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Decision-Making in Patients with Gallstones: Therapeutic Modalities

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Introduction

Since decision-making in patients with gallstones is a very common surgical problem, the Permanent Working Party on Clinical Trials (CAS) has chosen it for an experiment for developing practice guidelines in gallstone disease. This experiment combined two methodologies: a carefully planned consensus development conference [1] and the production of a clinical algorithm by an electronically transmitted group response of both the members of the panel and of the general audience [2].

We will present a clinical algorithm for patients with gallstone disease based on aspects of treatment and prognosis of cholelithiasis which are regarded to be important for making a therapeutic decision in gallstone patients: natural course of the disease, perioperative risk analysis, postoperative pain and recovery, the present status of medical litholysis (bile acid therapy – BAT) and extracorporeal shock-wave lithotripsy (ESWL), the aspect of recurrence rate in noninvasive treatment and the role of open cholecystectomy in the laparoscopic era.

Nevertheless, it is absolutely necessary not to lose track of the individual case in connection with the subsequent presentation of the clinical algorithm. Its development for a typical, paradigmatic clinical scenario should not lead to its uncritical and schematic application in individual patients. Thus, the decision for the physician and patient is to prevent a potential future problem, either biliary pain or a biliary complication. To make this decision requires information about prognosis for the outcomes and about the efficacy, safety, and effort of these possible therapies.

Prevalence of Gallstone Disease and Natural Course

Gallstones are very common. The prevalence of cholelithiasis has been shown to be around 10% for females younger than 50 years as against 35% by age 75. In men the figures are 5% under 50 years and 15–20% respectively in the older group [3–5]. The natural course of the disease is shown in figure 1. Two thirds of these persons are asymptomatic and unaware of having gallstones [5, 6]. The annual rate of conversion

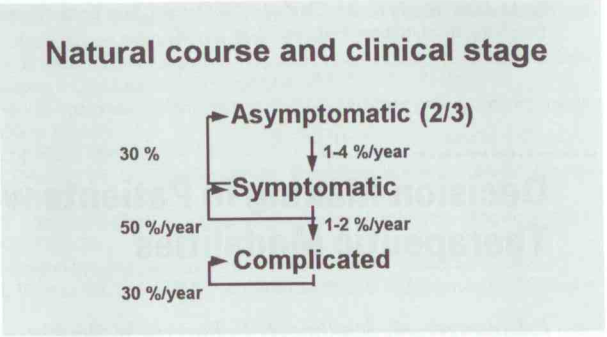


Fig. 1. Natural course and clinical stage of gallstone disease.

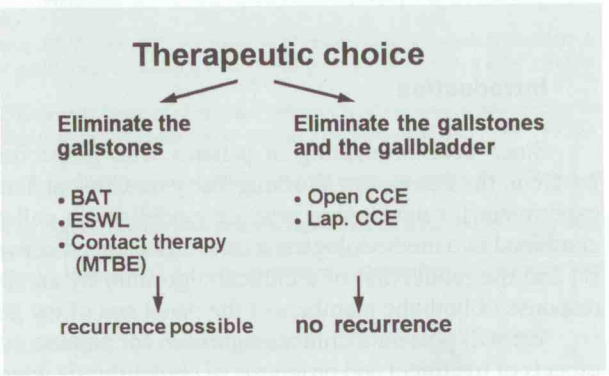


Fig. 2. Therapeutic choice in gallstone disease.

