Guidelines for the Clinical Application of Laparoscopic Biliary Tract Surgery

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I. PREAMBLE

Laparoscopic cholecystectomy has become the standard of care for patients requiring the removal of the gallbladder. In 1992, an NIH consensus development conference concluded “laparoscopic cholecystectomy provides a safe and effective treatment for most patients with symptomatic gallstones, laparoscopic cholecystectomy appears to have become the procedure of choice for many of these patients”[1]

SAGES first offered guidelines for the clinical application of laparoscopic cholecystectomy in May 1990. These guidelines have periodically been updated and the last guideline in November 2002 expanded the guidelines to include all laparoscopic biliary tract surgery.

This document updates and replaces the previous guideline.

The current recommendations are graded and linked to the evidence utilizing the definitions in appendices A and B.

II. DISCLAIMER

Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by systematic review of available data and expert opinion. Recommendations are not intended to be exclusive given the complexity of the health care environment. These guidelines are intended to be flexible and should be applied with consideration of the unique needs of individual patients and the evolving medical literature. These guidelines are applicable to all physicians who are appropriately credentialed and address the clinical situation in question, regardless of specialty.

Guidelines are developed under the auspices of SAGES and the Guidelines Committee, and are approved by the Board of Governors. Each guideline undergoes multidisciplinary review and is considered valid at the time of production based on data available. Recent developments in medical research and practice pertinent to each guideline will be reviewed, and guidelines will be updated on a periodic basis.

III. INDICATIONS

The indications for laparoscopic operations on the gallbladder and biliary tree have not changed since the 1992 National Institutes of Health Consensus Development Conference Statement on Gallstones and Laparoscopic Cholecystectomy;[1] they remain similar to the indications for open surgery with relative and absolute contraindications as noted below. As stated in the NIH report "most patients with symptomatic gallstones are candidates for laparoscopic cholecystectomy, if they are able to tolerate general anesthesia and have no serious cardiopulmonary diseases or other co-morbid conditions that preclude operation". The indications include but are not limited to symptomatic cholelithiasis, biliary dyskinesia, acute cholecystitis, and complications related to common bile duct stones including pancreatitis (see additional references provided in sections below). Asymptomatic gallstones are generally not an indication for laparoscopic cholecystectomy.[2-7]

Indications for laparoscopic operations on the gallbladder and biliary tree

- Include but are not limited to symptomatic cholelithiasis, biliary dyskinesia, acute cholecystitis, and complications related to common bile duct stones including pancreatitis with few relative or absolute contraindications.(Level II, Grade A).

IV. RELATIVE CONTRA-INDICATIONS AND INDICATIONS FOR PLANNED OPEN PROCEDURES

Relative contra-indications for laparoscopic biliary tract surgery include many of the usual contra-indications for laparoscopic surgery in general. These include, but are not limited to, generalized peritonitis, septic shock from cholangitis, severe acute pancreatitis, untreated coagulopathy, lack of equipment, lack of surgeon expertise, previous abdominal operations which prevent safe abdominal access or progression of the procedure, advanced cirrhosis with failure of hepatic function, and suspected gallbladder cancer.[1] Laparoscopic cholecystectomy may be performed safely in patients with cirrhosis and acute cholecystitis (see additional references provided in sections below), but there are cases in which the open approach may be safer. Indications for planned open procedures include a patient's informed request for an open procedure, known dense adhesions in the upper abdomen, known gallbladder cancer, and surgeon preference.

Relative contra-indications for laparoscopic biliary tract surgery

- Untreated coagulopathy, lack of equipment, lack of surgeon expertise, hostile abdomen, advanced cirrhosis/liver failure, and suspected gallbladder cancer.(Level II, Grade A).

V. PRE OPERATIVE PREPARATION

A. Antibiotic Prophylaxis. Preoperative antibiotics in elective laparoscopic biliary tract surgery have been discussed with strong opinions on both sides. A recent meta-analysis of randomized

controlled trials concluded prophylactic antibiotics do not prevent infections in low risk patients undergoing laparoscopic cholecystectomy, while the usefulness of prophylaxis in high risk patients (age > 60 years, the presence of diabetes, acute colic within 30 days of operation, jaundice, acute cholecystitis, or cholangitis) remains uncertain.[8] The most recent randomized, prospective study included in the above mentioned meta-analysis showed no difference in the postoperative wound infection rate, although the control group had a 1.5% infection rate and the antibiotic group had a 0.7% infection rate; since there was a total of 277 patients in the study, a Type II error might have been committed.[9] Among papers suggesting antibiotic prophylaxis is helpful is a recent randomized study which found fewer wound infections with ampicillin-sulbactam versus cefuroxime, particularly for infection caused by enterococcus in the setting of high-risk patients undergoing elective cholecystectomy.[10] If antibiotics are used they should be limited to a single preoperative dose given within one hour of skin incision, and re-dosed if the procedure is more than 4 hours long.[11]

Antibiotic prophylaxis

- Antibiotics are not required in low risk patients undergoing laparoscopic cholecystectomy. (Level I, Grade A).
- Antibiotics may reduce the incidence of wound infection in high risk patients (age > 60 years, the presence of diabetes, acute colic within 30 days of operation, jaundice, acute cholecystitis, or cholangitis). (Level I, Grade B).
- If given, they should be limited to a single preoperative dose given within one hour of skin incision. (Level II, Grade A).

B. Deep Venous Thrombosis Prophylaxis. This prophylaxis is necessary for most laparoscopic biliary tract procedures and is addressed in a separate SAGES guideline[12] and should consist of either pneumatic compression stockings or subcutaneous Heparin given prior to operation in patients with two or more risk factors. See the above referenced citation for further information.

Deep Venous Thrombosisprophylaxis

- Prophylaxis is addressed in a separate SAGES guideline.[12]

VI. BASIC OPERATIVE TECHNIQUE

A.Room set-up and patient positioning. There are two basic room set-ups for performing laparoscopic biliary tract surgery. The first is the standard supine position with the surgeon standing at the patient’s left and monitors at the head of the bed on both sides. The second is with the patient in stirrups the surgeon standing between the legs. The latter is commonly used in Europe and the former in the Americas. Some surgeons tuck the left arm to improve the working

space of the operating surgeon. The patient is generally placed in a reverse Trendelenburg position and rotated right side up. The SAGES manual[13] describes room set-up, patient positioning, and the remainder of the procedure in further detail.

