

Post-Cholecystectomy Gall Bladder Remnant and Cystic Duct Stump stone: surgical pitfalls, causes of occurrence and completion cholecystectomy (open versus laparoscopic) as a safe surgical option of treatment: short and long term outcome. Randomized Controlled Clinical Trials.

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Abstract

Introduction: cholecystectomy is the standard surgical option of symptomatic gallbladder disease. The symptoms persist after cholecystectomy in 10 - 20% of cases. Residual gall bladder/cystic duct stump stone is one of the most important cause.

Aim : to compare between open and laparoscopic completion cholecystectomy for gall bladder (GB) remnant and cystic duct stump stones as regard short and long term outcome.

Methods: This study was conducted on 84 cases with residual GB/cystic duct stump stone that were divided into 2 groups, the open completion cholecystectomy group and the laparoscopic completion cholecystectomy group. The diagnosis was made by ultrasound and magnetic resonance cholangio-pancreatography.

Results: The mean operative time was 120±13 minutes in open group and 160±10 in laparoscopic group. Blood loss occurred in 8 cases in open group and 2 cases in laparoscopic group that necessitated blood transfusion. Biliary injuries detected intraoperative occurred in 3 cases with open approach and 2 cases with laparoscopic approach and suture immediately by vicryl 3/0. The mean hospital stay was shorter in laparoscopic group than open group.

Conclusion: laparoscopic Completion cholecystectomy is a safe surgical approach for cystic duct stump stone.

<u>Research question</u>: is laparoscopic completion cholecystectomy is safe in managing gall bladder and cystic duct stump stones?

<u>Hypothesis</u>: laparoscopic completion cholecystectomy is safe in managing gall bladder and cystic duct stump stones.

All ethical approval was given by our local Faculty of Medicine ethical committee.

<u>Registration</u> at clinicaltrials.gov protocol registration quality control review criteria: NCT04329143 registered in 31 March 2020.retrospective registered

The work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans.

1. Introduction:

The incidence of gall bladder and cystic duct stump stones occurs in 5% of cases underwent urgent cholecystectomy but the incidence is much less after elective cholecystectomy [1]. The incidence of cystic duct stump stone after laparoscopic cholecystectomy is higher than open cholecystectomy; the

former represents about 13.3% [2]. Some surgeons perform incomplete removal of gall bladder during difficult dissection of triangle of Calot for fear of injury of important structure in the vicinity [3].

The incidence of gall bladder and cystic duct stump stone can be prevented by complete skeletonization of cystic duct for a distance not exceeding 1 cm from the common bile duct and stone in cystic duct is pushed back in gall bladder if present [4] [5] [6].

The presence of stone in cystic duct can be diagnosed by intraoperative palpation of the cystic duct but intraoperative cholangiography may be used in diagnosis but not routinely used [7] [8].

The term of cystic duct stump syndrome falls under the differential diagnosis of post-cholecystectomy syndrome that may be caused by different causes like reflux esophagitis, peptic ulcer, irritable colon and colitis. This may lead to delay in diagnosis of cystic duct stump syndrome. [9] [10]

To reach the diagnosis of cystic duct stump syndrome, history of post-cholecystectomy persistent symptoms that are present postoperative, in addition to different diagnostic modalities as ultrasonography, computed tomography (CT) scan, endoscopic retrograde cholangiopancreatography (ERCP), and magnetic resonance cholangiopancreatography (MRCP). [11].

The purpose of this study is to evaluate the role of laparoscopic completion cholecystectomy as the best surgical option for cystic duct stump and gall bladder remnant syndrome as regard safety to the patients.

2. The Aim Of The Work:

to assess the best surgical approach for treatment of gall bladder and cystic duct stump syndrome as regard safety to the patients.

3. Patients And Methods:

Study design: Prospective Randomized controlled clinical study.

Study place: our study was conducted in the general surgical unit of our University Hospitals.

Study period: January 2013 to January 2018.

Source of data: Patients admitted with clinical diagnosis of gall bladder and cystic duct stump syndrome.

Sample size: A total of 84 patients with a clinical diagnosis of gall bladder and cystic duct stump syndrome

Sampling method: simple random sample with a balance

Method of sample size calculation: with confidence 95 and power 80 and based on previous paper blood loss and biliary injuries between two approach sample sizes will be 42 in each group.

Ethical consent: consents were taken from all patients.

Patient selection criteria:

A-Inclusion criteria:

- Age: 30-50
- Both sex(male-female)
- Previous cholecystectomy(open or laparoscopic)
- Symptomatic or asymptomatic
- b. Exclusion criteria:
- patients unfit for surgery
- Patient refused surgery.

Numbers of patients excluded from the study were 10 patients: because of mild symptoms that the patients refused surgery and preferred medical treatment (8 patients) and patients unfit for surgery due to medical diseases (2 cases).

The following investigations were performed immediately on admission:

- a. imaging diagnosis (Ultrasonography-Magnetic resonance cholangio-pancreatography) (pic 1 and 2)
- b. Complete blood count
- c.Liver Function Tests, Serum Bilirubin (Total and Direct bilirubin) and alkaline phosphatase.
- d. Hepatitis markers.

