

PATIENTS SATISFACTION WITH THE METHODS OF TREATMENT USED FOR GALLSTONES: A CROSS-SECTIONAL STUDY

ABSTRACT

Background: If gallstones are not causing discomfort, there is usually no need to treat them. Many people with gallstones do not experience any symptoms for a long time. In addition, any treatment can have side effects, and operations are always associated with a certain level of risk. Gallbladder stones are treated differently than stones in the bile duct. If symptoms such as cramp-like pain (colic) occur, they can be relieved with medication. Such pain can only be prevented permanently by removing the gallbladder. An operation is also an option for people without symptoms but with very large gallstones - or with a porcelain gallbladder. The wall of the gallbladder is calcified and there is an increased risk of gallbladder cancer.

Methods: This was an analytical cross-sectional study to spot light on the satisfaction levels of Saudi Population towards the different treatment options for gallstones. The study was carried out at universities, hospitals and malls in KSA. Data were collected from patients and general population during a period from June to October 2021.

Results: Most of patients were highly satisfied with the treatment clarification done by the treating doctor (n= 42, 8.8%), the treatment choice for gallstones, the complications occurred during their treatment period (n= 34, 7.1%), their condition after the end of treatment period (n= 41, 8.6%), and the treatment method for condition (n=35, 7.3%). On the other hand, there was a proportion of participants who were

not satisfied with the treatment duration (n= 39, 8.1%) and the follow up after the end of treatment period (n= 46, 9.6%).

Conclusion:

Participants are highly satisfied with treatment choice and treatment effectiveness. However, they were not satisfied with treatment duration and treatment complications.

UNDER PEER REVIEW

INTRODUCTION

Gallstones are crystallized components of the bile. They can develop in the gallbladder or the bile duct, favored by factors such as obesity and the female gender. Gallstones usually do not cause any symptoms. Depending on the location and size, they can also cause pain - from moderate discomfort in the right upper abdomen to severe biliary colic (1).

With a simple ultrasound examination, the doctor can identify gallstones with an accuracy of more than 95 percent (2). Gallbladder stones that are discovered only by chance and do not cause symptoms, do not require therapy. In the case of biliary colic, the first thing to do is to relieve the pain. Then the therapy of choice is the removal of the gallbladder - usually with the help of the keyhole method, i.e., laparoscopically. Stones in the bile ducts - if present - must be removed beforehand. This is usually also done endoscopically by means of a so-called ERCP (3). If the gallbladder is inflamed, it should be surgically removed early, i.e., already in the acute stage.

LITERATURE REVIEW

An estimated 5 to 25 percent of the population have gallstones. Women are two to three times more likely to be affected than men. In addition, the risk of gallstones increases significantly from the age of 40 (4).

Gallstones are crystallized components of bile. This fluid is produced in the liver and collected in the gallbladder just below, which is only a few centimeters long (5). If necessary, the bile is passed through the bile duct into the small intestine, where it helps digest fat. The main component of bile is about 80 percent water. In addition, there are bile acids, proteins and bilirubin (yellowish breakdown product of the red blood pigment hemoglobin). The bile also

contains cholesterol. Both bilirubin and cholesterol can crystallize - very fine stones a few millimeters in size (gravel) or gallstones up to several centimeters in size develop (6).

Depending on which substance predominates in the gallstones, the following two main groups are differentiated (7):

- Cholesterol stones: These consist mainly of cholesterol and are responsible for around 80 percent of all gallstone diseases.
- Bilirubin (pigment) stones: They consist of a cholesterol core to which bilirubin has attached. Bilirubin stones cause about 20 percent of gallstone disease.

Another distinguishing criterion is the location of the gallstones. A distinction is made between:

- Gallbladder stones (cholecystolithiasis): They arise in the gallbladder, the reservoir for the bile.
- Bile duct stones (choledocholithiasis): They are located in the duct connecting the gallbladder and the small intestine. Sometimes they are created on site. Often, however, it is actually gallbladder stones that have been washed out into the bile duct (secondary bile duct stones).