Room set-up and patient positioning:

- With no data to guide choices, surgeon preference should dictate room set-up. (Level III, Grade A).

B. Equipment needed for laparoscopic cholecystectomy. The equipment needed for laparoscopic cholecystectomy and intraoperative cholangiography is well established with specific preferences left to the discretion of the operating surgeon. The equipment needed for laparoscopic common bile duct exploration is also at the discretion of the operating surgeon and should be available if that is a possibility when performing cholecystectomy. One potential approach to equipment selection is covered in the SAGES manual.[13]

Equipment:

- In the absence of data, surgeon preference should dictate choice of equipment. (Level III, Grade A).

C. Abdominal access. There are a variety of techniques for gaining initial abdominal access for laparoscopic surgery; these include: 1) Veress needle. 2) The open Hasson technique. 3) Direct trocar placement without prior pneumoperitoneum. 4) The optical view technique, in which the laparoscope is placed within the trocar so that the layers of the abdominal wall are visualized as they are being traversed. In general, all of the mentioned approaches to abdominal access are safe. A recent metaanalysis[14] of 17 randomized controlled trials studying a total of 3,040 individuals comparing a variety of open and closed access techniques found no difference in complication rates; potentially life threatening injuries to blood vessels occurred in 0.9 per 1000 procedures and to the bowel in 1.8 per 1000 procedures. Currently, there are no demonstrable differences in the safety of open versus closed techniques for establishing access and creating the initial pneumoperitoneum, therefore decisions regarding choice of technique are left to the surgeon and should be based on individual training, skill, and case assessment.[15]

Abdominal access:

- There are no demonstrable differences in the safety of open versus closed techniques for establishing access; decisions regarding choice of technique are left to the surgeon and should be based on individual training, skill, case assessment. (Level I, Grade A).

D. Safe technique. The safety of laparoscopic cholecystectomy is based largely on determining the anatomy of the cystic duct, common bile duct, cystic artery and hepatic arteries. Since major bile

duct injuries with laparoscopic cholecystectomy are most frequently due to duct misidentification[16, 17], techniques for prevention and/or recognition focus primarily on careful anatomic definition[18] to ensure the “critical view” prior to dividing any structures[19, 20] including dissection 1) to completely expose and delineate the hepatocystic triangle, 2) to identify a single duct and a single artery entering the gallbladder, and 3) to completely dissect the lower part of the gallbladder off the liver bed. Though the protective effect of the practice continues to be debated, routine use of intraoperative cholangiography may decrease the risk or severity of injury and improve injury recognition.[17, 21-23] The general principle of not dividing any structure until you are certain of its identification applies here; the need for caution and vigilance cannot be overstated given evidence which supports visual misperception as an underlying cause of major bile duct injury[24], coupled with the potential for complacency which may result from the rarity of bile duct injuries.

Safe technique:

- The safety of laparoscopic cholecystectomy requires correct identification of relevant anatomy. (Level I, Grade A).
- Intraoperative cholangiogram may reduce the rate or severity of injury and improve injury recognition. (Level II, Grade B).

E. Common Bile Duct Assessment. The primary methods for assessing the common bile duct for stones or injury during cholecystectomy are intraoperative cholangiogram and intraoperative ultrasound.

1. Intraoperative cholangiography has been used for many years; fluoroscopy saves time and has improved its usefulness. The issue of routine verses selective cholangiography has been long debated. Studies have suggested routine use of intraoperative cholangiography may decrease the risk of injury and improve injury recognition while others have suggested cholecystectomy may be performed without cholangiogram with low rates of injury.[17, 21-23] In residency programs, a policy of routine cholangiography may be supported by the need to train residents how to do that portion of the procedure.[25] In addition, the skills developed and maintained by routine cholangiography provide a platform for progression to transcystic clearing or stenting of the common bile duct[25]; in many cases clearing can be accomplished with simple measures such as administration of glucagon and flushing with saline.[26] In terms of detecting bile duct stones, 2-12% of patients will have choledocholithiasis on routine intraoperative cholangiogram, and recent studies suggest as many as 10% of these are unsuspected prior to operation.[27-29] A meta-analysis performed in 2004[30] revealed that the incidence of unsuspected retained stones was 4% with only 15% of these going on to cause clinical problems. The conclusion from that study was that a selective policy should be advocated, though creating a reliable algorithm for predicting the presence of stones and thus the need for selective cholangiogram has been unsuccessful.[31, 32]
2. Laparoscopic ultrasound. This technique has been used increasingly; while it does not by

itself offer potentially therapeutic access to the bile ducts, it does help delineate relevant anatomy including bile ducts and vascular structures, and can diagnose choledocholithiasis without opening the biliary system, all without exposure to ionizing radiation. Several recent studies have examined the use of laparoscopic ultrasound during cholecystectomy. Potential advantages and disadvantages of the technique have been summarized by Perry et.al.; advantages include high rates of successful studies, the ability to repeat the examination during difficult dissections, less time required for completion, and lower overall cost, while disadvantages include technical difficulties for certain patients, inability to confirm the flow of bile into the duodenum, and the experience required to learn the technique of examination and image interpretation.[33] The authors of the included studies used the technique routinely with no reported bile duct injuries and minor bile leaks due to secondary to liver bed injury a rare event (0.2%), and with high sensitivity and specificity for the detection of common bile duct stones.[33-36]

Common Bile Duct Assessment:

- Intraoperative cholangiography may decrease the risk of bile duct injury when used routinely and allows access to the biliary tree for therapeutic intervention; reliable algorithms to determine the need for selective cholangiography have yet to be developed. (Level II, Grade B).
- In experienced hands, intraoperative laparoscopic ultrasound helps delineate relevant anatomy, detect bile duct stones, and decrease the risk of bile duct injury. (Level II, Grade B).