Efforts to decrease bias in the study:

- For pretrial bias: Good Define objectives. Risk and outcome .Select patients on probability sample with adequate sample size. Define confound factors and avoid it
- To avoid during trial bias: Standardize reaction and management of patients blindly-Objective data use rather than subjective-Good handling of data- plan designed for drop out
- To avoid after trial bias: Suitable statistical analysis used-Good and carefully interpretation-Control of confound

Methods: (pic3-15)

Open surgery was done through ordinary right Kocher's subcostal incision, while laparoscopic approach started by Hasson's technique to enter the abdominal cavity, followed by standard 4 port laparoscopy

procedures; all were applied strictly under vision. Identification of the liver, duodenum, colon and common bile duct were important anatomic landmarks for initial dissection and adhesiolysis commenced till exposure of the gall bladder fossa. The gall bladder remnant or cystic duct stump was dissected free from surrounding structures. Lastly excision of cystic stump or gall bladder remnant was done. An abdominal drain was placed in all patients.

4. Statistical Analysis:

Data collected throughout history, basic clinical examination, laboratory investigations and outcome measures coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis. According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean ± SD, the following tests were used to test differences for significance; difference and association of qualitative variable by Chi square test (X2). Differences between quantitative independent groups by t test or Mann Whitney,. P value was set at < 0.05 for significant results & <0.001 for high significant result.

5. Results:

Table (1)
Preoperative data

	Open completion cholecystectomy (n = 42 cases)	Lap completion Cholecystectomy (n = 42 cases)	X ²	Р
Age < 40 years > 40 years Mean ± SD	13 cases (33%) 29 cases (67%) 48.65 ± 8.65	10 cases (25%) 32 cases (75%) 49.21 ± 7.65	0.53 t = 0.58	0.46 P = 0.42
Sex Male female	6 cases (15%) 36 cases (85%)	15 cases (37%) 27 cases (63%)	5.14	0.021*
Initial cholecystectomy operation Open lap	33 cases (80%) 9 cases (20%)	29 cases (70%) 13 cases (30%)	0.98	0.32
Onset of symptom after initial cholecystectomy < 1 year > 1 year	27cases (65%) 15 cases (35%)	24 cases (57%) 18 cases (43%)	0.44	0.51
Site of residual stone Gall bladder remnant Cystic duct stump	19 cases (45%) 23 cases (55%)	11 cases (27%) 31 cases (73%)	3.31	0.06
Complaints Abdominal pain Jaundice Dyspepsia asymptomatic	38 cases (90%) 9 cases (20%) 19 cases (47%) 3 case (9.5%)	39 cases (93%) 4cases (9.5%) 21 cases (50%) 4 case (9.5%)	0.04 3.31 0.09 0.0	0.82 0.06 0.76 1.0
Female significantly associated with open and male with laparoscope				

Table (2) intraoperative data

	Open completion cholecystectomy (42 cases)	Lap completion Cholecystectomy (42 cases)	X ²	Р
Operative time mean ± SD (min)	120 ± 13	160 ± 10	t = 14.25	0.00**
Blood loss during operation	8 cases (20%)	2 cases (4.7%)	9.02	0.0026*
Biliary injury	3 cases (7.1%)	2 cases (4.7%)	0.33	0.56
Operative time significantly higher at laparoscope and blood loss was significantly associated with open				

Table (3)

postoperative data

	Open completion cholecystectomy (42 cases)	Lap completion Cholecystectomy (42 cases)	t/X²	Р
Length of hospital stay ; mean ± SD (days)	5.4 ± 1.6	4.3 ± 1.2	2.41	0.021*
Analgesic intake < 5 days > 5 days	16 cases (38%) 26 cases (62%)	36cases (87%) 6 cases (13%)	20.19	0.00**
Hospital stay was sig longer among open and also analgesic intake stay longer significantly among open				

Table (4) immediate postoperative complication

Open completion cholecystectomy (42 cases)	Lap completion Cholecystectomy (42 cases)	X ²	Р
4(9.5%) 0 0	2(4.7%) 2(4.7%) 0	2.66	0.104
6 (15.0%)	4(9.5%)	0.71	0.39
4 (9.5%) 2 (4.7%)	1 (2.3%) 3 (7.1%)	4.8	0.02*
4(9.5%)	2 (4.7%)	1.66	0.19
16 (40%)	4(9.5%)	18.1	0.00002**
6 (15%)	3(7.1%)	2.91	0.08
	cholecystectomy (42 cases) 4(9.5%) 0 6 (15.0%) 4 (9.5%) 2 (4.7%) 4(9.5%) 16 (40%)	cholecystectomy Cholecystectomy (42 cases) (42 cases) 4(9.5%) 2(4.7%) 0 2(4.7%) 0 4(9.5%) 4 (9.5%) 1 (2.3%) 2 (4.7%) 3 (7.1%) 4(9.5%) 2 (4.7%) 16 (40%) 4(9.5%)	cholecystectomy (42 cases) Cholecystectomy (42 cases) 4(9.5%) 2(4.7%) 0 2(4.7%) 0 0 6 (15.0%) 4(9.5%) 1 (2.3%) 4.8 2 (4.7%) 3 (7.1%) 4(9.5%) 2 (4.7%) 1.66 16 (40%) 4(9.5%) 18.1