Women in particular have an increased risk of developing gallstones. It is believed that the female sex hormone estrogen promotes the formation of gallstones. Other risk factors are obesity, age (40+) and family history (8). Diabetes, cirrhosis of the liver, hypothyroidism, overactive parathyroid glands and inflammatory bowel disease also promote the development of gallstones (9).

Most gallstones go clinically unnoticed. This is called asymptomatic gallstones, which are usually detected by chance during a routine ultrasound examination (10). With biliary colic, on

the other hand, those affected complain of cramp-like, wave-like pain in the upper abdomen, which extends into the back or under the right shoulder blade, possibly in connection with vomiting. These complaints can last from a few minutes to many hours (11).

There are also inflammatory diseases of the gallbladder. This includes: 1] Acute cholecystitis: Mostly dull, persistent pain, radiating in different directions from the right upper abdomen. Fever can also occur. The situation is usually caused by a stone that attaches to the gallbladder outlet and prevents it from emptying. In doing so, the gallbladder wall is poorly supplied with blood as a result of overstretching, and bacteria can now act on the gallbladder wall. 2] Chronic cholecystitis: As a rule, stones also cause flare-ups of inflammation with recurring unspecific symptoms. 3] Ascending cholangitis: Here, attacks of fever occur in connection with signs of a disturbance in the drainage of the bile. The build-up of bile in the liver can be a sign of jaundice with yellowing of the skin, the dermis of the eyes and darkening of the urine. In contrast, the lack of bile in the stool manifests itself as discoloration (cement gray). Possible causes of biliary backlog: stones in the bile duct, scarring of the sphincter muscle, tumor formation (12).

If gallstones are suspected, there are various diagnostic options. In the first place is the ultrasound examination. With this method gallstones can be determined, but also measure a possible expansion of the bile duct. In acute inflammation, a thickening of the gallbladder wall can be determined. In addition, the collection of specific liver and inflammation values by taking a blood sample can provide information and lead to further examination steps. In some cases, computed tomography can be useful to expand the examination (13). If there are signs of a bile duct obstruction, magnetic resonance imaging can be used in the next step. With it, the cause can be narrowed down; in particular, both stones and tumor formations can be detected. Alternatively, so-called endoscopic retrograde cholangiography (ERCP) can also be used as an

endoscopic examination method. The bile ducts through the stomach and duodenum are searched for (retrograde) and displayed with a contrast agent (cholangiography). During this examination, treatment can be carried out directly at the same time, because the confluence of the bile duct into the duodenum can be widened (papillotomy), stones can be grasped and removed or a drainage tube (stent) can be inserted (14). Discomfort in the upper abdomen can also have other causes. For example, an ulcer in the stomach or duodenum can cause symptoms similar to gallstone problems. In these cases, an additional gastroscopy is useful, especially if the gallstones are not clear.

Conservative methods of treatment

Treating gallstones without surgery not only takes a long time, it also requires long-term medication. In addition, conservative treatment offers no guarantee that stones will be formed again. If there are no complaints or noticeable laboratory changes, observation remains. Removal of the gallbladder can make sense in the case of even minor complaints in order to avoid possible colic (15).

Operative treatment methods

Surgical removal of the gallbladder is the treatment of choice for gallbladder stones that have led to symptoms. This can also be considered in the case of very large gallbladder stones. If there are bile duct stones that cause discomfort, they should first be removed, followed by the surgical removal of the gallbladder. Surgical removal of the gallbladder is considered the first-choice treatment for gallstones that have caused symptoms (16). Usually, the open operation is no longer used, but the so-called keyhole method (laparoscopic cholecystectomy): The necessary instruments are pushed into the abdominal cavity through three incisions that are only a few

millimeters long. Under camera control, the entire gallbladder can be removed through the tiny incisions. This low-risk procedure results in very small scars at best (17).