F. Management of choledocholithiasis.

1. 1. Approaches to suspected choledocholithiasis. With increasing laparoscopic expertise, exploration the common bile duct either via the cystic duct or by primary choledochotomy has become a viable option, but the treatment of symptomatic or suspected common bile duct stones in the era of laparoscopic cholecystectomy remains a complex and controversial issue. Leaving aside open cholecystectomy/bile duct exploration, which is superior to ERCP for stone clearance[37], as described by Kharbutli and Velanovich[38] there are two approaches to patients with possible choledocholithiasis who are undergoing laparoscopic cholecystectomy, both for patients who are asymptomatic undergoing elective cholecystectomy, and for patients with recent episodes of jaundice or gallstone pancreatitis: (1) laparoscopic cholecystectomy with intraoperative cholangiogram, then address choledocholithiasis if found, or (2) preoperative ERCP to diagnosis and remove choledocholithiasis, followed by laparoscopic cholecystectomy. For choice (1), a number of additional choices are possible for stones found during intraoperative imaging studies: (A) transcystic laparoscopic common bile duct exploration, (B) common bile duct exploration via choledochotomy), (C) Placement of an endobiliary stent, (D) postoperative ERCP, and intraoperative ERCP. Several recent studies including at least two meta-analyses have

attempted to compare the relative merits of the above approaches, and one stage treatment combining laparoscopic cholecystectomy with laparoscopic common bile duct exploration usually prevails in terms of cost with no discernable difference in morbidity and mortality. With that said, pre-operative ERCP should not be used for diagnosis alone; routine pre-operative ERCP will likely result in a higher than acceptable mortality and morbidity rates with some unnecessary procedures. The single stage laparoscopic or the combined laparoscopic with intraoperative endoscopic approaches require time, equipment, and a degree of skill and experience which are not universal among surgeons and facilities performing laparoscopic cholecystectomy. Finally, post-operative ERCP leads to longer hospital stays with increased numbers of procedures required to treat the problem.[37-44]

1. Transcystic common bile duct exploration. Given the scope of issues detailed above, the choice of technique to treat common duct stones will likely depend largely on local expertise. However, both short and long term data from a number of studies suggest transcystic common bile duct exploration, which may be augmented by choledocoscopy, is as safe and efficacious as other minimally invasive approaches.[31, 37, 40, 45-49] The postoperative course after successful transcystic clearance is similar to laparoscopic cholecystectomy alone.[25, 45] Transcystic stone clearance may be hampered by analomous anatomy, proximal (hepatic duct) stones, strictures and large (>6mm) or numerous stones (>5).[25, 31, 40, 47]
2. Choledochotomy. Laparoscopic common bile duct exploration via choledochotomy requires advanced laparoscopic skills and longer operative times; most authors see choledochotomy as an alternative to failed transcystic exploration though some explore via choledochotomy exclusively, all with generally good results in terms of stone clearance. The open bile duct may be addressed with closure over a T-tube, an exteriorized transcystic drain, or primary closure with or without endoluminal drainage.[49-51] Closure over a T-tube may be required if the common bile duct is inflamed[52] and in any case allows for postoperative radiographic evaluation of the biliary system, the possibility of extraction of retained stones, and the possibility of a controlled biliary fistula, but can be complicated by premature dislodgement, bile leak and peritonitis, localized pain, prolonged fistula, and late biliary stricture.[50] Studies comparing primary closure versus T-tube drainage suggest similar rates of complications with shorter operating times and a trend toward shorter hospital stays with primary closure.[51, 53]
3. Laparoscopic endobiliary stent placement. This treatment option for choledocholithiasis effectively bridges the gap between laparoscopic common bile duct exploration and ERCP; the technique involves placing a stent through the cystic duct into the common bile duct and across the ampulla of Vater, then closing the cystic duct. The advantages of this approach include decompression of the biliary tree allowing the option of semi-elective postoperative ERCP which for most patients maintains the minimally invasive approach and ambulatory nature of laparoscopic cholecystectomy; the stent adds little operative time to the procedure, the stent facilitates ERCP and stone clearance while potentially reducing the

incidence of post-ERCP pancreatitis, and deployment does not require advanced laparoscopic skills.[54-57]

4. ERCP with stone extraction. ERCP with stone extraction is another alternative when faced with choledocholithiasis; it may be performed before, during or after cholecystectomy. As dicussed by Costi et.al.[58], “performing ERCP before surgery raises questions regarding patient selection because systematic preoperative ERCP before LC means an intolerably great number of unnecessary and potentially harmful procedures. Complex scoring systems aimed at identifying asymptomatic patients to undergo ERCP have not been adopted as clinical practice, nor have new examinations such as echoendoscopy and biliary magnetic resonance imaging (MRCP), which are costly and not always available. Performing ERCP contextually to LC implies organizational problems concerning the availability of an endoscopist in the operating theater whenever needed. Finally, performing ERCP after surgery would raise the dilemma of managing CBD stones whenever ERCP fails to retrieve them because a third procedure would then be needed.” With no discernable difference in morbidity and mortality and similar clearance rates when compared to laparoscopic common bile duct exploration, duct clearance with postoperative ERCP is a viable alternative.[37-44] While, in experienced hands, the two approaches are at least equivalent, there are surgeons for whom the preferred approach is ERCP with stone extraction.[41] However, unless performed intraoperatively, ERCP requires at least one additional procedure, and does have associated complications such as pancreatitis, bleeding, and duodenal perforation, and as noted above, ERCP may fail, leading to multiple procedures for stone clearance. As described by Karaliotas et.al., the following entities increase the possibility of failure of endoscopic CBD stone clearance: stone impaction, gastrectomy or Roux-en-y anatomy, recurrent bile duct stones stones after prior open exploration of the CBD and biliodigestive anastomosis, periampullary diverticula, and Mirizzi syndrome. [52]

2. Altered anatomy. Rearrangement of the upper gastrointestinal tract can make it difficult, if not impossible, to perform standard ERCP. With the recent increase in the number of Roux-en-Y gastric bypass procedures performed for morbid obesity, it becomes ever more likely that surgeons will encounter patients who have gallstone disease and limited endoscopic access to the biliary system. As described by Ahmed et.al, options for treatment include percutaneous transhepatic instrumentation of the common bile duct, percutaneous transgastric ERCP, laparoscopic transgastric ERCP, transenteric ERCP, retrograde endoscopy in which the scope is passed antegrade down to the jejunojejunostomy and then retrograde up the biliopancreatic limb, and open or laparoscopic common bile duct exploration.[59]

Management of Choledocholithiasis:

- There are several approaches and current data does not suggest clear superiority of any one approach; decisions regarding treatment are most appropriately made based on

surgeon preference as well as the availability of equipment and skilled personnel. (Level I, Grade A).

