

# **Diagnostic Laparoscopy**

## **Clinical Application**

For the diagnosis of intra-abdominal diseases, Diagnostic laparoscopy is minimally invasive surgery. The procedure enables the direct inspection of large surface areas of intra-abdominal organs and facilitates obtaining biopsy specimens, cultures, and aspiration. Laparoscopic ultrasound can be used to evaluate deep organ parts that are not amenable to inspection. Diagnostic laparoscopy not only facilitates the diagnosis of intra-abdominal disease but also therapeutic intervention made possible by it.

## **Literature Review Methods**

A large body of literature about DL exists. DL has been applied in many clinical situations which add complexity to the analysis of the literature. Our systematic literature search of MEDLINE for the period 1995-2005, limited to English language articles, identified 663 relevant reports. The search strategy is shown in **Figure 1** at the end of this document. Using the same strategy, we searched the Cochrane database of evidence-based reviews and the Database of Abstracts of Reviews of Effects (DARE), which identified an additional 54 articles. Thus, a total of 717 abstracts were reviewed by three committee members (DS, WR, LC) and divided into the following categories:

- a) Randomized studies, meta-analyses, and systematic reviews
- b) Prospective studies
- c) Retrospective studies
- d) Case reports
- e) Review articles

For further review Randomized controlled trials, meta-analyses, and systematic reviews were selected along with prospective and retrospective studies that included at least 50 patients; studies with smaller samples were reviewed when other available evidence was lacking. The most recent reviews were also included. All case reports, old reviews, and smaller studies were excluded. According to these exclusion criteria, 169 articles were reviewed by the three committee members (DS, WR, LC).

To maximize the efficiency of the review, the articles were divided in the following subject categories:

### 1) Staging laparoscopy for cancer

- a) Esophageal cancer
- b) Gastric cancer
- c) Pancreatic and periampullary cancers
- d) Liver cancer
- e) Biliary tract cancer
- f) Colorectal cancer
- g) Lymphoma

### 2) For acute conditions-Diagnostic laparoscopy

- a) Acute abdomen
- b) Trauma
- c) ICU

### 3) For chronic conditions-Diagnostic laparoscopy

- a) Chronic pelvic pain and endometriosis
- b) Liver disease (including cirrhosis)

- c) Infertility
- d) Cryptorchidism
- e) Other

## 1) Diagnostic Laparoscopy in the ICU

### Rationale for the Procedure

A number of reports have described the use of DL in ICU patients. The main argument for the use of DL in ICU patients has been for the diagnosis of suspected intra-abdominal pathology in critically ill patients without the need for transport to the operating room with its potential complications. Furthermore, such an approach allows for the uninterrupted treatment of the ICU patient and may minimize the cost of the intervention.

### Technique

Many studies have documented the feasibility of the procedure. The most common reason that the procedure failed in the initial reports on DL for ICU patients, the procedure was performed in the operating room, most recent studies have applied the procedure exclusively at the bedside. Local anesthesia, sedation, and occasionally paralytics have been used for the procedure at the bedside. Many patients who are breathing spontaneously require intubation before the procedure; however, the procedure has also been applied successfully in nonintubated patients. In most instances, a portable laparoscopic cart, which contains a monitor, video camera, light source, and gas supply, is used. A cut-down technique and the Veress needle technique have been used for initial access without reported untoward events. For initial access, the periumbilical region is the most used site; however, concerns about intra-abdominal adhesions may dictate the use of another “virgin” site. Pneumoperitoneum has been kept at lower levels (8-12 mm Hg) by many authors due to concerns of hemodynamic compromise in already compromised patients. No studies have compared different insufflation pressures in ICU patients. Although most studies have used CO<sub>2</sub> for insufflation, the use of N<sub>2</sub>O has also been described. At the periumbilical trocar site for inspection of the intra-abdominal organs, an angled scope is used, including the surface of the liver, gallbladder, stomach, intestine, pelvic organs, and visible retroperitoneal surfaces along with examination of free intra-peritoneal fluid. For potential therapeutic intervention, additional (5-mm) trocars are used at the discretion of the surgeon as needed for exposure. The use of laparoscopic ultrasound has not been described in ICU patients. In short duration the procedure is done, ranging between 10 and 70 minutes, with an average duration of about 30 minutes.

### Indications/Symptoms:

The main indication for DL in the ICU has been unexplained sepsis, systemic inflammatory response syndrome, and multi-system organ failure. In addition, the procedure has been used for abdominal pain or tenderness associated with other signs of sepsis without an obvious indication for laparotomy (i.e., pneumoperitoneum, massive gastrointestinal bleeding, small bowel obstruction), fever and/or leukocytosis in an obtunded or sedated patient not explained by another identifiable problem (such as pneumonia, line sepsis, or urinary sepsis), metabolic acidosis not explained by another process (such as cardiogenic shock), and increased abdominal distention that is not a consequence of bowel obstruction.