from asymptomatic to symptomatic disease with biliary pain is only 1–4% [7]. 30% of these patients will return to an asymptomatic stage without having further symptoms or complications in the further course of the disease. In contrast, patients having symptoms of gallstone disease have a risk/year of 50% to re-experience upper abdominal biliary pain and show an annual rate to develop biliary complications of 1–2% [7]. Since almost all patients with asymptomatic cholelithiasis develop symptoms before they develop complications there is little evidence and no indication for any prophylactic treatment in the management of asymptomatic gallstones. Exceptions are a calcified gallbladder, which should be removed because of a risk of malignancy that exceeds 25% [8, 9] and, perhaps, gallstones >3 cm in diameter because of possible higher incidence of gallbladder cancer in these patients [10]. In general, the risk/year of developing a gallbladder carcinoma having an asymptomatic gallstone disease appears to be only 0.01% [11]. In contrast, symptomatic patients should be treated to avoid recurrent biliary pain and complications. Today, many treatments are available. The therapeutic choice is to eliminate the gallstones only with the risk of recurrence or to eliminate both the stones and the gallbladder (fig. 2). This distinction between the two types of treatment is important and will be discussed later.

Signs and Symptoms of Gallstones

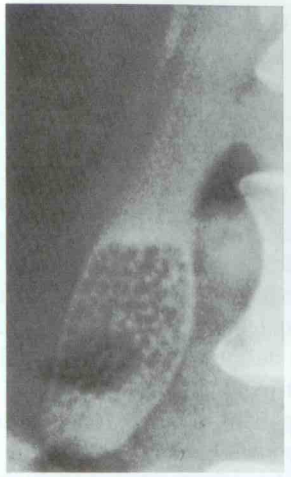
As we have mentioned before, it is of importance to differentiate between symptomatic and asymptomatic gallstones because the indication for any treatment is based upon the presence of symptoms.

It has been clearly shown that so-called dyspeptic complaints such as unspecific upper abdominal pain, fullness, meteorism, nausea, vomiting, fat intolerance, diarrhea as well as constipation occur in comparable frequencies in patients with and without gallstones [12]. In many such cases, gastrointestinal symptoms are due to irritable bowel syndrome, peptic ulcer, or symptomatic hiatal hernia. Therefore, the term 'symptomatic gallstone' must be defined avoiding all kinds of unspecific upper abdominal complaints. We define a symptomatic gallstone as the cause for severe continuous pain in the right hypochondrium or in the epigastrium, lasting 15 min to 5 h, with often waking the patient at night. The symptoms disapper spontaneously or by spasmolytic therapy. There is general agreement that only patients with symptomatic gallstones are candidates for treatment including surgery or nonsurgical management [5, 13–15]. For persons with asymptomatic gallstones, watchful waiting is the best course because natural history is so benign that treatment is generally not recommended [5, 15].

Obligatory Diagnostics

A patient presenting with clinical signs of gallstone disease nowadays undergoes ultrasound examination as the first step and the best choice of noninvasive diagnostics [16, 17]. It has been shown that the presence of gallstones in the gallbladder is accurately estimated by ultrasound in 74–96% of cases [16, 17]. Besides the information about gallstones, ultrasound provides data about the wall of the gallbladder (acute cholecystitis, >4 mm in chronic cholecystitis), the contracting function of the gallbladder (important for BAT and ESWL) and gives information about the common bile duct. However, the accuracy in detecting common bile duct concrements appears to be approximately 30% only [16]. The minimum blood or serum analysis in the management of a gallstone patient includes blood leukocytes to check the degree of inflammation, and serum alkaline phosphatase and total bilirubin to see whether the common bile duct is obstructed by additional stones.

If a nonsurgical treatment is considered, an oral cholecystography should be part of the diagnostic work-up to decide if the patient fulfills the strict inclusion criteria for medical litholysis (BAT) or ESWL (fig. 3, 4). If there surgical therapy is considered, preoperative routine intravenous cholangiography is an easy and noninvasive method to select patients for endoscopic retrograde cholangiopancreaticography (ERCP), also because of its high accuracy in detecting common bile duct stones in 60–90% of all cases [16] with the possibility to remove them endoscopically prior to the operation. Nowadays many surgeons are in favor of routine intraoperative cholangiography during laparoscopic cholecystectomy. The goal of the examination is no longer the detection of unsuspected common bile duct stones only, but also the visualization of anatomical variations of the bile ducts to prevent bile duct injuries [18]. In this question a controversy persists and the standard management is not yet established.