- Laparoscopic transcystic common bile duct exploration may employ a number of techniques from simple to advanced; it is frequently successful, but may be hampered by analomous anatomy, proximal stones, strictures and large or numerous stones. (Level II, Grade B).
- Laparoscopic choledochotomy requires advanced laparoscopic skills, but has good clearance rates; the open bile duct may be addressed with closure over a T-tube, an exteriorized transcystic drain, or primary closure with or without endoluminal drainage.(Level II, Grade B).
- Laparoscopic endobiliary stent placement adds little operative time to the cholecystectomy, and facilitates ERCP and stone clearance.(Level II, Grade B).
- ERCP with stone extraction may be performed selectively before, during or after cholecystectomy with little discernable difference in morbidity and mortality and similar clearance rates when compared to laparoscopic common bile duct exploration, though routinely performed preoperative ERCP will likely result in unnecessary procedures with higher than acceptable mortality and morbidity rates. (Level I, Grade A).

G.Dissection of the gallbladder from the liver bed. The conventional technique for dissection of the gallbladder from the liver bed is to start from the gallbladder infundibulum and work superiorly using electrocautery to remove the gallbladder from the bed. The technique of top down dissection has also been advocated, particularly in cases with significant inflammation.[60-62] Ultrasonic dissection has been studied for dissection of the gallbladder from the liver bed, as well as division and sealing of the cystic artery and cystic duct without clips; in prospective randomized trials, ultrasonic dissection has been found to be comparable in terms of operative times, gallbladder perforation, bleeding, and bile leak.[61, 63] In addition, hydrodissection with a high-pressure water stream has been used to dissect the gallbladder from the liver bed.[64] The standard technique works well and, with no compelling data to use these alternative techniques, the choice is left to the operating surgeon.

Dissection of the gallbladder from the liver bed:

- The more conventional approach starting at the gallbladder infundibulum and working superiorly, or the top down approach, may be used with electrocautery, ultrasonic dissection, or hydrodissection as the surgeon prefers. (Level II, Grade B).

H.Extraction of the gallbladder. The gallbladder is generally extracted from either the epigastric port or the umbilical port. The decision is left up to the operating surgeon. Some surgeons use a 5 mm port in the epigastric position, necessitating removal through the umbilicus. Likewise, most difficult extractions due to the large size of the gallbladder should be done through the umbilicus because it is easier to expand the fascial incision. The use of an endoscopic bag is also at the discretion of the operating surgeon. There are no randomized studies to guide use of these techniques.

Extraction of the gallbladder:

- With no data to guide choice of technique, the gallbladder may be extracted as the surgeon prefers. (Level III, Grade C).

I.Use of drains. While use of drains postoperatively after laparoscopic biliary tract surgery is at the discretion of the operating surgeon, recent studies including a randomized controlled trial and meta-analysis of 6 randomized controlled trials found drain use after elective laparoscopic cholecystectomy increases post-operative pain, wound infection rates and delays hospital discharge; the authors furthered stated they could not find evidence to support the use of drains after laparoscopic cholecystectomy.[65, 66]

Use of Drains:

- Drains are not needed after elective laparoscopic cholecystectomy and their use may increase complication rates. (Level I, Grade A).
- Drains may be useful in complicated cases particularly if choledochotomy is performed. (Level III, Grade C).

J.Conversion to laparotomy. Conversion from laparoscopic to open cholecystectomy should not be considered a complication, but is rather an attempt to avoid complications and ensure patient safety.[67] Factors which are associated with conversion to open cholecystectomy include: acute cholecystitis with a thickened gallbladder wall, previous upper abdominal surgery, male gender, advanced age, obesity, bleeding, bile duct injury, and choledocholithiasis.[67-73] Ultimately, individual surgeons must base the decision to convert to an open procedure on their own intraoperative assessment, weighing the severity of inflammatory changes, clarity of the anatomy, and their skill/comfort in proceeding.[72] Overall conversion rates have been reported to be between 2-15%[67], and in cases of acute cholecystitis from 6-35%.[71]

Conversion to laparotomy:

- Conversion should not be considered a complication and surgeons should have a low threshold for conversion; the decision to convert to an open procedure must be based on intraoperative assessment weighing the clarity of the anatomy and the surgeon’s skill/comfort in proceeding. (Level II, Grade A).

VII. INTRAOPERATIVE COMPLICATIONS

A.Access injuries. Establishing access and creating the initial pneumoperitoneum necessary to perform laparoscopic biliary tract procedures may lead to significant complications. Reviews of data regarding device-related injury and death as reported to the Food and Drug Administration(FDA)[74] as well as thorough reviews of the available literature[15] suggest vascular and visceral injuries are

the major causes of morbidity and mortality related to abdominal access. The true rates of injury are difficult to gauge; injuries are probably underreported both to the FDA and in the literature, and there is a paucity of prospective data, but it is likely that injuries which occur while establishing pneumoperitoneum account for a significant proportion of complications during laparoscopy.[15, 74, 75] Laparoscopic cholecystectomy is the procedure most frequently associated with both fatal and nonfatal trocar injuries, and almost all fatal injuries were made with shielded or optical trocars.[74] A recent metaanalysis of 17 randomized controlled trials studying a total of 3,040 individuals comparing a variety of open and closed access techniques found no difference in complication rates; potentially life threatening injuries to blood vessels occurred in 0.9 per 1000 procedures and to the bowel in 1.8 per 1000 procedures. [14] Currently, there are no demonstrable differences in the safety of open versus closed techniques for establishing access and creating the initial pneumoperitoneum, therefore decisions regarding choice of technique are left to the surgeon and should be based on individual training, skill, and case assessment.[15] A high index of suspicion and prompt conversion to laparotomy are required to recognize and treat complications related to access.

