



## Complete Summary

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### GUIDELINE TITLE

Treatment of gallstone and gallbladder disease.

### BIBLIOGRAPHIC SOURCE(S)

Society for Surgery of the Alimentary Tract (SSAT). Treatment of gallstone and gallbladder disease. Manchester (MA): Society for Surgery of the Alimentary Tract (SSAT); 2003. 4 p.

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates the previously issued version: Society for Surgery of the Alimentary Tract, Inc. Treatment of gallstone and gallbladder disease. J Gastrointest Surg 1998 Sep-Oct;2(5):485-6.

## COMPLETE SUMMARY CONTENT

SCOPE  
METHODOLOGY - including Rating Scheme and Cost Analysis  
RECOMMENDATIONS  
EVIDENCE SUPPORTING THE RECOMMENDATIONS  
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS  
QUALIFYING STATEMENTS  
IMPLEMENTATION OF THE GUIDELINE  
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
CATEGORIES  
IDENTIFYING INFORMATION AND AVAILABILITY  
DISCLAIMER

## SCOPE

### DISEASE/CONDITION(S)

- Gallstone and gallbladder disease
- Acute cholecystitis, gallstone pancreatitis, choledocholithiasis (common duct stones), and cholangitis

### GUIDELINE CATEGORY

Diagnosis  
Evaluation

Risk Assessment  
Treatment

## **CLINICAL SPECIALTY**

Family Practice  
Gastroenterology  
Internal Medicine  
Surgery

## **INTENDED USERS**

Physicians

## **GUIDELINE OBJECTIVE(S)**

To guide primary care physicians to the appropriate utilization of surgical procedures on the alimentary tract or related organs

## **TARGET POPULATION**

Patients with symptomatic gallstone disease

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Diagnosis/Evaluation**

1. Assessment of symptoms
2. Ultrasonography
3. Radionuclide scanning (not recommended)

### **Treatment**

1. Cholecystectomy: laparoscopic and/or open procedures for removal of gallstones
2. Alternative nonstandard forms of treatment, including dissolution of gallstones with oral agents, extracorporeal shock wave lithotripsy, instillation of solvents directly into the gallbladder (Note: Oral dissolution therapy has limited efficacy and is costly. Shock wave lithotripsy and contact dissolution are not approved by the United States Food and Drug Administration [FDA] for definitive treatment of gallstones.)
3. Endoscopic and surgical approaches for removal of common duct stones

## **MAJOR OUTCOMES CONSIDERED**

- Pain relief
- Bile duct injury rate
- Length of hospital stay
- Mortality due to cholecystectomy

## METHODOLOGY

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Not stated

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

### **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Not stated

### **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

Not applicable

### **METHODS USED TO ANALYZE THE EVIDENCE**

Review

### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not applicable

### **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

### **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

The Society for Surgery of the Alimentary Tract (SSAT) guidelines are based on statements and recommendations that were overwhelmingly supported by clinical evidence. Each represents a consensus of opinion and is considered a reasonable plan for a specific clinical condition.

(See companion document Gadacz TR, Traverso LW, Fried GM, Stabile B, Levine BA. Practice guidelines for patients with gastrointestinal surgical diseases. J Gastrointest Surg 1998;2:483-484.)

### **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

The guidelines were reviewed by several committee members and then by the entire committee on several occasions. Each guideline was then sent back to the original author for final comment and reviewed again by the committee. Each guideline was approved by the Board of Trustees of the Society for Surgery of the Alimentary Tract and final comments were reviewed by the committee.

(See companion document Gadacz TR, Traverso LW, Fried GM, Stabile B, Levine BA. Practice guidelines for patients with gastrointestinal surgical diseases. J Gastrointest Surg 1998;2:483-484.)

## **RECOMMENDATIONS**

### **MAJOR RECOMMENDATIONS**

#### **Symptoms and Diagnosis**

Most patients with gallstones do not have symptoms. Natural history studies show that patients with asymptomatic gallstones incidentally discovered will develop symptoms at a rate of approximately 1.5 to 2.0% per year. Typical biliary pain due to gallstones is a temporary (between 1/2 hour to 24 hours) epigastric or right upper abdominal pain following meals. The pain may at times radiate to the right flank or back. In some patients, the symptoms are mild and consist of vague indigestion or dyspepsia. The diagnosis of gallstones is usually established by ultrasonography. Ultrasound findings of a thickened gallbladder wall and fluid around the gallbladder suggest the presence of acute cholecystitis. Radionuclide scanning is not a useful test for the diagnosis of gallstones.

#### **Treatment**

A surgeon should see the patient within a few weeks if the acute episode has resolved or symptoms are mild. Patients with significant right upper quadrant tenderness, fever, or elevated white blood cell count should be seen the same day. The presence of gallstones without abdominal symptoms is not an indication for cholecystectomy unless there is a predisposition for malignancy (i.e., the gallbladder wall is calcified or there is a family history of gallbladder cancer). Once a patient with gallstones becomes symptomatic, elective cholecystectomy is indicated. The primary indication for urgent cholecystectomy is acute cholecystitis.

Gallstone pancreatitis, choledocholithiasis (common duct stones), and cholangitis require surgical consultation. Patients with recurrent symptoms typical of biliary pain, but without gallstones on ultrasound, should be referred for surgical consultation.