Treatment of biliary leakage was sig different between group and site infection was significantly higher among open

Table 5 delayed postoperative complication

	Open completion cholecystectomy (42 cases)	Lap completion Cholecystectomy (42 cases)	X ²	Р
Biliary stricture	2(4.7%)	1(2.3%)	1.28	0.25
Treatment of biliary Stricture ERCP ,dilatation and stent Hepatico-jejunostomy	1(2.3%) 1(2.3%)	1(2.3%) 0	Fisher exact 0.18	0.66
Mortality rate	3 (7.1%)	1 case (2.3%)	2.77	0.095
No significant difference or association				

Follow up: 2 years for all patients

6. Discussion:

Cystic duct stump syndrome is commonly seen in females than males. this is attributed to the fact that gall bladder disease is more common in female than male. In present study; the incidence was 70% in females (14 cases) compared to 30% in males (6 cases). This higher incidence in females was also reported by a study that stated that the male to female ratio was 1:1.45. [12]

A study showed that patients with gall bladder and cystic duct stump stones may be asymptomatic and discovered accidentally on performing investigations for unrelated condition [15], while other studies stated that the patients may be presented with post-cholecystectomy symptoms that may be acute symptoms (symptoms of acute cholecystitis or biliary colic) or chronic symptoms (pain radiating to the shoulder, dyspepsia, food intolerance) [13][14]. In the present study, most cases presented with right hypochondrial pain (77 cases) and asymptomatic cases are 7 cases and discovered accidently by ultrasonography for other unrelated symptoms.

A study stated that the length of cystic duct necessitate to cause post-cholecystectomy cystic duct stump stone should be longer than 1 cm [16]. In the present study, all cystic duct stumps were more than 1 cm in length.

Some studies claimed that the incidence of cystic duct stump syndrome increased in the last years due to popularity of laparoscopic cholecystectomy, and the cystic duct stump stone is the cause of post-cholecystectomy cystic duct stump syndrome in 16% of cases. [17] [18]. In the present study, opposite data were found that cystic duct stump and gall bladder remnant stones were common in previous open cholecystectomy than laparoscopic cholecystectomy and in the emergency cases than elective cases. This may be explained by the fact that during laparoscopic cholecystectomy, the cystic duct must be found and completely skeletonised to apply clips on it, while in open cholecystectomy you may divide the gall bladder just below Hartmann's pouch especially in acute cholecystitis cases for fear of injury of biliary tract especially when Callot triangle is masked by adhesion.

Some studies stated that the time between initial cholecystectomy till diagnosis of gall bladder or cystic duct stump stone was 8.3 months [19] and 9.5 years [15]. In the present study, most cases present within one year after previous cholecystectomy (12 cases).

Some studies stated that the diagnosis of gall bladder remnant or cystic duct stump stones is established by different diagnostic modalities like ultrasound, CT scan, ERCP, and MRCP [14] [19] [20] [21]. In our study, the primary diagnosis was established by expert abdominal ultrasonography and MRCP modality that were done in all cases.

Previously, open completion cholecystectomy is preferred as a safer technique as regard disturbed anatomy from previous adhesion and the possibility of stone tactile sensation identification during surgery, but nowadays laparoscopic approach is accepted as a safe approach by other studies [15][19] [21][22].in our study, laparoscopic approach is safe as regard intraoperative and postoperative parameters.

Many studies had variations regarding the operative time and blood loss. A study reported a mean operative time was 62 min for open approach and the mean blood loss was 50 ml [21], other study stated that mean operative time was 102.4 min for laparoscopic approach, and the hospital stay was 2–4 days [14], other study reported mean operative time of 127 ± 31.32 min for laparoscopic approach and mean blood loss 165 ± 74.5 ml, and mean hospital stay of 3.2 ± 1.8 days[23]. In the present series, mean operative time was 120 ± 13 minutes for open approach and 160 ± 10 minutes for laparoscopic approach. ten cases received blood transfusion intraoperative, 8 cases during open approach and 2 cases during laparoscopic approach, and the length of hospital stay was 5.4 ± 3.2 days for open versus 4.3 ± 4.5 days for laparoscopic group.

In the immediate postoperative period, 8 patients developed fresh bleeding coming continuously from the drain that required re-exploration. 6 cases from cystic artery stump ligature slippage and managed easily by ligation of the bleeding artery and 2 cases from port site bleeding and treated by figure of 8 fixations of the port site.no major vessels injury recorded.