In rare cases, the gallbladder may need to be removed even in patients with no symptoms. This is useful, for example, if there are very large gallstones or a stone-filled so-called porcelain gallbladder (18). With the latter, there is a risk that gallbladder cancer could develop. Therefore, the gallbladder should be removed as a precaution in this case.

The previously described method of using an endoscope to get through the mouth, esophagus, stomach and small intestine into the biliary tract (ERCP) is also sometimes used for therapy. If the ultrasound has shown that a stone in the bile duct causes colic, it can be removed or smashed with the help of ERCP. The opening of the bile duct into the intestine (Ampulla of Vater) can also be enlarged with an endoscopic procedure (endoscopic papillotomy). This makes it easier for the stones or pieces of stone to come off or be removed (3).

Experts nowadays advise against crushing stones with shock waves or lasers, as this method does not represent a complete renovation or new stone formation can occur again and again. Even after years of long-term therapy with a bile acid (UDCA) for pure cholesterol stones, stones can reappear (19).

METHODS

Study design

This was an analytical cross-sectional study to spot light on the satisfaction of Saudi people with regards to treatment methods used in gallstones.

Study setting

The study was carried out at universities, hospitals and malls in KSA. Data were collected from general population during a period from June to October 2021.

Sampling and sample

Participants were chosen via probability simple random sampling technique. Participants were selected from the general population. The final number of sample size was 300 participants. However, the study included 479 participants.

Inclusion criteria: General population

Exclusion criteria: none.

Instruments

Data collection tool was self-designed and base on latest literature. It contained the following information: (1) Sociodemographic characteristics: age, gender and education level, and (2)

Disease related information: most common presentation and satisfaction of method of treatment.

Statistical analysis

Data was entered and analyzed using SPSS version 23. Descriptive statistics were performed and categorical data were displayed as frequencies and percentages while measures of patients with gallstone disease and measures satisfaction in relation of method of treatment were used to summarize continuous variables.

Univariate and multivariate analysis will be performed to investigate association between age, gender, and most common presentation of gallstone and method of treatment satisfaction. statistical significance is set at a P value of 0.05 or less.

Permission and ethical considerations

Administrative approval will be sought from the unit of biomedical ethics research committee Ethical approval was sought from the ethical committee of the faculty of medicine, king Abdul-Aziz university. An informed consent was sought from the participants.

RESULTS

This study was conducted in order to evaluate patients' satisfaction with method of treatment used for gallstones. This study included 479 participants. The most frequent age group was 25-34 years with least frequent age group was 55 and above years. The distribution of age groups is presented in figure 1. The study included 282 females (58.9%) and 197 males (41.1%). Table 1 shows the distribution of age groups by gender among study participants.