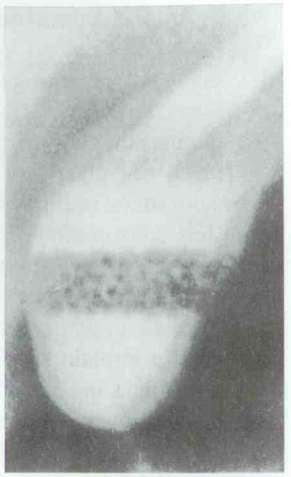


Fig. 3. Oral cholecystogram showing pigmented stones with sedimentation during cholecystogram unsuitable for BAT (*a*). In comparison there are multiple floating cholesterol stones < 7 mm fulfilling the inclusion criteria for BAT (*b*).

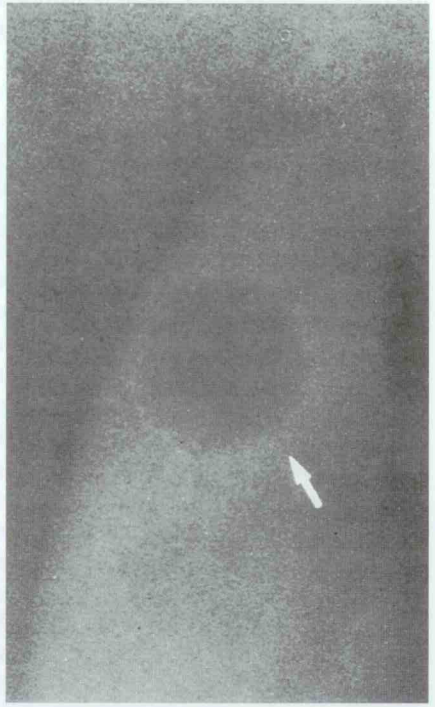


Fig. 4. Oral cholecystogram with a single radiolucent stone < 20 mm suitable for ESWL.

Common Bile Duct Stone Management

Common bile duct stones are known to be found in approximately 10% in patients with cholelithiasis under age 60 [19], and in 15–60% in patients over 60 years [20]. If ultrasound, intravenous cholangiography and/or the serum cholestasis indica-

Medical Litholysis (BAT)

UDC/CDC 7-8 mg/kg tid over 18-24 months

Inclusion criteria

- radiolucent (floating) cholesterol stones < 15 mm
- contracting gallbladder > 60 %
- open cystic duct

⇨ 3-20 % suitable

Fig. 5. Inclusion criteria for medical litholysis (BAT).

tors raise suspicion for common bile duct stones, ERCP with facultative papillotomy is mandatory. By this means and including ESWL as well as local shock-wave lithotripsy [21] the endoscopist is able to treat 90–95% of common bile duct stones without the need for surgery [22]. Furthermore, it has been shown that selective preoperative ERCP and stone removal have a very low morbidity and mortality in the laparoscopic treatment of a complicated gallstone disease [23].

Gallbladder Stone Management: Therapeutic Modalities

Having excluded common bile duct stones or having cleared the ductus choledochus by adequate endoscopic intervention, we will face the alternatives for the treatment of gallbladder stones. Now and for the foreseeable future, laparoscopic cholecystectomy is the procedure of choice for treatment of symptomatic gallstones with the alternatives of BAT, ESWL and conventional cholecystectomy.

