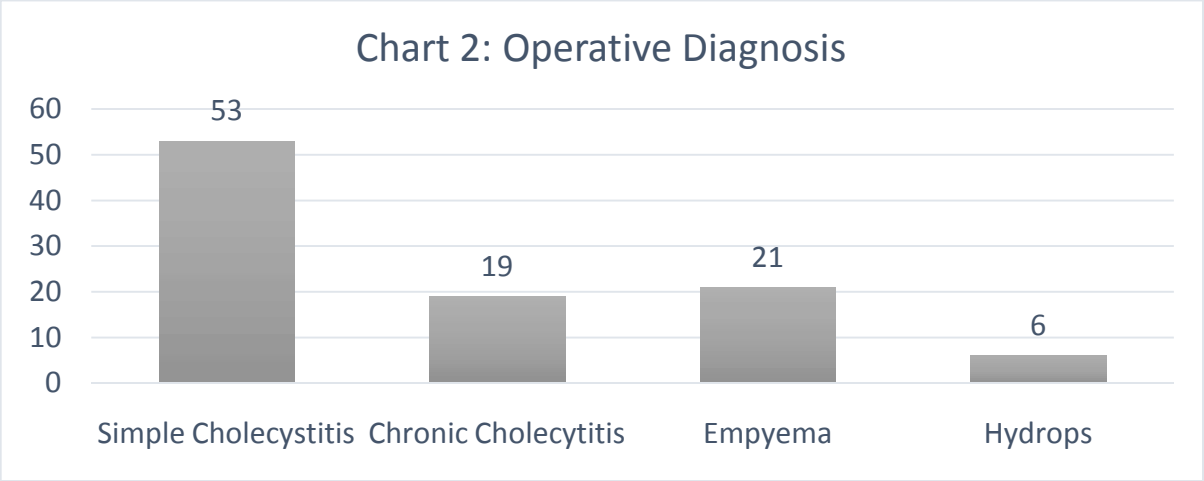
14.3 Operative diagnosis of patients who underwent mini-cholecystectomy

- A personal standardized technique for mini-cholecystectomy was established after more than 10-year experience of performing the operation in patients with acute and/or cholecystitis. The incision was started approximately 3 cm to the right of the midline and ran obliquely parallel to and 3 cm below the right costal margin. The initial length of the incision was 3-5cm, depending on the size of the patient and the degree of gallbladder distension; it was extended if necessary. Extensions beyond 5cm are not considered as mini-cholecystectomy.

- The rectus muscle was split or divided. In a patient with a markedly distended gallbladder, decompression of the gallbladder was the first step after entering the abdominal cavity. Most patients underwent retrograde cholecystectomy. The stumps of the cystic duct and cystic artery were ligated with delayed absorbable suture material. The term ‘operative time’ was defined as the period starting at ‘knife to skin’ and finishing at ‘last stitch’. Anesthesia time was timed from time of induction to extubation.

- Following the above operative procedure, 53% of patients were found to have simple calculous cholecystitis, the rest had chronic cholecystitis, empyema, and Hydrops in 19%, 21%, and 6% of cases respectively.

Chart 2: Operative diagnosis



11 In this study we tried to compare preoperative diagnosis with intraoperative findings. Results showed that almost two third of patients, 63%, had similar findings intraoperatively. It also showed that one third of patients with preoperative diagnosis of contracted cholecystitis have associated gallbladder hydrops. Crosstabulation of these two was found to be significant with a p-value of <0.001.

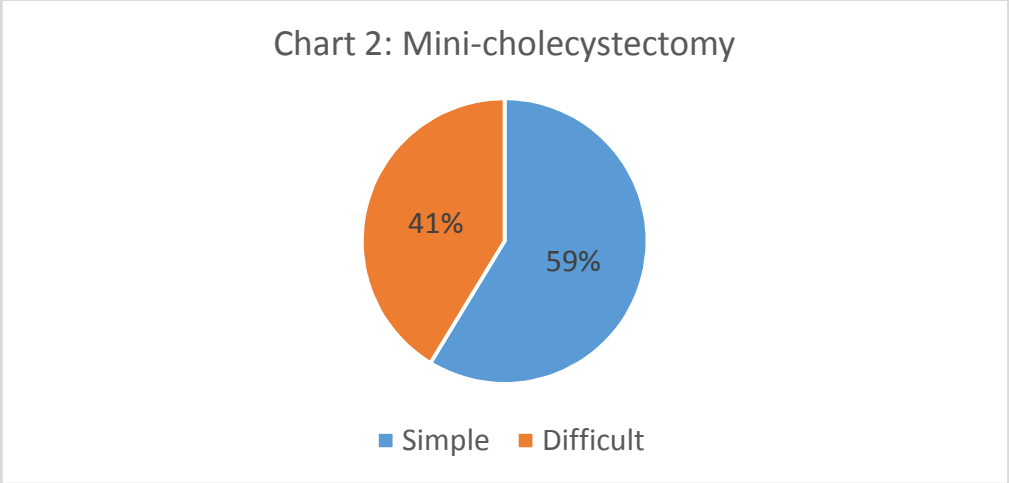
Table 6: Relations of preoperative diagnosis with operative findings