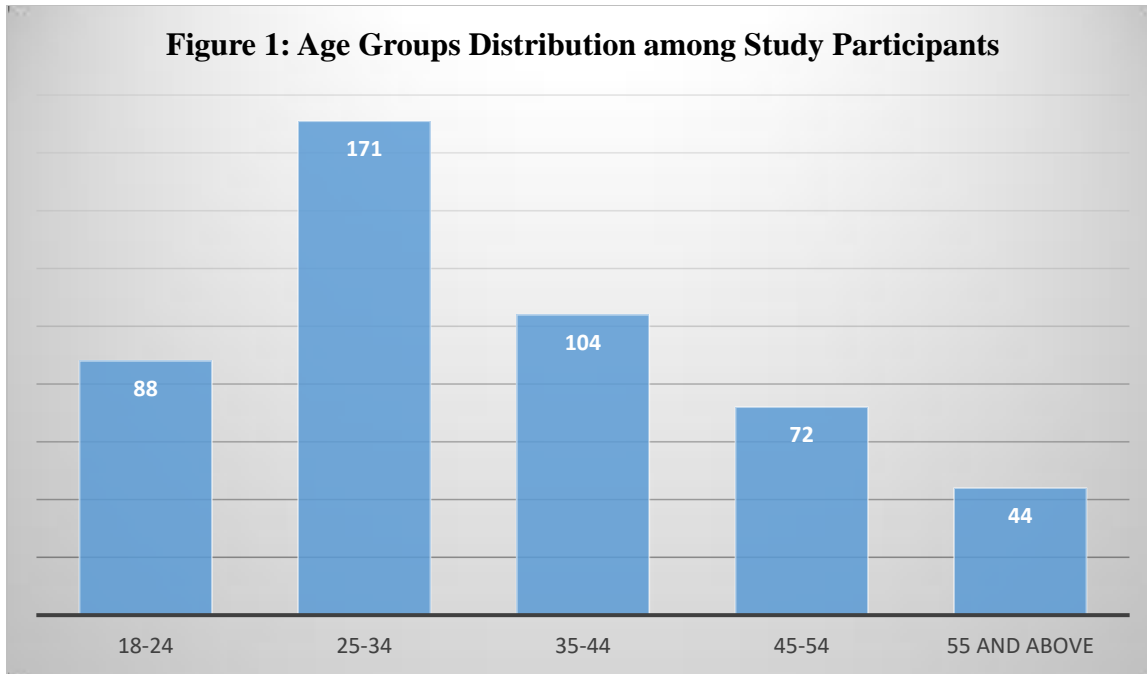
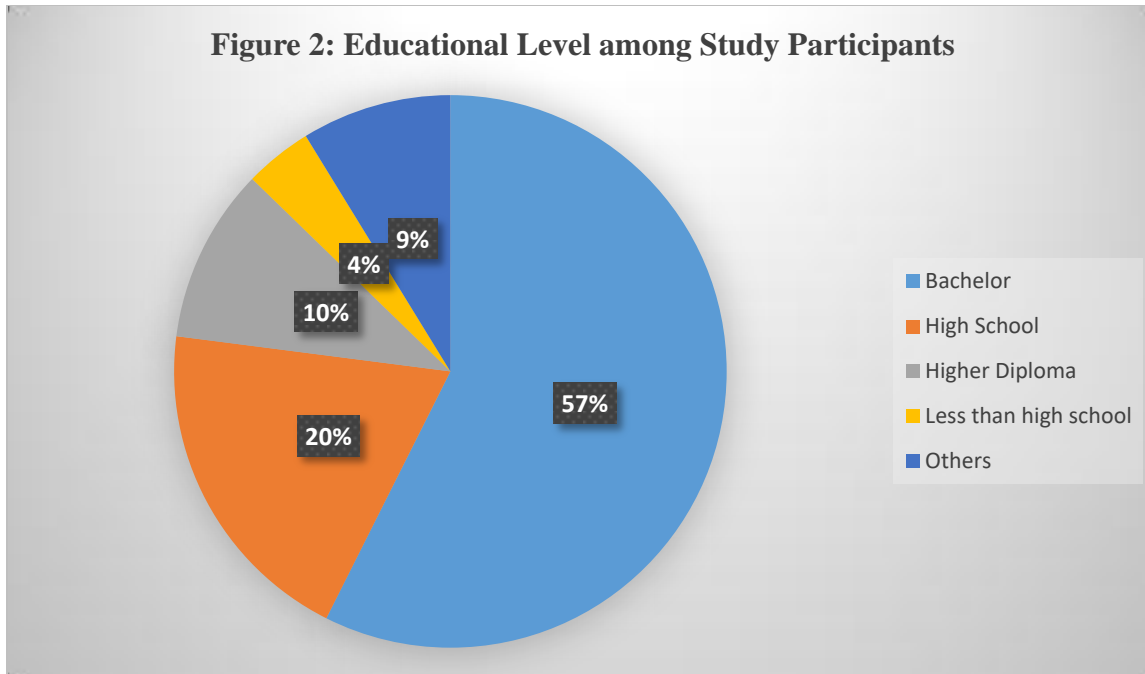


Table 1: Age groups distribution among study participants according to gender

Age groups	Male	Female
18-24	30	58
25-34	66	105
35-44	36	68
45-54	39	33
55 and above	26	18

Educational level varied among study participants. The most frequent age group was bachelor's degree (n= 275, 57.4%). The rest of educational levels are presented in figure 2.