Access injuries

- There are no demonstrable differences in the safety of open versus closed techniques for establishing access; decisions regarding choice of technique are left to the surgeon and should be based on individual training, skill, case assessment. (Level I, Grade A).
- A high index of suspicion and prompt conversion to laparotomy are required to recognize and treat complications related to access.(Level III, Grade A).

B.Common bile duct injuries. A great deal continues to be written about bile duct injuries in laparoscopic cholecystectomy, which serves to underscore the seriousness of the complication and the perception that it can and should be avoided. The current rate of major bile duct injury in laparoscopic cholecystectomy has stabilized at 0.1-0.6%[18, 21-23, 76-78] and series with no major bile duct injuries have been reported[20] ; while many believe the rate of major bile duct injury in open cholecystectomy is lower than laparoscopic cholecystectomy, controversy remains.[76, 78] A host of factors have been associated with bile duct injury including surgeon experience, the patient's age, male sex, [22] and acute cholecystitis, though the effect acute cholecystitis has on injury rates remains controversial.[23, 79, 80] Bile duct injuries which occur with laparoscopic cholecystectomy frequently involve complete disruption and excision of ducts, and may be associated with hepatic vascular injuries.[81-83] If major bile duct injuries do occur, whether recognized at the time of the primary operation or in the postoperative period, outcomes are improved by early recognition and by referring patients immediately to experienced specialists for further diagnosis and treatment. Repair should not be attempted by the primary surgeon unless the primary surgeon has significant experience in biliary reconstruction.[77, 84-86] Since major bile duct injuries with laparoscopic cholecystectomy are most frequently due to duct misidentification[16, 17], techniques for prevention and/or recognition focus primarily on careful anatomic definition[18] to ensure the "critical view" prior to dividing any structures[19, 20] and though the protective effect of the practice continues to be

debated, use of intraoperative cholangiography may decrease the rate or the severity of common bile duct injury.[17, 21-23]

Common bile duct injuries:

- Factors which have been associated bile duct injury include surgeon experience, patient age, male sex, and acute cholecystitis. (Level II, Grade C).
- The safety of laparoscopic cholecystectomy requires correct identification of relevant anatomy. (Level I, Grade A).
- Intraoperative cholangiogram may reduce the rate or severity of injury and improve injury recognition. (Level II, Grade B).
- If major bile duct injuries occur, outcomes are improved by early recognition and immediate referral to experienced hepatobiliary specialists for further treatment before any repair is attempted by the primary surgeon, unless the primary surgeon has significant experience in biliary reconstruction.(Level II, Grade A).

VIII. SPECIAL CONSIDERATIONS

A.Biliary dyskinesia. Patients with symptoms of biliary obstruction without evidence of gallstones, but with abnormal gall bladder emptying may benefit from laparoscopic cholecystectomy.[87-92] Symptoms may include episodic, severe, steady pain, frequently with fatty food intolerance, located in the right upper quadrant or epigastrium, with or without radiation to the back or shoulder lasting at least 30 minutes but less than several hours, and may potentially be associated with nausea and vomiting.[89, 90] Abnormal gallbladder emptying is usually defined as a gallbladder ejection fraction of less than 35% with cholescintigraphy after injection of cholecystokinin.[88-90] Severe symptoms, a very low gallbladder ejection fraction (65 years) may be associated with higher morbidity and mortality[122, 123].

Acute cholecystitis:

- Laparoscopic cholecystectomy has become the preferred approach in patients with acute cholecystitis. (Level II, Grade B).
- Early cholecystectomy (within 24-72 hours of diagnosis) may be performed without increased rates of conversion to an open procedure, without an increased risk of complications, and may decrease cost and total length of stay. (Level I, Grade A).
- In critically ill patients with acute cholecystitis, radiographically guided percutaneous cholecystostomy is an effective temporizing measure until the patient recovers sufficiently to undergo cholecystectomy. (Level II, Grade B).

C.Gallstone pancreatitis. Acute pancreatitis caused by gallstones is an important indication for cholecystectomy. The incidence of acute pancreatitis due to gallstones appears to be increasing.[124, 125] Based on a study of one large state’s discharge data, one-third of cases of

acute pancreatitis among US adults are caused by gallstones with an incidence of gallstone pancreatitis of approximately 14.5 per 100,000, [125] which translates into 31,500 cases per year nationally. While laparoscopic cholecystectomy has become the preferred approach for removing the source of stones,[126] the timing of the cholecystectomy, as well as the choice and timing of procedures for evaluating and clearing associated common bile duct stones, remain controversial, particularly in cases of mild, self-limited gallstone pancreatitis. There is agreement that severe pancreatitis with ongoing multi system organ failure requires immediate clearing of any biliary obstruction, usually with ERCP, followed by supportive care until the patient recovers sufficiently to tolerate cholecystectomy.[127] However, when pancreatitis caused by gallstones is mild and self limited, the issue becomes preventing recurrent episodes of biliary symptoms, including acute pancreatitis. Currently, the majority of surgeons advocate and perform cholecystectomy urgently, when symptoms have subsided and laboratory values have normalized, usually during the same hospital admission[96, 126-133], while others delay cholecystectomy for weeks; decision making algorithms regarding approaches to pre- versus intraoperative common bile duct evaluation and clearance are even more provider dependent, though patients with mild pancreatitis generally do not benefit from preoperative ERCP.[126, 134] A recent meta-analysis[39] showed no difference in morbidity and mortality when endoscopic removal of common bile duct stones with cholecystectomy was compared to cholecystectomy with intraoperative removal of common bile duct stones; the authors went on to state that treatment should be determined by local resources and expertise.