		Operative diagnosis				P-Value
		Calculous simple chronic cholecystitis	Calculous shrunken or contracted cholecystitis	Calculous gallbladder empyema	Hydropic acute cholecystitis	
Preop. diagnosis	Calculous cholecystitis	**108**	36	39	6	**0.001**
		57.1%	19.0%	20.6%	3.2%	
	Calculous gallbladder empyema	1	1	**6**	1	
		11.1%	11.1%	**66.7%**	11.1%	
	Calculous shrunken or contracted cholecystitis	1	2	0	**5**	
		12.5%	**62.5%**	0.0%	25.0%	

14.4 Mini-cholecystectomy procedure details

- The procedures were labeled difficult if the surgeon operated on either a contracted gallbladder with or without empyema and faced significant adhesions. With this, 58.7% of the procedures were simple, the rest being difficult.

Chart 2: Ease of mini-cholecystectomy



- The average surgery time for Mini-cholecystectomy was found to be **35min** and **43min** for anesthesia. The time ranges from 20min to 120min.

14.5 Factors affecting ease of mini-cholecystectomy

- Multivariate analysis showing factors affecting ease of doing cholecystectomy showed statistically significant association between patients having chronic contracted cholecystitis resulting in difficult mini-cholecystectomy, (AOR=7.63, P-value <0.05)

Table 7: Multivariate analysis of variables with ease of cholecystectomy

	AOR	P-Value	95% CI
Associated symptoms	6.594	0.08	-18.536 – 11.661
Diabetes	22.286	0.1	-46.243 – 6.614
Hypertension	21.294	0.07	-34.328 – 3.342
Obesity	7.162	0.08	-41. 385 – 10. 081
Duration of Symptoms	1.498	0.098	-18.559 - 55.416
Calculous cholecystitis	48.14	0.1	-.857 - 98.69
Chronic	**7.63**	**0.003**	**2.301-52.643**

contracted cholecystitis			
Gallbladder Empyema	30.92	0.06	-74.637 - 11.797

14.6 Duration of surgery and operative diagnosis

- This study showed that 80% of the mini-cholecystectomies lasted 20-40minutes. Furthermore, 77.5% of the procedures lasting more than 40 minutes were done in those with empyema or contracted gallbladder.

Table 8: Duration of Surgery versus Operative diagnosis

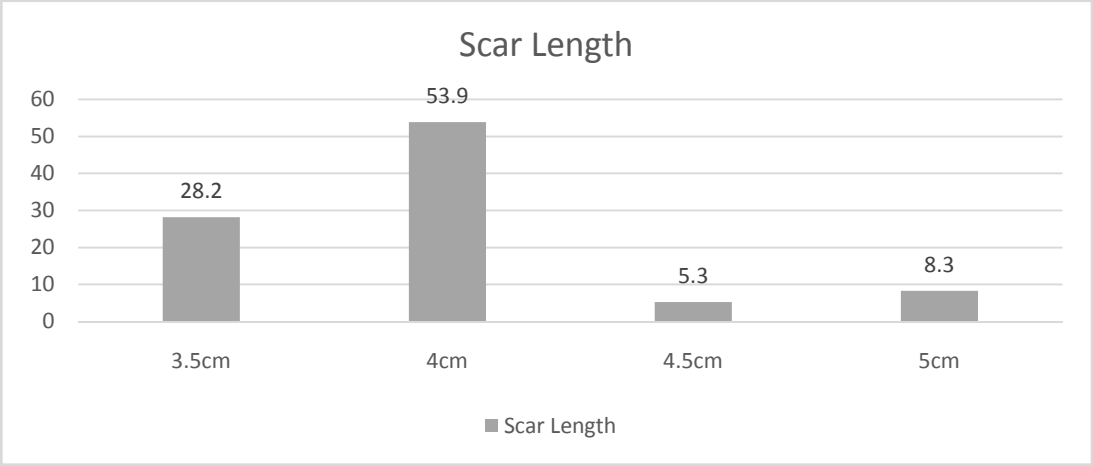
			Operative Diagnosis				P-Value
			Calculous simple chronic cholecystitis	Calculous shrunken or contracted cholecystitis	Calculous gallbladder empyema	Hydropic acute cholecystitis	
Duration of Surgery	20 – 40 min		105	28	25	8	0.001
			63.3%	16.9%	15.1%	4.8%	
	>40min		5	11	20	4	
			12.5%	**27.5%**	**50.0%**	10.0%	