A study stated that the incidence of bile duct injuries of different forms (cutting, wrong site clips and thermal injuries) is more common in laparoscopic completion cholecystectomy than open approach. The patient presents with abdominal pain and fever and the diagnosis is confirmed by ultrasonography the reveals biloma collection in gall bladder bed [24]. In the present study, ten patients developed biliary leakage, six patients after open approach and 4 patients after laparoscopic approach. They presented mostly one week after the operation with abdominal pain, fever and jaundice, and a biloma was diagnosed by ultrasonography and aspiration. five cases underwent sonar guided catheter drainage and ERCP with plastic stent insertion in common bile duct, and five cases of mild symptoms underwent conservative treatment in the form of nasogastric tube, third generation cephalosporin injection, metronidazole 500 mg injection with adequate hydration and the patient improved after 10 days by absent collection radiologically and improvement of symptoms and signs. In the postoperative follow up period, three cases developed biliary stricture that necessitated ERCP dilatation with stent insertion in two

cases, and one was severely stenosed that treated successfully by hepaticojejunostomy after failure of ERCP dilatation and stenting.

Some studies stated that surgical approaches for post-cholecystectomy gall bladder remnant and cystic duct stump stone are safe with no mortality and minor morbidity[14] [21]. In the present study, intestinal injuries discovered nearly ten days after operations occurred in 4 patients after open approach and 2 patients after laparoscopic approach. The patients diagnosed with abdominal pain and intra-abdominal collection that was diagnosed by oral contrast computerized tomography and showing the leakage that confirmed by sonar guided aspiration. all cases were open bowel with no peritonism and so conservative treatment were first option in all cases. Four patients showed complete recovery clinically, laboratory and radiologically and 2 cases required re-exploration.one case showed duodenal injury that was treated with closure the defect and gastrojejunostomy and the other was transverse colon injury that was treated by temporarily colostomy and 2 months later ,the continuity of gastrointestinal tract was restored. In present study, mortality occurred in four cases of due to postoperative pancreatitis in two cases, one cases that had duodenal injury and the last one from postoperative pulmonary atelectasis. Pancreatitis postoperatively was in patients aged 62 old male and 67 old female that diagnosed postoperatively by abdominal pain, vomiting, fever, abdominal tenderness and diagnosis confirmed by CT. patient underwent conservative treatment with nothing per mouth, fluid and antibiotic but died after 5 days and 11 days respectively from sepsis and multisystem organ failure.

7. Conclusions:

Completion cholecystectomy (open or laparoscopic) is the most common treatment modality reported in the literature for the management of residual gallbladder stump with stones. Laparoscopic completion cholecystectomy for gall bladder remnant and cystic duct remnant can be performed safely.

8. Recommendation:

1-open completion cholecystectomy for all cases

- 1- To avoid this problem:
- 1. proper skeletonization of cystic duct and common bile duct.
- 2. pushing cystic duct stone back into gall bladder.
- 4. short cystic duct stump less than half centimeter.
- 5. Trans-fixation of cystic duct stump, if indicated, should be done only with absorbable suture material.

9. List Of Abbreviation:

GB: gall bladder

CT: Computed Tomography Scan.

ERCP: Endoscopic Retrograde Cholangio-pancreatography.

MRCP: Magnetic Resonance Cholangiopancreatography.

Declaration

10-Limitation: the limitation of this study is small sample size. The future hope is to perform a study including larger sample size

11- ETHICAL APPROVAL:

Yes all ethical approval was given by our Faculty of Medicine medical ethical committee.

12-Authors contributions:

All authors shared in the study design, data analysis, writing and critical revision of the manuscript for important intellectual contents. they shared in the final approval of the version to be submitted.

13-Funding: no.

14-Availability of data and materials: Not applicable

15- CONFLICT OF INTEREST: None declared.

16- GUARANTOR: The corresponding author.

17- Consent: Written informed consent for the cases to be published (including images, case history and data) was obtained from the patient(s) for publication, including accompanying images.

18- Registration at clinicaltrials.gov protocol registration quality control review criteria: NCT04329143 registered in 31 March 2020.retrospective registered

18-Acknowledgement:

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Figures

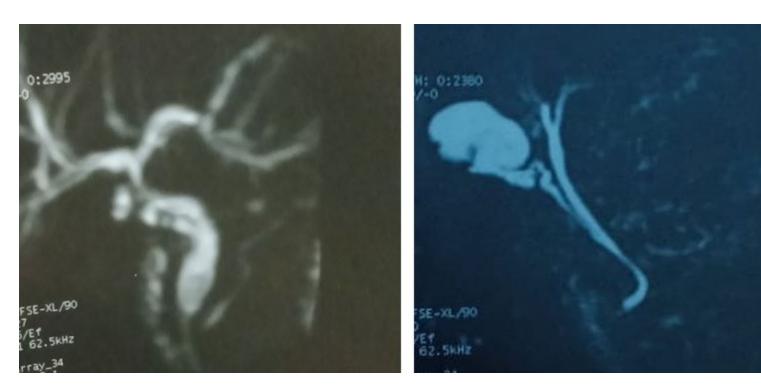


Figure 1

MRCP obtained in 47 years and 52 years old women with cystic duct stump showing stone (pic 1) and gall bladder remnant(pic 2)