Figure 2: Educational Level among Study Participants



On asking participants whether they had gallstone or not, there were 84 participants had gallstone (17.5%). Those participants were further asked about the first symptom they had when diagnosed with gallstone. The most frequent symptom was sudden intense pain in the right upper quadrant (n= 44, 9.2%). The rest of symptoms are presented in table 2.

Table 2: Distribution of Symptoms among study participants who had gallstone

Symptom	Frequency	Percent
Asymptomatic	4	0.8
Back pain between the shoulder blades	6	1.3
Nausea or vomiting	14	2.9
Rapid intense pain in the center of the abdomen	16	3.3

Sudden intense pain in the right upper quadrant	44	9.2
---	----	-----

Most of patients were highly satisfied with the treatment clarification done by the treating doctor (n= 42, 8.8%). The same percentage was for satisfaction about the treatment choice for gallstones. However, there was a proportion of participants who were not satisfied with the treatment duration (n= 39, 8.1%). On the other hand, participants were satisfied about their condition after the end of treatment period (n= 41, 8.6%). Nevertheless, participants were not satisfied about the follow up after the end of treatment period (n= 46, 9.6%). Participants were somewhat satisfied regarding the complications occurred during their treatment period (n= 34, 7.1%). Finally, participants were satisfied regarding the treatment method for condition (35, 7.3%).

DISCUSSION

The prevalence of gallstone disease makes it imperative for responsibility of care to remain the domain of the generalist in the district general hospital, and referral to a specialist center is practicable only for difficult clinical cases. In spite of the uniform availability and growing skill and safety of LC, the provision of an acceptable standard of care. It would also benefit the patient if a surgeon agreeing to care for a patient with gallstone disease as part of his on-call commitment had an in-hospital special-interest team to refer the patient onward for definitive care. The specialist team would be able to give greater priority to the case than the receiving surgeon who is quite likely to be committed to targets specific to his area of special interest. This team will also be keen to keep abreast of new skills and methods evolving in the treatment of gallstones and therefore continue to provide optimal care to every patient seeking treatment from his local hospital.

Cholecystectomy has evolved over a span of a century from the initial open cholecystectomy described by Langenbuck in 1882 to LC described by French surgeon Phillippe Mouret of Lyon in March 1987 (20), (21). The introduction of modern imaging techniques and the widespread availability of LC has brought about a paradigm shift with regards to management of gallstone disease. Surgical options can now be offered even to elderly individuals who were previously denied open cholecystectomy due to comorbid features. Even with asymptomatic gallstones, the principle seems to have moved from “best left alone if not troublesome” to one that says, “leave alone only if you have to”! The recognition that a significant proportion of patients suffer repeated symptoms and complications has prompted this change. LC allows inspection of the gallbladder without the need for commitment to completion or a large abdominal incision.

Patients referred through the community have different treatment needs compared with those presenting as acute emergencies. Patients presenting through A&E had a varied spectrum of gallstone symptoms like acute cholecystitis, CBD stones, jaundice, pancreatitis, and other complications of gallstone disease (22) and needed control of these before they could undergo LC. The challenge is to achieve these ideally within 4 days of onset of acute symptoms, which is by and large accepted as the best time for cholecystectomy in the acute setting though this can vary based on the surgeon's level of experience and the individual patient (23), (24). The common problems that prevent immediate LC are obstruction of the CBD by stones, empyema of the gallbladder with sepsis, and pancreatitis.

Patients with CBD stones confirmed by imaging underwent ERCP at the earliest and then LC at the next available opportunity during regular hours (25). Those with pancreatitis without CBD stones were observed for clinical and biochemical recovery before having LC (26).