- The average hospital stay of patients was found to be 72hrs, where 99% of them stayed for a day before surgery and 96% stayed 48hrs postop.

14.7 Post-Operative Complications and followup

- Only 3 patients developed Superficial surgical site infections. Bile duct injury occurred in 1 patient (0.45%) which resolved with re-exploration and drainage only. Dense Adhesion found during surgery in both patients who developed leak. No patients developed obstructive jaundice and incisional hernia or death in the study period.
- The conversion rate to standard open cholecystectomy was found to be 2.9%. Extension defined as initial incision length greater than 5cm. Close to 85% of patients had scar length of 4cm or less. All measurements did not take scar contracture into consideration.
- Postoperatively patients were followed for an average time of 2 months with the time ranging from 1 to 12 months. Around 86% of patients were followed for at least 2 months. Scar length was measured using a standard meter with in the first post op month.

Chart 3: Post-operative scar length



- During the follow up period, patients were assessed for any residual symptoms and 22.5% of patients claim to have persistent dyspepsia despite PPI treatment. Majority of the patients had uneventful postoperative course with complete resolution of symptoms. Only 1 patient developed scar keloid.

Table 9: status on post-operative follow up.

Comorbidity	Frequency	Percent
Uneventful Outcome	99	48.5
Dyspepsia	**46**	**22.5**
Faint scar line	58	28.4
Scar keloid	1	.5

15 Discussion

- A total of 201 patients underwent mini-cholecystectomy during the study period with 2 conversions to standard cholecystectomy, making the conversion rate to be 2.9%. Similar study showed a comparable conversion rate of 2.8% for chronic cholecystitis and 4.8% for acute cholecystitis (10).We believe mini-cholecystectomy produces “minimal trauma” and may have similar level of invasiveness as laparoscopic cholecystectomy (10, 11).

- In the majority of cases, either mini-cholecystectomy or laparoscopic cholecystectomy can be used. However, in some cases, mini-cholecystectomy may be the preferred treatment. As intra-abdominal adhesions could make the laparoscopic approach technically difficult, patients with previous abdominal surgery should receive mini-laparotomy cholecystectomy. The inability to perform a full survey of the peritoneal cavity is a major drawback of the mini-cholecystectomy approach. However modern progress in preoperative diagnostic imaging essentially diminishes the significance of this drawback (2).

- The benefits of the mini-laparotomy over the laparoscopic approach include: (1) absence of pneumoperitoneum; (2) absence of problems associated with specimen removal; (3) operative technique similar to a standard open procedure—additional procedures on the choledochus can be easily added; (4) complete isolation of the operative field from the rest of the abdomen (important in acute cholecystitis); can be used in patients with previous abdominal surgery(5).

- In our study, we found that hypertension to be the commonest comorbidity found in patients with gallstone disease, 16%, followed by diabetes found in 10% of the patients.Other similar studies incriminate obesity as commonest comorbidity in patients with gallstone disease. (12). Multivariate analysis of variables included revealed that patients with chronic contracted cholecystitis are more likely to have difficult mini-cholecystectomy and maybe carefully selected preoperatively. In a study done comparing laparoscopic and open cholecystectomy found similar findings (12).

- Post-operative biliary leak rate was 0.45%.A study done in Ethiopia reported a leak rate of 0.4% for open cholecystectomy and none for laparoscopic cholecystectomy. (12) There was no death. Three patients (1.4%) developed superficial surgical site infection. In this regard, a study from Ethiopia reported mortality rate of 0.15%, and complication rate of 2.9%. Another study from Kenya reported complication rate of 2.1%, no death and no biliary tract injury.