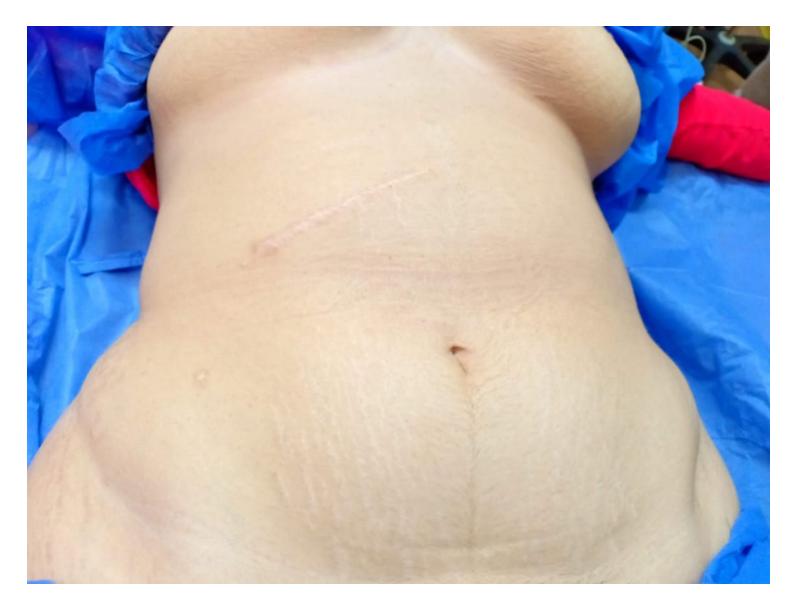


Figure 3
Scar of previous open cholecystectomy

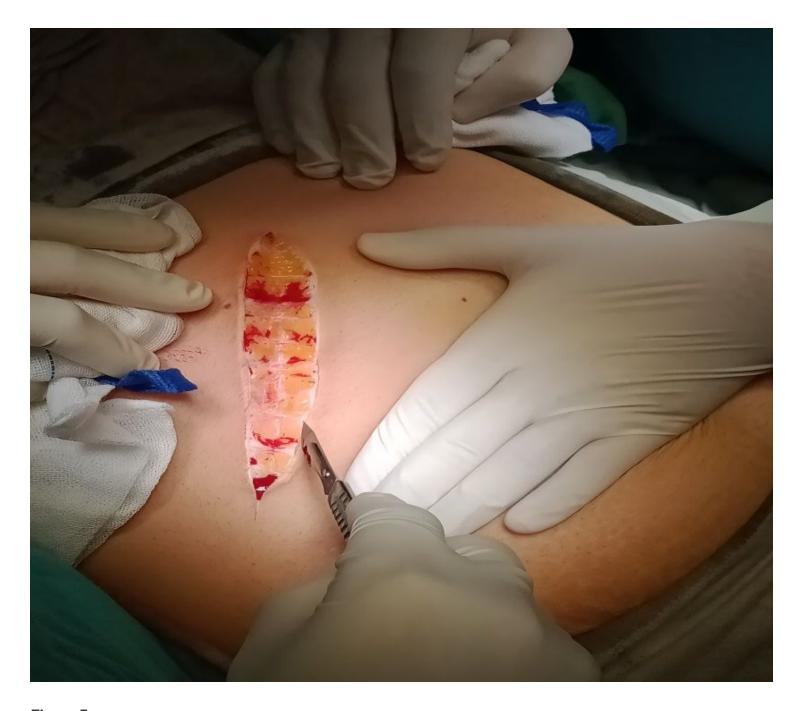


Figure 5
Incision at the site of previous scar (Kocher's incision)