Most outpatient referrals for gallstone disease can be safely treated either as outpatient cases or as short overnight (23 hour) in-hospital cases (27). Inpatient care would only be needed for those with medical comorbidities and social care needs for a smooth pre- and postoperative journey. Whilst we have endeavored to provide surgery at the earliest in this subgroup of patients.

The concept of LSC has gained increasing acceptance over the past decade. One of the commonest reasons for conversion from LC to open cholecystectomy used to be the discovery of a “frozen” Calot's triangle due to adhesions from previous attacks of cholecystitis. At this juncture, it would not be untrue to say that the risk of iatrogenic collateral biliary or vascular injury involved with dissection of a difficult frozen Calot's triangle is no higher with laparoscopic surgery than with conventional open surgery. We join many other peers in continuing with this concept of LSC, because we do not see any benefits in conversion to open surgery towards achieving a better result in such cases (28), (29).

Being able to choose and deliver effective treatment thus needs training, experience, and a team approach to the problem involving experts from the field of imaging, upper GI endoscopy, and minimal access surgery.

CONCLUSION

Participants are highly satisfied with treatment choice and treatment effectiveness. However, they were not satisfied with treatment duration and treatment complications. The treatment of gallstone disease has evolved from the singular option of having a major abdominal operation to present practice based on the latest interventional and minimal access surgery techniques. The treatment of gallstone disease continues to remain the bane of the generalist in district general hospitals. Though treatments by individuals with general interests may appear to give

satisfactory results, optimum results and minimal complications are best achieved when treatment is delivered by a specialized multidisciplinary team of experts in the district hospital, who have good experience, commitment, and continued training in the management of gallstone disease.

UNDER PEER REVIEW

REFERENCES

1. Njeze GE. Gallstones. *Niger J Surg Off Publ Niger Surg Res Soc.* 2013 Jul;19(2):49–55.
2. Scruggs W, Fox JC, Potts B, Zlidenny A, McDonough J, Anderson CL, et al. Accuracy of ED Bedside Ultrasound for Identification of gallstones: retrospective analysis of 575 studies. *West J Emerg Med.* 2008 Jan;9(1):1–5.
3. Meseha M, Attia M. Endoscopic Retrograde Cholangiopancreatography. In *Treasure Island (FL)*; 2021.
4. Stinton LM, Myers RP, Shaffer EA. Epidemiology of gallstones. *Gastroenterol Clin North Am.* 2010 Jun;39(2):157–69, vii.
5. Dowling RH. Review: pathogenesis of gallstones. *Aliment Pharmacol Ther.* 2000 May;14 Suppl 2:39–47.
6. Di Ciaula A, Garruti G, Lunardi Baccetto R, Molina-Molina E, Bonfrate L, Wang DQ-H, et al. Bile Acid Physiology. *Ann Hepatol.* 2017 Nov;16(Suppl. 1: s3-105.):s4–14.
7. Sanders G, Kingsnorth AN. Gallstones. *BMJ.* 2007 Aug;335(7614):295–9.
8. Ansari-Moghaddam A, Khorram A, Miri-Bonjar M, Mohammadi M, Ansari H. The Prevalence and Risk Factors of Gallstone Among Adults in South-East of Iran: A Population-Based Study. *Glob J Health Sci.* 2015 Jul;8(4):60–7.
9. Pak M, Lindseth G. Risk Factors for Cholelithiasis. *Gastroenterol Nurs Off J Soc Gastroenterol Nurses Assoc.* 2016;39(4):297–309.
10. Brand B, Lerche L, Stange EF. Symptomatic or asymptomatic gallstone disease: is the gallbladder motility the clue? *Hepatogastroenterology.* 2002;49(47):1208–12.
11. Sigmon DF, Dayal N, Meseha M. Biliary Colic. In *Treasure Island (FL)*; 2021.
12. Helmberger H, Kammer B. [Inflammatory diseases of the gall bladder and biliary system. I. Imaging--cholelithiasis--inflammation of the gall bladder]. *Radiologe.* 2005 May;45(5):479–90; quiz 491.
13. Lee JYJ, Keane MG, Pereira S. Diagnosis and treatment of gallstone disease. *Practitioner.* 2015 Jun;259(1783):2,15-19.
14. Singla S, Piraka C. Endoscopic retrograde cholangiopancreatography [Internet]. Vol. 4, *Clinical Liver Disease.* 2014 [cited 2021 Nov 26]. p. 133–7. Available from: <https://www.niddk.nih.gov/health-information/diagnostic->