- The post-operative period was smooth in the majority of patients. Good cosmetic results were achieved.

16 Conclusion

- Mincholecystectomy is well tolerated, and is associated with minimal complications and conversions. When it is carried out with the appropriate surgical skill set, it is an alternative to laparoscopic cholecystectomy for chronic cholecystitis.

17 Recommendations

- Mini-cholecystectomy is a safe method of cholecystectomy in experienced hands which can be practiced in a resource limited setting without undue complication.

- A randomized controlled trial is needed to further define the best alternative for the removal of the gallbladder in a resource limited setting.

18 Limitations of the study

- All procedures were performed by a single surgeon
- Intraoperative incision length was not measured.
- Short Post-operative follow-up.
- All procedures took place in a private setup and cost analysis was not done.

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20. Annex 1

Mini-cholecystectomy Questionnaire

1. Age ———years.

2. Sex 2.1. Male 2.2. Female

3. Card No.—————

4. Family history of gallstone disease 4.1 Yes 4.2. No 4.3 Unknown

5. Main Presenting Symptom 5.1 RUQ pain 5.2 Epigastric pain 5.3 RUQ and epigastric pain 5.4 Other site pain (specify)_____

6. Associated symptoms 6.1 Vomiting 6.2 Fat intolerance 6.3 Dyspepsia 6.4 Jaundice 6.5 Constipation 6.6 Fever 6.7 Other (specify) _____

7. Duration of main presenting symptom ———months

8. Comorbid condition 8.1 Hypertension 8.2 Diabetes Mellitus 8.3 Bronchial asthma 8.4. Obesity 8.5 Lipidemia 8.6 Other (specify)_____

9. Physical Findings 9.1 Obesity 9.2 RUQ tenderness 9.3 Epigastric tenderness 9.4 RUQ and epigastric tenderness 9.5 Tender palpable gallbladder 9.6 Hepatomegaly 9.7 Jaundice 9.8 Pallor 9.9 Other (specify) _____

10. Laboratory 10.1 White blood cell count—————10. 2 Hemoglobin———10.3 Platelet count—————10.4 FBS———10.5 Urea———10.6 Creatinine—————10.7 GOT——10.8 GPT——10.9 ALP——— 10.10 Cholesterol ———10.11 TG———10.12 LDL———10.13 Other (specify)_____

11. Abdominal ultrasound report 11.1 Solitary gallstone 11.2 Multiple gallstones 11.3 Contracted gallbladder 11.4 Hydropic gallbladder 11.5 Chronic cholecystitis 11.6 Acute cholecystitis 11.6 Choledocholithiasis 11.7 Other (specify)———————————————

12. Preoperative diagnosis 12.1 Calculous cholecystitis 12.2 Calculous gallbladder empyema 12.3 Hydropic acute cholecystitis 12.4 Other (specify)————————

13. Operative diagnosis 13.1 Calculous simple chronic cholecystitis 13.2 Calculous shrunken or contracted cholecystitis 13.5 Calculous gallbladder empyema 13.6 Hydropic acute cholecystitis 13.6 Omental adhesions 13.7 Other (specify)————————

14. Mini-cholecystectomy 14.2 Simple 14.2 Difficult 14.3 Other (specify)—————————
15. Duration of 15.1 operation ———minutes 15.2 anesthesia—————minutes.

16. Complications of operation 16.1 Wound infection 16.2 Bile peritonitis 16.3 Obstructive jaundice 16.4 Bile duct injury y 16.5 Incisional hernia 16.6 Other (specify)_____16.7 None

17. Preoperative hospital stay 17.1. Half day 17.2 One day 17.3 Two days

18. Postoperative hospital stay 18.1 One day 18.2 Two days 18.3 Three days 18.4 Other (specify)-----days 19. Antibiotics used 19.1 Prophylactic 19.2 Therapeutic 19.3 None

20. Length of skin scar 20.1 3.5cm 20.2 4.0cm 20.3 4.5cm 20.4 5.0cm

21. Follow up duration ———months.

22. Status of patient at last followup visit 22.1 Uneventful course 22.2 Dyspepsia 22.3 Faint scar line 22.4 Scar keloid 22.5 Others(specify)_____