Medical Litholysis (BAT)

Medical litholysis is possible applying chenodesoxycholic acid (CDC) in combination with ursodesoxycholic acid (UDC) perorally over 18–24 months. In summary, only 3–20% of all gallstone patients are suitable for this treatment [15, 24] because of the strict inclusion criteria. These are cholesterol stones (roentgen-negative) < 15 mm in size localized in a functioning (contracting) gallbladder with an open cystic duct. Under these conditions the dissolution rate is 60–90% within 1–3 years [15, 24]. The best candidates for this treatment seem to have cholesterol stones that are < 5 mm in diameter and float during oral cholecystography (fig. 3, 5, 6). Disadvantages of BAT are patient selection and compliance, long treatment time and a recurrence rate 2–5 years after successful lysis of 25–50% [15, 24]. On the other hand, the treatment with bile acids is noninvasive, has no mortality and low side effects as transient diarrhea in 2–5% and stone calcification in 5–15% of treated patients [24]. From a surgical point of view, only patients with a considerable comorbidity and patients who choose to avoid operation should be selected for this long-term medical treatment. Because of limited efficacy and inconvenience, BAT has not become very popular in the last years. There are some newly developed techniques of direct litholysis using methyl

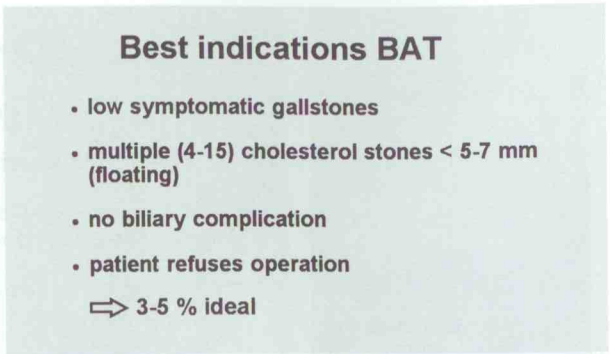


Fig. 6. Best indications for medical litholysis (BAT).

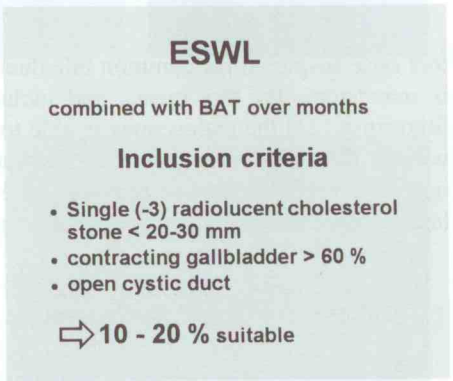


Fig. 7. Inclusion criteria for ESWL.

tert-butyl ether (MTBE) [25]. These approaches are invasive and still represent experimental techniques with considerable morbidity and stone recurrence as high as it is known for oral litholysis [25]. With regard to the rapidly growing experience and standards in performing laparoscopic cholecystectomy, direct ether lysis seems to be an obsolete treatment.

Extracorporeal Shock-Wave Lithotripsy

The fascinating idea of noninvasive shock-wave lithotripsy of gallstones which held great hope in the beginning [26] is now also being restricted to a very selected group of patients. Not more than 10–20% of all symptomatic gallbladder stone patients fulfill the strict inclusion criteria for ESWL [27, 28] which are a radiolucent cholesterol-rich solitary gallbladder stone up to 20 mm in diameter in a well-contracting gallbladder with an open cystic duct (fig. 7, 8). Within this small group of patients, 60–85% are stone-free after 1 year [27, 28]. Patients with multiple (up to 3) and larger stones (up to 30 mm in diameter) have a success rate of only 30–50% within 12 months [27]. Again these patients generally need an additional long-term treatment with medical litholysis for 8–10 months and the recurrence of stones, which is frequently associated with the recurrence of biliary pain, occurs in about 23–30% of patients after 5 years' follow-up [27, 28]. At the end there are only 5–10% of patients which are optimal candidates for ESWL treatment.