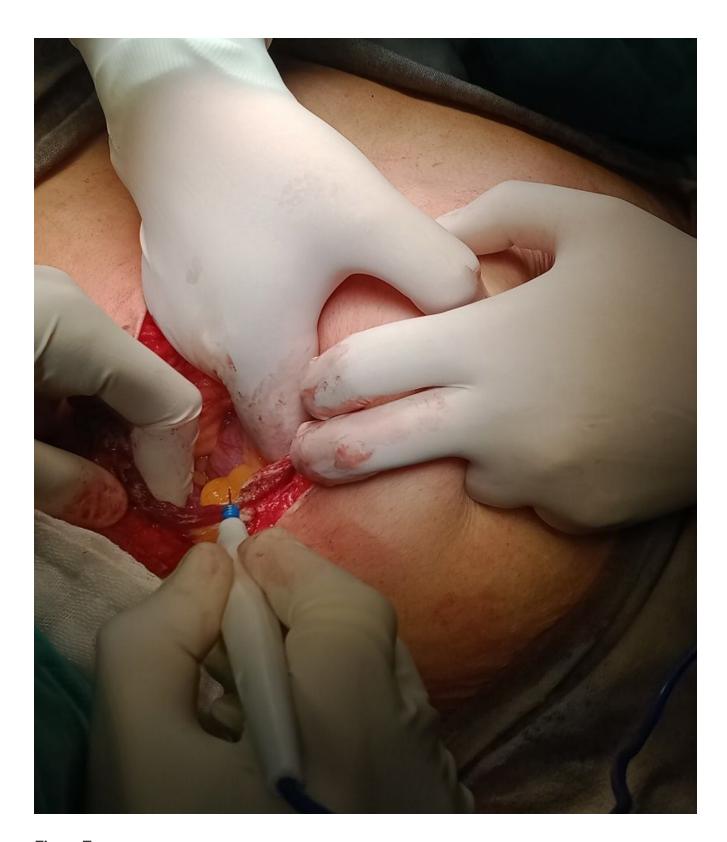


Figure 7
entrance of the abdomen with care

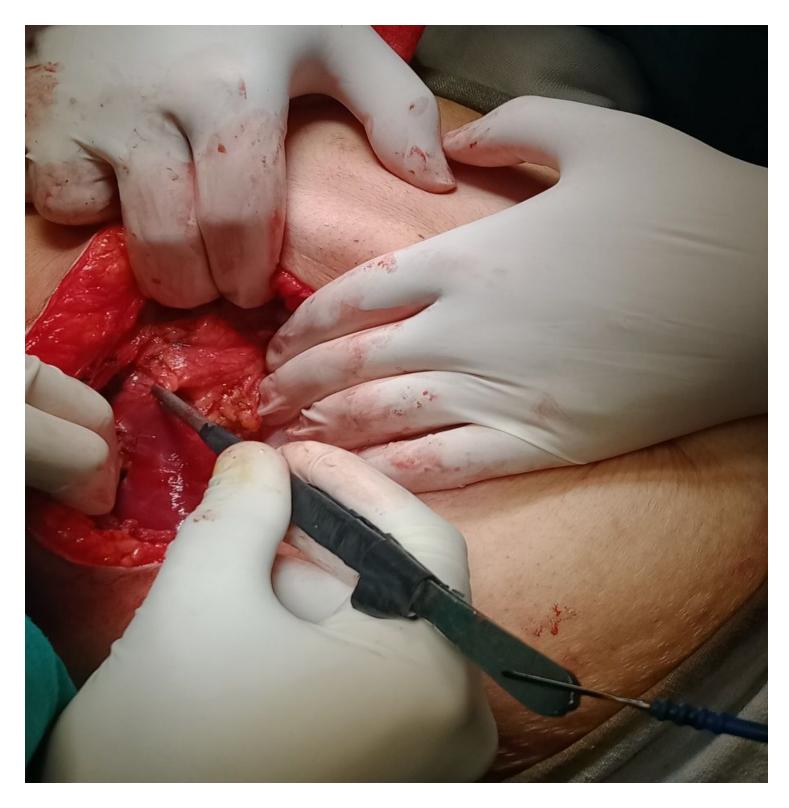


Figure 9

adhesion with the colon is released with care

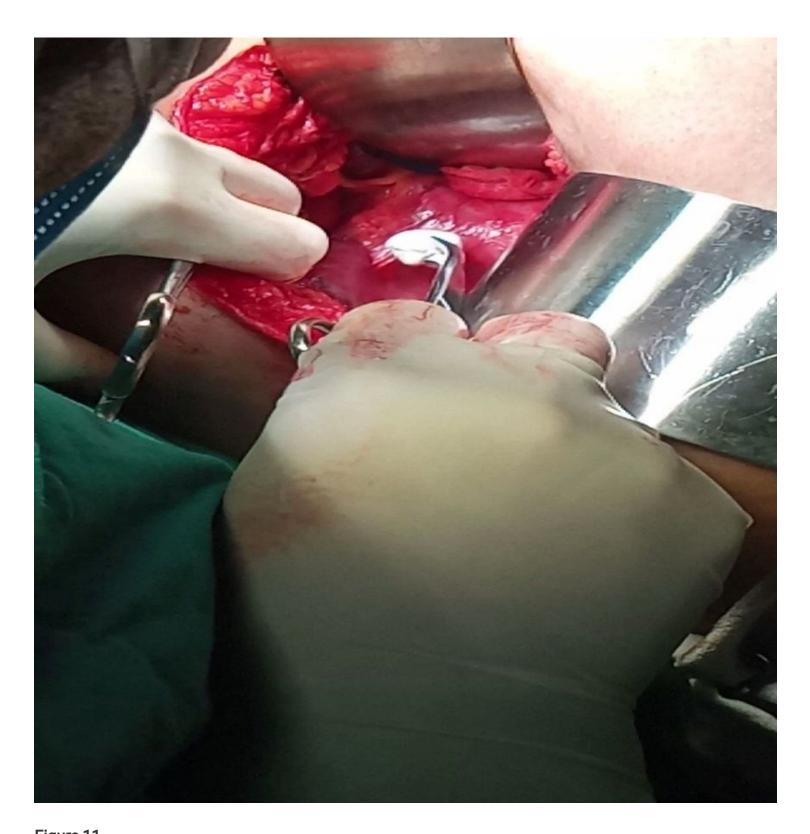


Figure 11
blunt dissection of gall bladder bed



Figure 13
another case with gall bladder remnant held by forceps

