

# **Patients Satisfaction with the Methods of Treatment used for Gallstones: A**

## **Cross-sectional Study**

Authors and affiliations

### **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 spotlight the satisfaction levels of the 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 the general population during a period from June to October 2021.

**Results:** Most of the patients were highly satisfied with the treatment clarification done by the treating doctor (n= 42, 8.8%), the treatment choice for gallstones, the complications that occurred during their treatment period (n= 34, 7.1%), their condition after the end of the 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 the 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.

## **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 has 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 (the 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. These are 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 the darkening of the urine. In contrast, the lack of bile in the stool manifests itself as discoloration (cement gray). Possible causes of the 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 but 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 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 a 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 spotlight the satisfaction of Saudi people with regard to treatment methods used in gallstones.

### Study setting

The study was carried out at universities, hospitals, and malls in KSA. Data were collected from the 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 sample size was 300 participants. However, the study included 479 participants.

Inclusion criteria: General population

Exclusion criteria: none.

### Instruments

The data collection tool was self-designed and base on the 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 to the method of treatment were used to summarize continuous variables.

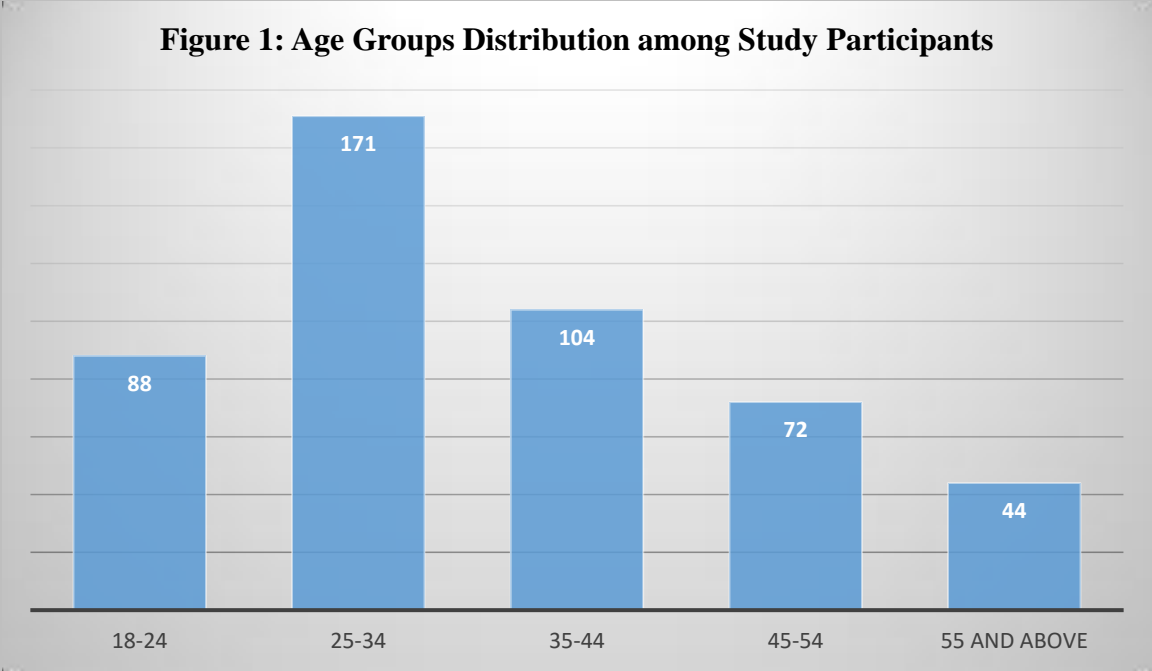
Univariate and multivariate analysis will be performed to investigate the association between age, gender, and most common presentation of gallstone and method of treatment satisfaction. statistical significance is set at a P value of 0.05 or less.