### Contraindications (Absolute or Relative)

- Patients with an obvious indication for surgical intervention such as a bowel obstruction or perforated viscus
- Patients with abdominal wall infection (e.g., cellulitis, soft tissue infection, open wounds)
- Patients unable to tolerate pneumoperitoneum or who are so sick that there is no realistic chance of survival even if a “treatable” intra-abdominal process were found
- Patients with an uncorrectable coagulopathy or uncorrectable hypercapnia >50 torr
- Patients with a tense and distended abdomen (i.e., clinically suspected abdominal compartment syndrome)

- Patients with extensive previous abdominal surgery with multiple incisional scars or after a laparotomy within the last 30 days

### **Risks**

- Delay in the diagnosis and treatment of patients if the procedure is false negative
- Procedure- and anesthesia-related complications
- Missed pathology and its associated complications

### **Benefits**

- Expedient diagnosis of suspected intra-abdominal pathology
- Avoid the morbidity of open exploration
- Minimization of treatment interruption by not moving the patient outside the ICU
- Ability to provide therapeutic intervention
- Avoid potential risks associated with transportation to the operating room or radiology for diagnostic tests

### **Diagnostic Accuracy of the Procedure**

The diagnostic accuracy of the procedure is high, ranging between 90% and 100%. The main limitation of the procedure is for the evaluation of retroperitoneal structures with the few false negative reported findings attributed to retroperitoneal processes like pancreatitis. Nevertheless, the accuracy of the procedure appears to have excellent, when evaluating for two of the most prevalent diseases in this population, acalculous cholecystitis and ischemic bowel. In 36%-95% of patients, the procedure has been reported to prevent unnecessary laparotomies. Its sensitivity has also been demonstrated in patients with suspected abdominal complications after cardiac surgery.

After comparison of Diagnostic laparoscopy with diagnostic peritoneal lavage and found to have superior diagnostic accuracy in critically ill patients. It has also been found to be superior to computed tomography (CT) or ultrasound of the abdomen.

### **Complications and Outcomes**

The procedure can be performed safely, is well tolerated in ICU patients, and only a few minor complications have been described (bradycardia and increased peak airway pressure that resolved after release of pneumoperitoneum and perforation of a gangrenous gallbladder during manipulation). Overall morbidity has been reported between 0% and 8%, and no mortality directly associated with the procedure has been described. Nevertheless, the ICU patient population has very high mortality rates (33-79%) regardless of the findings of DL.

### **Cost-effectiveness**

There is no existence of direct evidence, while it has been implied that DL in the ICU rather than the operating room can yield substantial cost savings.

### **Limitations of the Available Literature**

A few single-center studies of limited quality, which include small patient cohorts, address the role of DL in the ICU population making generalizations difficult and allowing institutional and personal biases to be introduced into the results. Due to lack of uniformity and details in the reported selection criteria and noninvasive imaging prior to the procedure the limitations of the available literature and the high mortality

rates of this patient population make it difficult to draw firm conclusions about the impact of the procedure on patient outcomes and its cost-effectiveness. Furthermore, the impact of the surgeon's laparoscopic expertise on the diagnostic accuracy of the procedure is unknown.

## **2) Trauma and Diagnostic Laparoscopy**

### **Basis of Surgery**

Exploratory laparotomies in trauma patients with suspected intra-abdominal injuries are associated with a high negative laparotomy rate and significant procedure-related morbidity. To prevent unnecessary exploratory laparotomies with their associated higher morbidity and cost for trauma patients Diagnostic laparoscopy has been proposed.

### **Technique**

Many studies have documented the feasibility and safety of the procedure in trauma patients. General anesthesia is used in performing this procedure; however, local anesthesia with IV sedation has also been used successfully. The latter, in conjunction with a dedicated mobile cart, facilitates the procedure in the emergency department. Under local anesthesia in the emergency department over standard DL in the operating room, a recent study demonstrated the safety and advantages of awake laparoscopy. Low insufflation pressures have been used by many (8-12 mm Hg); however, pressures up to 15 mm Hg have been described without untoward events. Special attention should be given to the possibility of a tension pneumothorax caused by the pneumoperitoneum due to an unsuspected diaphragmatic rupture. Usually through a periumbilical incision, the pneumoperitoneum is created using a Veress needle or open technique after insertion of a nasogastric tube and a Foley catheter.

In the case of penetrating wounds, with sutures air leaks can be controlled. A 30-degree laparoscope is advantageous, and additional trocars are used for organ manipulations. The peritoneal cavity can be examined systematically taking advantage of patient positioning manipulations. The colon can be mobilized and the lesser sac inspected. Suction/irrigation may be needed for optimal visualization, and methylene blue can be administered IV or via a nasogastric tube to help identify urologic or stomach injuries, respectively. In penetrating injuries, peritoneal violation can be determined.