Gallstone pancreatitis:

- Laparoscopic cholecystectomy has become the preferred approach for removing the source of stones in cases acute pancreatitis due to gallstones. (Level II, Grade B).
- Severe pancreatitis with ongoing multi system organ failure requires immediate clearing of any biliary obstruction followed by supportive care until the patient recovers sufficiently to tolerate cholecystectomy. (Level I, Grade A).
- When pancreatitis caused by gallstones is mild and self limited, urgent cholecystectomy should be performed after symptoms have subsided and laboratory values have normalized, usually during the same hospital admission. (Level II, Grade B).

D. Laparoscopic cholecystectomy in the setting of pregnancy. Please see the published SAGES guidelines and associated review article regarding diagnosis and laparoscopic treatment of surgical diseases during pregnancy.[135]

Laparoscopic cholecystectomy in the setting of pregnancy:

- Please see the published SAGES guidelines and associated review article regarding diagnosis and laparoscopic treatment of surgical diseases during pregnancy.[135]

E. Laparoscopic cholecystectomy surgery in the setting of cirrhosis. Cirrhosis places patients at an

increased risk for gallstone formation[136-138] Since the NIH consensus conference on gallstones and laparoscopic cholecystectomy in 1992 suggested patients with cirrhosis were “not usually candidates for laparoscopic cholecystectomy”[1] studies continue to be published supporting the safety of the approach in patients with Child’s A or B cirrhosis (including downgrading from C after appropriate treatment)[39] with almost no data using the MELD score to compare patients[139]; though there is little published data for Child’s C patients, what is available suggests it should be avoided in favor of non-operative approaches such a percutaneous cholecystostomy.[140] Recent studies generally agree laparoscopic cholecystectomy in selected cirrhotics has a relatively low conversion rate (0- 11%), complication rate (9.5-21%), and risk of dying (0-6.3%), with most showing worsening liver failure, including the presence of ascites and coagulopathy, predicting poorer outcomes[139-144]; a recent prospective randomized trial found laparoscopic cholecystectomy was safer than open cholecystectomy in cirrhotics.[145] Some authors have suggested laparoscopic subtotal cholecystectomy as an alternative to laparoscopic cholecystectomy.[146, 147] Most authors caution that bleeding is the most frequent and worrisome complication suggesting that coagulopathy and thrombocytopenia be corrected preoperatively, and that dilated pericholecystic and abdominal wall veins or recanalized umbilical veins be treated with care, with one author noting “conversion to open does not correct coagulopathy”.[142, 143]

Laparoscopic cholecystectomy surgery in the setting of cirrhosis:

- Laparoscopic cholecystectomy is relatively safe in patients with Child’s A or B cirrhosis. (Level I, Grade B).
- Laparoscopic cholecystectomy is not recommended for Child’s C patients. (Level III, Grade C).
- Bleeding is the most frequent complication; coagulopathy and thrombocytopenia should be corrected preoperatively, and dilated pericholecystic and abdominal wall veins or recanalized umbilical veins be treated with care. (Level II, Grade A).

F. Laparoscopic cholecystectomy in the setting of systemic anticoagulation. There is little published data regarding laparoscopic cholecystectomy in the setting of systemic anticoagulation, but there are at least two recently published studies of patients taking warfarin for long term systemic anticoagulation.[148, 149] In both, patients had their warfarin discontinued and were bridged to surgery with low molecular weight heparin as inpatients, and laparoscopic cholecystectomy was performed after their INR was 1.5 or less. In one study of 44 anticoagulated patients, postoperative bleeding was significantly more common in the oral anticoagulation group (25%) versus the control group (1.5%), and in the majority of cases, bleeding in the oral anticoagulation group was serious, requiring blood transfusion or reoperation with a concomitantly longer hospital stay with standard laboratory tests not predicting postoperative hemorrhage,[148] while the other study with 33 anticoagulated patients reported no bleeding complications.[149] Based on similar rates of bleeding from other studies of laparoscopic procedures reviewed by the authors, caution in chronically anticoagulated patients is warranted, particularly in those requiring bridging with low molecular weight heparin.[148]

Laparoscopic cholecystectomy in the setting of systemic anticoagulation:

- Caution in chronically anticoagulated patients is warranted even after cessation of pharmacotherapy, particularly in those bridged with low molecular weight heparin. (Level III, Grade B).

G. Porcelain gallbladder. The relationship between calcification of the gallbladder wall and gallbladder cancer has been oft-repeated; however there is relatively little published data regarding the relationship between the two with almost no published data from this decade. One of the most recent available studies from 2000[150] reviewed pathological findings from 25,900 cholecsytetomies over 27 years; there were 150 gallbladders with cancer and 44 with calcified walls, 17 with complete intramural calcification (the classic porcelain gallbladder) and 27 with selective mucosal calcification. None of the specimens with complete intramural calcification had concomitant associated cancer while only 2 of the 27 with selective mucosal calcification had associated cancer correlating with a 5% incidence in calcified gallbladders (0% in true porcelain gallbladders). There is one study from 2004 addressing calcified gallbladders in laparoscopic cholecystectomy[151] with 13 of 1,608 laparoscopic cholecystectomy specimens having calcified walls, again noting no cancer in 10 gallbladders with complete intramural calcification while 1 of 3 specimens with selective mucosal calcifications had associated cancer, which suggests patients with suspected calcifications should be carefully studied, with open cholecystectomy recommended for those with selective mucosal calcifications.

Porcelain gallbladder:

- Patients with suspected gallbladder calcifications should be carefully studied, with open cholecystectomy recommended for those with selective mucosal calcifications. (Level III, Grade B).