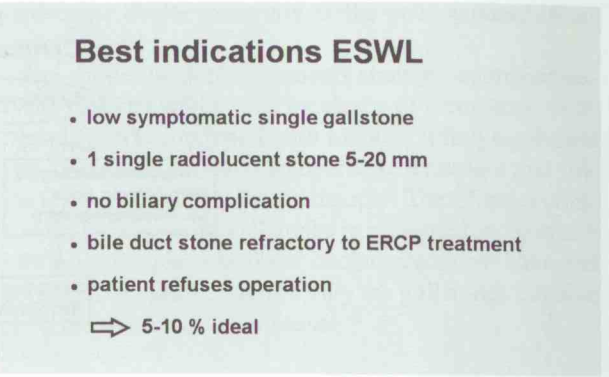


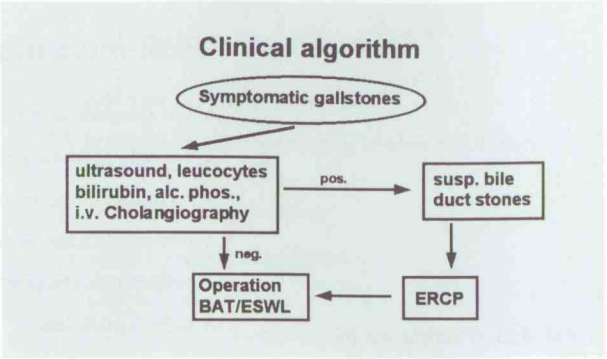
Fig. 8. Best indications for ESWL.

Conventional Cholecystectomy

One hundred and ten years ago the first cholecystectomy was carried out by laparotomy [29]. Within this period of time this procedure has become a highly standardized method all over the world. Elective conventional cholecystectomy nowadays can be carried out with a mortality of 1.5% and a morbidity of around 5–15% [15]. The most serious complication is common bile duct injury, which may require difficult reparative surgery and repeated hospitalizations. However, bile duct injury in open cholecystectomy is uncommon and occurs in approximately 0.1–0.3% [15]. Although conventional cholecystectomy has gained this favorable standard, meanwhile laparoscopic cholecystectomy has won the game because the latter represents the smaller operative trauma with all consequences from that finding. Therefore, the indication for conventional cholecystectomy is restricted to patients with suspected cancer in the gallbladder, certain cases of severe acute or chronic inflammation, liver cirrhosis with portal hypertension, pregnancy, severe upper abdominal adhesions following previous surgery, in patients with cholecystoenteric fistulas and in higher risk patients with complicated biliary disease.

Laparoscopic Cholecystectomy: The New Standard Treatment

Since the introduction of laparoscopic cholecystectomy in 1987 [30] this procedure has initiated a revolution in general surgery. Meanwhile, more than 80% of all elective cholecystectomies are performed laparoscopically in hospitals using this technique [31]. However, this treatment can be restricted by morbid obesity, cardiopulmonary diseases, syndrome of Mirizzi, empyema of the gallbladder, a contracted gallbladder and pregnancy as relative contraindications including severe acute or chronic inflammation and patients who have undergone upper abdominal surgery [32]. A suspected cancer of the gallbladder, liver cirrhosis with portal hypertension, severe coagulopathy and cholecystoenteric fistulas are seen as absolute contraindications for laparoscopic treatment [32]. Acute cholecystitis nowadays may be treated by laparoscopic cholecystectomy, but the safety and timing of surgery should be conclusively evaluated [33]. The intraoperative conversion rate to conventional (open) cholecystectomy is around 5–8% because of adhesions, acute cholecystitis or bleeding complications in most cases [34]. In comparison with open cholecystectomy the patients experience less pain, less postoperative morbidity (pulmonary affections) and a



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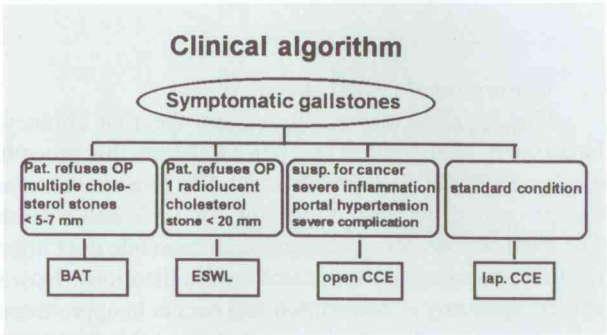