tests/endoscopic-retrograde-cholangiopancreatography

15. Gutt C, Schläfer S, Lammert F. The Treatment of Gallstone Disease. *Dtsch Arztebl Int.* 2020 Feb;117(9):148–58.
16. Gurusamy KS, Davidson BR. Surgical treatment of gallstones. *Gastroenterol Clin North Am.* 2010 Jun;39(2):229–44, viii.
17. Hassler KR, Collins JT, Philip K, Jones MW. Laparoscopic Cholecystectomy. In *Treasure Island (FL)*; 2021.
18. Machado NO. Porcelain Gallbladder: Decoding the malignant truth. *Sultan Qaboos Univ Med J.* 2016 Nov;16(4):e416–21.
19. Veld J V, van Huijgevoort NCM, Boermeester MA, Besselink MG, van Delden OM, Fockens P, et al. A systematic review of advanced endoscopy-assisted lithotripsy for retained biliary tract stones: laser, electrohydraulic or extracorporeal shock wave. *Endoscopy.* 2018 Sep;50(9):896–909.
20. Beckingham IJ. ABC of diseases of liver, pancreas, and biliary system. Gallstone disease. *BMJ.* 2001 Jan;322(7278):91–4.
21. Fulcher AS, Turner MA. Benign diseases of the biliary tract: Evaluation with MR cholangiography. *Semin Ultrasound, CT MRI* [Internet]. 1999;20(5):294–303. Available from: <https://www.sciencedirect.com/science/article/pii/S0887217199900616>
22. Litynski GS. Profiles in laparoscopy: Mouret, Dubois, and Perissat: the laparoscopic breakthrough in Europe (1987-1988). *JSL S J Soc Laparoendosc Surg.* 1999;3(2):163–7.
23. Glasgow RE, Cho M, Hutter MM, Mulvihill SJ. The spectrum and cost of complicated gallstone disease in California. *Arch Surg.* 2000 Sep;135(9):1021–7.
24. Lau H, Lo CY, Patil NG, Yuen WK. Early versus delayed-interval laparoscopic cholecystectomy for acute cholecystitis: a metaanalysis. *Surg Endosc.* 2006 Jan;20(1):82–7.
25. Papi C, Catarci M, D'Ambrosio L, Gili L, Koch M, Grassi GB, et al. Timing of cholecystectomy for acute calculous cholecystitis: a meta-analysis. *Am J Gastroenterol.* 2004 Jan;99(1):147–55.
26. Somasekar K, Shankar PJ, Foster ME, Lewis MH. Costs of waiting for gall bladder surgery. *Postgrad Med J.* 2002

Nov;78(925):668–9.

27. Alimoglu O, Ozkan O V, Sahin M, Akcakaya A, Eryilmaz R, Bas G. Timing of cholecystectomy for acute biliary pancreatitis: outcomes of cholecystectomy on first admission and after recurrent biliary pancreatitis. *World J Surg.* 2003 Mar;27(3):256–9.
28. Taylor E, Wong C. The optimal timing of laparoscopic cholecystectomy in mild gallstone pancreatitis. *Am Surg.* 2004 Nov;70(11):971–5.
29. Tseng LJ, Tsai CC, Mo LR, Lin RC, Kuo JY, Chang KK, et al. Palliative percutaneous transhepatic gallbladder drainage of gallbladder empyema before laparoscopic cholecystectomy. *Hepatogastroenterology.* 2000;47(34):932–6.

UNDER PEER REVIEW