Cholecystectomy may be performed by laparoscopic techniques or by laparotomy. The advantages of the laparoscopic approach are less pain, shorter hospital stay, faster return to normal activity, and less abdominal scarring. Alternative, nonstandard forms of treatment include dissolution of gallstones with oral agents, extracorporeal shock wave lithotripsy, and instilling solvents directly into the gallbladder. Oral dissolution therapy has limited efficacy and is costly. Shock wave lithotripsy and contact dissolution are not approved by the United States Food and Drug Administration (FDA) for definitive treatment of gallstones.

### **Conversion of Laparoscopic Cholecystectomy to an Open Procedure**

A laparoscopic approach is feasible in most patients. Conversion to an open procedure may be required because of the presence of adhesions, difficulty in delineating the anatomy, or a suspected complication. Conversion is more often necessary in elderly patients and those with prior upper abdominal operations, a thickened gallbladder wall, or acute cholecystitis. The incidence of conversion to an open procedure is about 5%, depending on the patient population.

### **Treatment of Common Duct Stones**

Common duct stones may be removed either endoscopically or surgically. The endoscopic approach may be indicated for patients with cholangitis, obstructive jaundice, and in selected patients with gallstone pancreatitis. Endoscopic clearance of common duct stones is an effective treatment but may be complicated by pancreatitis, bleeding or perforation in up to 10% cases. Surgical removal of common duct stones can be performed using open or laparoscopic techniques with appropriate equipment and surgical expertise. Open cholecystectomy with common bile duct exploration is a safe and effective treatment, especially in the acutely ill. Since most common duct stones arise from the gallbladder, cholecystectomy is also indicated unless the patient is a poor operative risk.

### **Qualifications for Performing Surgery on the Gallbladder**

At a minimum, surgeons who are certified or eligible for certification by the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or their equivalent should perform laparoscopic and open cholecystectomy. In addition to the standard residency training, qualifications should be based on training, experience, and outcomes.

### **CLINICAL ALGORITHM(S)**

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- After undergoing cholecystectomy for biliary pain, 95% of patients are relieved of the pain.
- The advantages of the laparoscopic approach to cholecystectomy are a shorter hospital stay, faster return to normal activities, and less abdominal scarring compared with the open approach.

### POTENTIAL HARMS

- The risks are low in patients undergoing elective cholecystectomy and include injury to the bile ducts, retained stones in the bile ducts, or injury to surrounding organs. The bile duct injury rate is approximately 0.5% for laparoscopic cholecystectomy. The presence of anatomic variations and/or inflammation contributes to an increased risk of complications including bile duct injury. The mortality rate in a good-risk patient undergoing elective operation is less than 0.1%. Operative risks usually arise from comorbid conditions such as cardiac or pulmonary disease.
- Endoscopic clearance of common duct stones may be complicated by pancreatitis, bleeding or perforation in up to 10% cases.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

These guidelines have been written by the Patient Care Committee of the Society for Surgery of the Alimentary Tract (SSAT). Their goal is to guide primary care physicians to the appropriate utilization of surgical procedures on the alimentary tract or related organs and they are based on critical review of the literature and expert opinion. Both of the latter sources of information result in a consensus that is recorded in the form of these Guidelines. The consensus addresses the **range** of acceptable clinical practice and should not be construed as a standard of care. These Guidelines require periodic revision to ensure that clinicians utilize procedures appropriately, but the reader must realize that clinical judgment may justify a course of action outside of the recommendations contained herein.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Getting Better  
Living with Illness

### **IOM DOMAIN**

Effectiveness  
Timeliness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

### **BIBLIOGRAPHIC SOURCE(S)**

Society for Surgery of the Alimentary Tract (SSAT). Treatment of gallstone and gallbladder disease. Manchester (MA): Society for Surgery of the Alimentary Tract (SSAT); 2003. 4 p.

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

1996 (revised 2003 Feb 1)

### **GUIDELINE DEVELOPER(S)**

Society for Surgery of the Alimentary Tract, Inc - Medical Specialty Society

### **SOURCE(S) OF FUNDING**

Society of Surgery of the Alimentary Tract, Inc.

### **GUIDELINE COMMITTEE**

Patient Care Committee

### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Not stated

### **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

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This guideline updates the previously issued version: Society for Surgery of the Alimentary Tract, Inc. Treatment of gallstone and gallbladder disease. J Gastrointest Surg 1998 Sep-Oct;2(5):485-6.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [Society for Surgery of the Alimentary Tract, Inc. Web site](#).

Print copies: Available from the Society for Surgery of the Alimentary Tract, Inc., 900 Cummings Center, Suite 221-U, Beverly, MA 01915; Telephone: (978) 927-8330; Fax: (978) 524-0461.

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following is available:

- Gadacz TR, Traverso LW, Fried GM, Stabile B, Levine BA. Practice guidelines for patients with gastrointestinal surgical diseases. J Gastrointest Surg 1998;2:483-484.

Electronic copies: Not available at this time.

Print copies: Available from the Society for Surgery of the Alimentary Tract, Inc., 900 Cummings Center, Suite 221-0, Beverly, MA 01915; Telephone: (978) 927-8330; Fax: (978) 524-8890.

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This summary was completed by ECRI on March 28, 2000. The information was verified by the guideline developer as of May 30, 2000. This summary was updated by ECRI on September 9, 2004.

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