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Fig. 9, 10. Clinical algorithm for decision-making in patients with gallstone disease.

dramatically shortened stay in the hospital [35] due to the smaller trauma. Also the more convenient and more cosmetic scar situation postoperatively has influenced the willingness of patients to get this operation. Interestingly, laparoscopic cholecystectomy has passed open cholecystectomy before the scientific data for the superiority of the former procedure were elaborated indicating the real advantages of this new operation. Although the operative mortality associated with laparoscopic cholecystectomy is 0.2% and less than that with open cholecystectomy, a major concern with the laparoscopic approach has been an increase in the incidence of bile duct injury arising 0.2–0.6% [15, 34]. Clearly, this problem has to be solved in the future. Future research should focus on refining the technique of laparoscopic cholecystectomy to maximize the safety.

Conclusion

Since decision-making in patients with gallstone disease is a very common medical problem with different therapeutic modalities, it is important to distinguish between gallstone patients with the possibility to find the ideal, patient-related gallstone treatment. Only symptomatic patients are candidates for treatment because of the benign natural course of asymptomatic gallstones. Minimal diagnostic requirements are ultrasound, determination of leukocytes, alkaline phosphatase and bilirubin in the blood, and preoperative oral or intravenous cholangiography. Detected common duct stones nowadays should be removed by ERCP. Symptomatic gallbladder stones nowadays are managed by laparoscopic cholecystectomy as the new standard treatment.

Conventional cholecystectomy should be done in patients showing contraindications for the laparoscopic approach. Because of the high incidence of recurrence medical stone dissolution with BAT and ESWL combined with medical litholysis should be restricted to a very small group of patients refusing an operative treatment and fulfilling the strict inclusion criteria for these noninvasive treatments. Therefore, a clinical algorithm for decision-making in patients with gallstones is presented in figures 9 and 10. The techniques of both laparoscopic and open cholecystectomy have the advantage over nonsurgical approaches of eliminating not only the gallstones but also the gallbladder, thereby preventing recurrence of the disease.

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History of Laparoscopic Cholecystectomy

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I enjoy convalescence.
It is the part that makes illne
worthwhile.
G. Bernard Shaw

Introduction

It may be unusual to read about the history of a single operation but, certain
some developments in surgery have had such a tremendous impact on the practice
medicine, that they well deserve their own history chapter. This is the case for lapar
scopic cholecystectomy (LC).

The popularization of LC has been unique for many reasons: LC started far o
side of university settings and major medical centers. The enthusiasm of a few init
tors was encountered first by a large amount of skepticism from the vast majority
the surgical world on one side and the unusual acceptance from laypersons – t
patients and the media – on the other. Finally, LC was introduced into clinical practi
at a speed and fashion which are without precedent in the history of surgery.

LC has become the standard treatment of gallstone disease and the major exp
nent of the so-called *minimal invasive surgery* in only 5 years.

At this point it is very difficult to state anything new about the impact and t
consequences of LC since, 'one should remember that seven years have elapsed sin
it was born, and that we have now reached the point at which all that could be said h
been said' [1]. Therefore, I would like to quote three of the descriptions regarding t
phenomenon of LC found in the medical literature:

'No other surgical development has had such a dramatic and pivotal inpact on abdomi
surgery as laparoscopic cholecystectomy.' [2]

'Over the past five years, a revolution has taken place in general surgery requiring retraining
tens of thousands of surgeons and the retooling of their operating rooms.' [3]

'Laparoscopic cholecystectomy has swept the world like a brushfire and is responsible for t
intense interest in and enthusiasm for surgical endoscopic procedures.' [4]

Antecedents of LC – From Diagnostic to Therapeutic Laparoscopy

Efforts to see within the body were undertaken centuries ago but were strong
limited by the lack of appropriate technology. Modern endoscopy had its start in 18