H. Gallbladder polyps. Polyploid lesions of the gallbladder, which can be found in about 1-5% of adults on ultrasound in Western populations [152, 153] and 9.6% in Asian populations[154], are defined as elevations of the gallbladder mucosa. Polyploid lesions of the gallbladder can be true polyps which demonstrate neoplastic changes and may be benign, dysplastic or malignant, or can be pseudopolyps such as cholesterol polyps, inflammatory polyps, or adenomyoma which are all benign.[152, 155] Gallbladder polyps are most frequently cholesterol polyps, which are usually small (less than 1cm) and multiple, and tend to remain stable with regard to size and number. Patients with cholesterol polyps usually do not develops concomitant stones or symptoms.[156] A recent comparison of preoperative ultrasound findings with pathological examination of cholecystectomy specimens in Western patients suggests size is the only reliable indicator for malignant potential with all malignancies found in polyps greater than 6mm[152] though non-Western populations may develop malignancies in smaller polyps.[155] There are no randomized studies to direct decisions regarding gallbladder polyps[157] and despite recent studies, the management of gallbladder polyps remains controversial. A reasonable approach would include laparoscopic cholecystectomy for

larger, especially single, polyps or those with associated symptoms with watchful waiting for small (Gallbladder polyps:

- Laparoscopic cholecystectomy should be considered for larger, especially single, polyps or those with associated symptoms, with watchful waiting for small (

I. Gallbladder cancer. The incidence of gallbladder cancer in the US is 1.2/100,000; the only curative therapy is surgical resection, and except for those with early stage disease, survival is extremely poor. Gallbladder cancer is found unexpectedly upon pathological examination in less than 1% specimens after laparoscopic cholecystectomy.[158, 159] Laparoscopic cholecystectomy is considered curative for cancers confined to the gallbladder mucosa (T1a), while cancers which invade the muscularis (T1b) may have lymph node metastases or lymphatic invasion which prompts some authors to recommend hepatoduodenal lymph node dissection for these lesions, but an initial open versus laparoscopic approach does not influence survival.[160-163] Inadvertent opening of cancerous gallbladders during laparoscopic cholecystectomy increases the likelihood of recurrence and port site metastases.[164-166] Cancers which are more locally advanced or those with nodal involvement should be referred to specialty centers for consideration of more extensive resection or re-resection.[159]

Gallbladder cancer:

- Laparoscopic cholecystectomy is considered curative for cancers confined to the gallbladder mucosa (T1a). (Level II, Grade B).
- Cancers which are more locally advanced or those with nodal involvement should be referred to specialty centers for consideration of more extensive resection or re-resection. (Level II, Grade B).

IX. POSTOPERATIVE MANAGEMENT

A. Length of stay. Patients undergoing uncomplicated laparoscopic cholecystectomy for symptomatic cholelithiasis may be discharged home on the day of surgery.[167] Control of postoperative pain, nausea, and vomiting are important to successful same day discharge,[168] and admission rates despite planned same day discharge are reported to be 1-39%; patients older than age 50 may be at increased risk for admission.[168-174] Readmission rates range from 0-8%; common causes for readmission after same day discharge include pain, intabdominal fluid collections, bile leaks, and bile duct stones.[167, 170] Time to discharge after surgery for patients with acute cholecystitis, bile duct stones, or in patients converted to an open procedure should be determined on an individual basis.

Length of stay:

- Patients undergoing uncomplicated laparoscopic cholecystectomy for symptomatic

cholelithiasis may be discharged home on the day of surgery; control of postoperative pain, nausea, and vomiting are important to successful same day discharge. (Level II, Grade B)
- Patients older than age 50 may be at increased risk for admission. (Level II, Grade B).
- Time to discharge after surgery for patients with acute cholecystitis, bile duct stones, or in patients converted to an open procedure should be determined on an individual basis. (Level III, Grade A).

X. REDUCED PORT AND SINGLE INCISION LAPAROSCOPIC CHOLECYSTECTOMY

All parts of the **SAGES GUIDELINES FOR THE CLINICAL APPLICATION OF LAPAROSCOPIC BILIARY TRACT SURGERY** apply to reduced port and single incision approaches to laparoscopic cholecystectomy. The indications, contra-indications and preoperative preparation for reduced port and single incision approaches are the same as those for multi port cholecystectomy. Access and equipment, are, in their essentials, the same for reduced port and single incision approaches and multiport procedures. Access to the abdominal cavity in reduced port and single incision approaches should follow accepted standards for safe entry including avoidance and recognition of complications. Standard instruments may be used in single incision or multi port procedures. With respect to specialized access devices and non-rigid instruments, there have been no trials or adequate evaluative studies yet published to offer any recommendation for these devices. Introduction of new instruments, access devices or new techniques should be done with caution and/or under study protocol, and, prior to the addition of any new instrument or device, it should, to the extent possible, be proven safe, and not limit adherence to established guidelines for safe performance of laparoscopic cholecystectomy. Adequate training should be obtained on any new device or instrument prior to utilization in a patient. As with any new technique, of outcomes should be continuously assessed to ensure continued patient safety as single incision techniques are developed; to date, only studies with limited numbers of patients have been reported.[175-177] Dissection performed during single incision procedures should follow “best practice” approaches recommended for multiport cholecystectomy including dynamic traction of the fundus of the gallbladder, dynamic lateral retraction of the gallbladder infundibulum, and identification and maintenance of the “critical view” of the cystic duct and artery to avoid inadvertent injury to the common bile duct or hepatic arteries. During initial procedures, a low threshold for using additional port sites should be maintained so as to not jeopardize a safe dissection and result.

Single incision cholecystectomy:

- The indications, contra-indications and preoperative preparation for reduced port and single incision approaches are the same as those for multi port cholecystectomy. (Level III, Grade A).
- Access to the abdominal cavity in reduced port and single incision approaches should follow accepted standards for safe entry including avoidance and recognition of complications. (Level III, Grade A).

- Introduction of new instruments, access devices or new techniques should be done with caution and/or under study protocol, and, prior to the addition of any new instrument or device, it should, to the extent possible, be proven safe, and not limit adherence to established guidelines for safe performance of laparoscopic cholecystectomy. (Level III, Grade A).
- During initial procedures, a low threshold for using additional port sites should be maintained so as to not jeopardize a safe dissection and result. (Level III, Grade A).