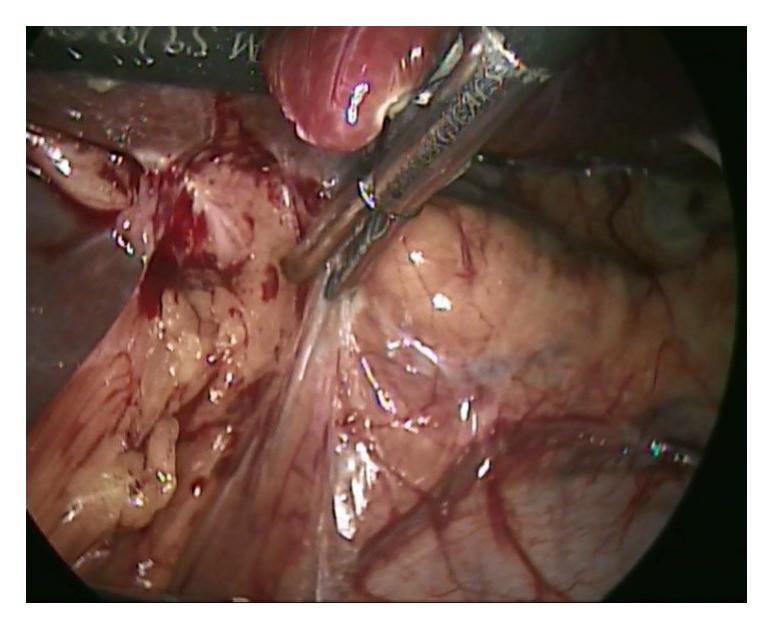


Figure 15

laparoscopic view with extensive adhesion

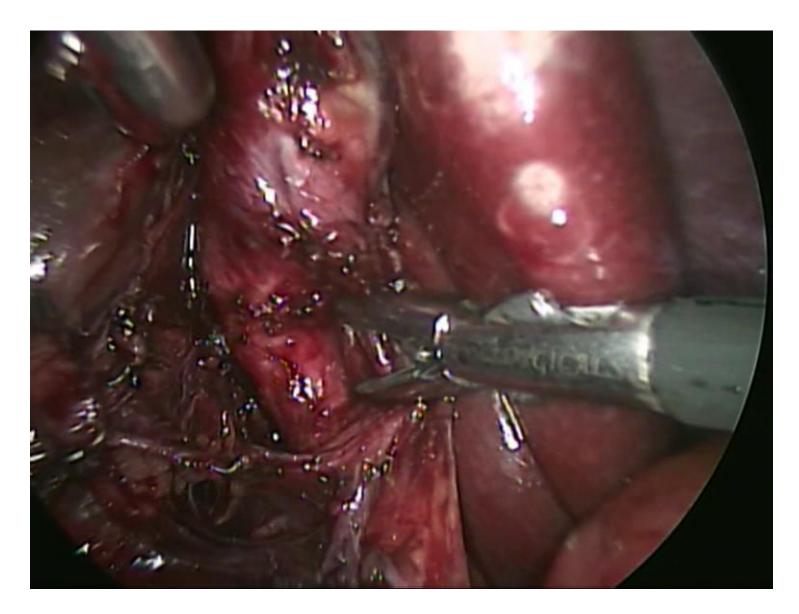


Figure 17
dissection of cystic duct

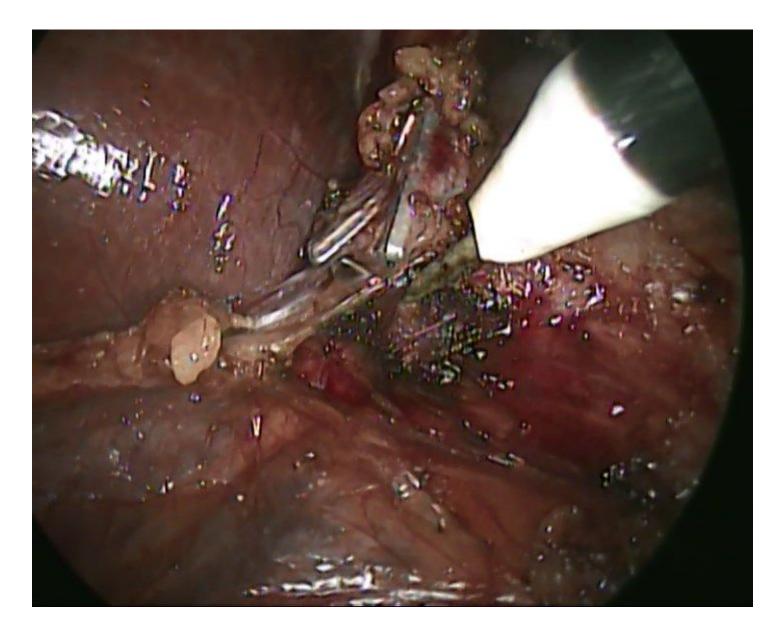


Figure 19
dissection of gall bladder remnant with clips

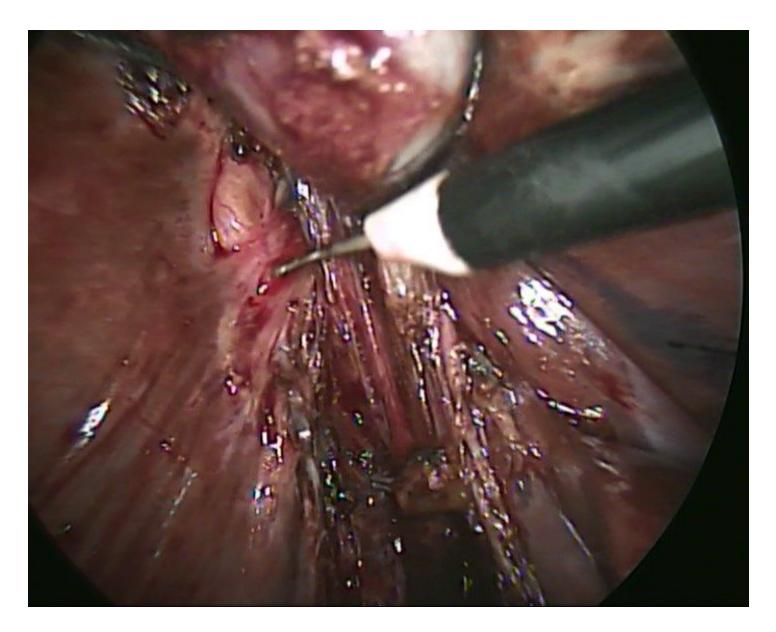