#### 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. Informed consent was sought from the participants.

### **RESULTS**

This study was conducted in order to evaluate patient's satisfaction with the method of treatment used for gallstones. This study included 479 participants. The most frequent age group was 25-34 years with the least frequent age group being 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.

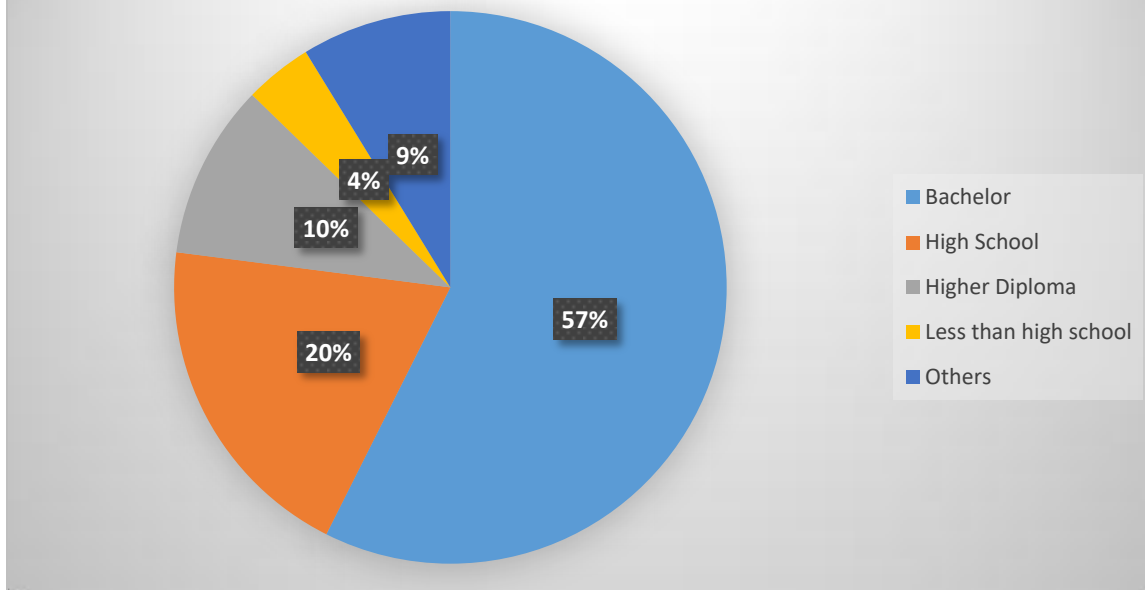


**Table 1: Age groups distribution among study participants according to gender**

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 the educational levels are presented in figure 2.

**Figure 2: Educational Level among Study Participants**



On asking participants whether they had gallstone or not, 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 the symptoms are presented in table 2.

<b>Table 2: Distribution of Symptoms among study participants who had gallstone</b>		
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
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Most of the 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 with their condition after the end of the treatment period (n= 41, 8.6%). Nevertheless, participants were not satisfied with the follow-up after the end of the treatment period (n= 46, 9.6%). Participants were somewhat satisfied regarding the complications that occurred during their treatment period (n= 34, 7.1%). Finally, participants were satisfied regarding the treatment method for the condition (35, 7.3%).

Male gender was found to be more correlated with the diagnosis of gallstones at a p-value of less than 0.001. On the other hand, educational level was more associated with the level of satisfaction with therapy (P= 0.003). The age group was not found to be significantly associated with any other variable.

## **DISCUSSION**

The prevalence of gallstone disease makes it imperative for the 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 Phillipe Mouret of Lyon in March 1987 (20). The introduction of modern imaging techniques and the widespread availability of LC has brought about a paradigm shift with regards to the 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 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 (21). 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. Those with pancreatitis without CBD stones were observed for clinical and biochemical recovery before having LC (22).

Most outpatient referrals for gallstone disease can be safely treated either as outpatient cases or as short overnight (23 hours) in-hospital cases (23). 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 (24).

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 a 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 a good experience, commitment, and continued training in the management of gallstone disease.

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