APPENDIX A: Levels of Evidence

Level I	Evidence from properly conducted randomized, controlled trials
Level II	Evidence from controlled trials without randomizationOrCohort or case-control studiesOrMultiple time series, dramatic uncontrolled experiments
Level III	Descriptive case series, opinions of expert panels

APPENDIX B: Scale Used for Recommendation Grading

Grade A	Based on high-level (level I or II), well-performed studies with uniform interpretation and conclusions by the expert panel
Grade B	Based on high-level, well-performed studies with varying interpretation and conclusions by the expert panel
Grade C	Based on lower level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

APPENDIX C: Literature Review Method, Search terms and results

I. LITERATURE REVIEW METHOD

Systematic literature searches for each topic were performed on MEDLINE during the course of the review. In general, the search strategy was limited articles to those in English, on humans, and published within the last 5 years. The abstracts were reviewed by the two committee members (DO, KA). Randomized controlled trials, metaanalyses, and systematic reviews were selected for further review along with prospective and retrospective studies including studies with smaller samples, which were considered when additional evidence was lacking.

II. SEARCH TERMS AND RESULTS

1. Indications.
    1. Search date: September, 2009.
    2. Search terms: “chlolecystectomy indications”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 91 articles, abstracts reviewed, 6 chosen as pertinent, one additional earlier landmark publication included.
2. Antibiotic prophylaxis.
    1. Search date: July, 2009.
    2. Search terms: “laparoscopic cholecystectomy prophylaxis antibiotics”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 13 articles, abstracts reviewed, 4 chosen as pertinent.
3. Abdominal access. See “Access injuries” below
4. Safe technique.
    1. Search date: August, 2009.
    2. Search terms: “laparoscopic cholecystectomy bile duct injury prevention”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 33 articles, abstracts reviewed, 8 chosen as pertinent.
5. Intraoperative cholangiography.
    1. Search date: August, 2009.
    2. Search terms: “intraoperative cholangiogram choledocholithiasis”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 69 articles, abstracts reviewed, 12 chosen as pertinent.
6. Intraoperative ultrasound.
    1. Search date: August, 2009.
    2. Search terms: “laparoscopic cholecystectomy intraoperative ultrasound”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 59 articles, abstracts reviewed, 4 chosen as pertinent.
7. Laparoscopic bile duct exploration, ERCP with stone extraction and altered anatomy.
    1. Search date: August, 2009.
    2. Search terms: “laparoscopic bile duct exploration”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 101 articles, abstracts reviewed, 15 chosen as pertinent.
8. Laparoscopic endobiliary stent placement.
    1. Search date: August, 2009.
    2. Search terms: “laparoscopic endobiliary stent”.
    3. Limits: None
    4. Results: 14 articles, abstracts reviewed, 4 chosen as pertinent.
9. Dissection of the gallbladder from the liver bed.
    1. Search date: August, 2009.
    2. Search terms: “laparoscopic cholecystectomy dissection”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 83 articles, abstracts reviewed, 5 chosen as pertinent.

10. Use of drains.
    1. Search date: August, 2009.
    2. Search terms: “laparoscopic cholecystectomy drains”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 9 articles, abstracts reviewed, 2 chosen as pertinent.
11. Conversion to laparotomy.
    1. Search date: February, 2009.
    2. Search terms: “laparoscopic cholecystectomy conversion to laparotomy”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 33 articles, abstracts reviewed, 7 chosen as pertinent.
12. Access injuries.
    1. Search date: August, 2009.
    2. Search terms: “laparoscopic access complication”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 90 articles, abstracts reviewed, 4 chosen as pertinent.
13. Common bile duct injuries.
    1. Search date: February, 2009.
    2. Search terms: “laparoscopic cholecystectomy bile duct injury”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Additional hand searching of bibliographies
    5. Results: 194 articles, abstracts reviewed, 19 chosen as pertinent.
14. Biliary dyskinesia.
    1. Search date: September, 2009.
    2. Search terms: “cholecystectomy biliary dyskinesia”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Additional hand searching of bibliographies
    5. Results: 40 articles, abstracts reviewed, 6 chosen as pertinent.
15. Acute cholecystitis.
    1. Search date: March, 2009.
    2. Search terms: “laparoscopic cholecystectomy acute cholecystitis”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 219 articles, abstracts reviewed, 38 chosen as pertinent.
16. Gallstone pancreatitis.
    1. Search date: April, 2009.
    2. Search terms: “laparoscopic cholecystectomy acute pancreatitis”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 77 articles, abstracts reviewed, 13 chosen as pertinent.
17. Laparoscopic cholecystectomy surgery in the setting of cirrhosis.
    1. Search date: April, 2009.
    2. Search terms: “laparoscopic cholecystectomy cirrhosis”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Additional hand searching of bibliographies

5. Results: 69 articles, abstracts reviewed, 13 chosen as pertinent.

18. Laparoscopic cholecystectomy surgery in the setting of systemic anticoagulation
    1. Search date: April, 2009.
    2. Search terms: “laparoscopic cholecystectomy acute pancreatitis”.
    3. Limits: None.
    4. Additional hand searching of bibliographies
    5. Results: 11 articles, abstracts reviewed, 2 chosen as pertinent.
19. Porcelain gallbladder.
    1. Search date: April, 2009.
    2. Search terms: “laparoscopic cholecystectomy porcelain gallbladder”.
    3. Limits: None.
    4. Additional hand searching of bibliographies
    5. Results: 16 articles, abstracts reviewed, 2 chosen as pertinent.
20. Gallbladder polyps.
    1. Search date: April, 2009.
    2. Search terms: “gallbladder polyps”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 59 articles, abstracts reviewed, 6 chosen as pertinent.
21. Gallbladder cancer.
    1. Search date: June, 2009.
    2. Search terms: “laparoscopic cholecystectomy gallbladder cancer”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 108 articles, abstracts reviewed, 9 chosen as pertinent.
22. Length of stay.
    1. Search date: July, 2009.
    2. Search terms: “laparoscopic cholecystectomy hospital discharge”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 58 articles, abstracts reviewed, 8 chosen as pertinent.
23. Single incision cholecystectomy.
    1. Search date: September, 2009.
    2. Search terms: “single incision laparoscopic cholecystectomy”.
    3. Limits: English language, humans, and published within the last 5 years.
    4. Results: 15 articles, abstracts reviewed, 3 chosen as representative.

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