Figure 21 remnant removal from bed

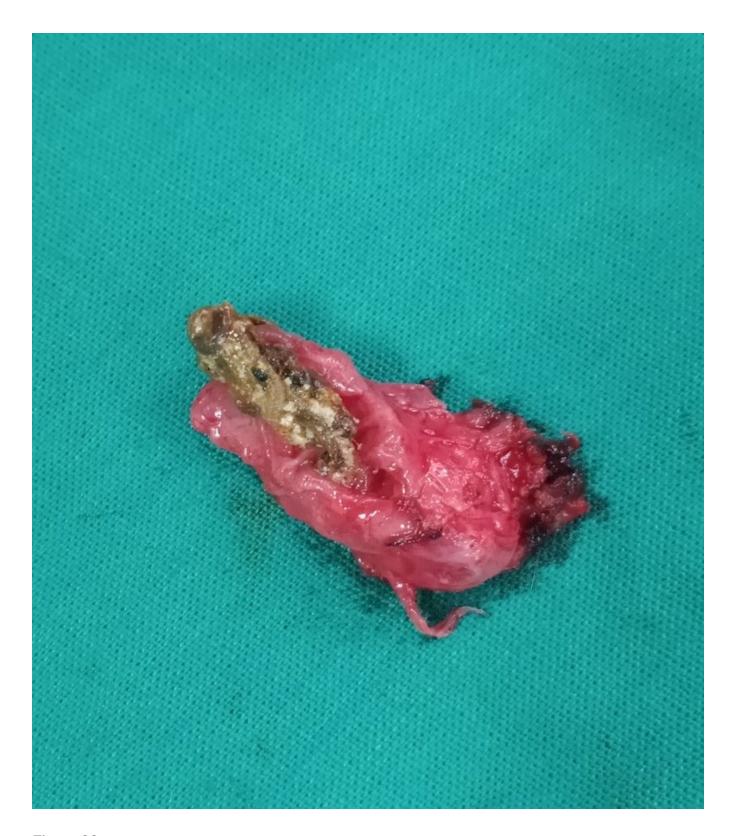


Figure 23

cystic duct stump with stone inside removed by open approach

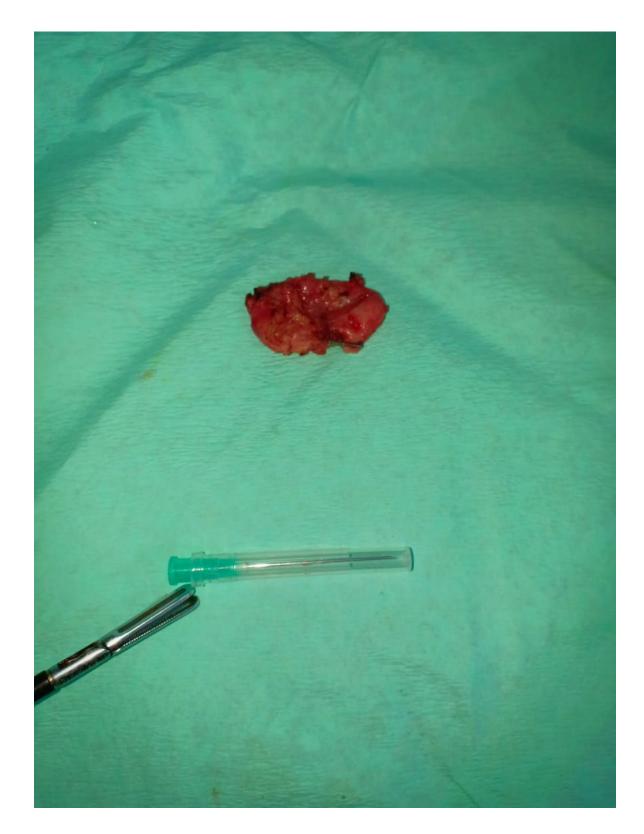


Figure 25

Gall bladder remnant removed by laparoscopic approach



Figure 27
gall bladder remnant removed by laparoscopic approach