### **Indications**

- Suspected but unproven intra-abdominal injury after blunt or penetrating trauma
- More specific indications include:
  - Abdominal gunshot wounds with doubtful intra-peritoneal trajectory
  - Creation of a trans-diaphragmatic pericardial window to rule out cardiac injury
  - Despite negative initial workup after blunt trauma suspected intra-abdominal injury
  - Abdominal stab wounds with proven or equivocal penetration of fascia
  - Diagnosis of diaphragmatic injury from penetrating trauma to the thoraco-abdominal area

### **Contraindications (Absolute or Relative)**

- Known or obvious intra-abdominal injury
- Limited laparoscopic expertise
- Hemo-dynamic instability (defined by most studies as systolic pressure < 90 mm Hg)
- A clear indication for immediate celiotomy such as frank peritonitis, hemorrhagic shock, or evisceration
- Posterior penetrating trauma with high likelihood of bowel injury

### **Risks**

- Delay to definitive treatment

- Procedure- and anesthesia-related complications
- Missed injuries with their associated morbidity

### **Benefits**

- Reduced rate of negative and non-therapeutic laparotomies (with a subsequent decrease in hospitalization, morbidity, and cost after negative laparoscopy)
- Ability to provide therapeutic intervention
- Accurate identification of diaphragmatic injury

### **Diagnostic Accuracy of the Procedure**

The sensitivity, specificity, and diagnostic accuracy of the procedure when used to predict the need for laparotomy are high (75-100%); however, they depend on several factors. As a screening tool, when DL has been used (i.e., early conversion to open exploration with the first encounter of a positive finding like the identification of peritoneal penetration in penetrating trauma or active bleeding/peritoneal fluid in blunt trauma patients), the number of missed injuries is <1%. Although early studies cautioned about the low sensitivity and high missed injury rates of the procedure when used to identify specific injuries, studies published recently consistently report a 0% missed injury rate even when DL is used for reasons other than screening. This rate holds true for studies that have used laparoscopy to treat the majority of identified injuries.

Studies of DL for trauma report negative procedures in a median 57% (range, 17-89) of patients, sparing them an unnecessary exploratory laparotomy. On the other hand, the median percentage of negative exploratory laparotomies after a positive DL (false positive rate) is reported to be around 6% (range, 0-44). While most authors have converted to open exploration after a positive DL, some authors have successfully treated the majority of patients (up to 83%) laparoscopically. The procedure with safety and accuracy has also been demonstrated in pediatric trauma patients.

### **Procedure-related Complications and Patient Outcomes**

In up to 11% of patients and are usually minor, procedure-related complications occur. A 1999 review of 37 studies, which included more than 1,900 patients, demonstrated a procedure-related complication rate of 1%. Recent studies report a median of 0 (range, 0-10%) morbidity and 0% mortality. Sometimes the occurrence of Intra-operative complications during creation of the pneumoperitoneum, trocar insertion, or during the diagnostic examination is found. These complications include tension pneumothorax caused by unrecognized injuries to the diaphragm, perforation of a hollow viscus, laceration of a solid organ, vascular injury (usually trocar injury of an epigastric artery or lacerated omental vessels), and subcutaneous or extra-peritoneal dissection by the insufflation gas. During the postoperative course Port site infections may occur.

Negative DL is associated with shorter postoperative hospital stays compared with negative exploratory laparotomy (2-3 days vs. 4-5 days, respectively) (level II, III). Although a few studies have even demonstrated shorter stays after therapeutic laparoscopy compared with open (level III), the only level I study available demonstrated a statistically significant shorter hospital stay after DL (5.1 vs. 5.7 days). In a very recent study, awake laparoscopy in the emergency department under local anesthesia resulted in discharge of patients from the hospital faster compared with DL in the operating room (7 vs. 18 hours, respectively;  $p < 0.001$ ).

Suggestion by Comparative studies also lower morbidity rates after negative DL compared with negative exploratory laparotomy, whereas similar outcomes have shown by other studies.

### **Cost-effectiveness**

Higher costs have been demonstrated by a number of reports (up to two times higher) after negative exploratory laparotomy compared with negative DL as a direct consequence of shorter hospital stays. Nevertheless, a level I study did not demonstrate cost differences when an intention-to-treat analysis was

used to compare a DL-treated group with that of an exploratory laparotomy-treated group. Recently a level III study reported cost savings of \$2,000 per patient when awake laparoscopy under local anesthesia was used in the emergency department compared with DL in the operating room.

### **Shortcomings of the Available Literatures**

The available literature has limited quality (only one small, level I study exists) and is very inhomogeneous, making generalizations and conclusions difficult. Study populations have been variable (blunt, penetrating, or mixed), and some studies have focused only on patients with suspected diaphragmatic injuries or blunt bowel injuries. Moreover, the indication for conversion to exploratory laparotomy has also been inconsistent. Most studies use peritoneal penetration or bleeding and free peritoneal fluid as an immediate reason for conversion, whereas others have converted only after specific injuries have been identified, and others have converted only when laparoscopic repair was impossible. On the diagnostic accuracy of the procedure, the impact of laparoscopic expertise has not been fixed. Since the sensitivity, specificity, accuracy, and number of missed injuries can be substantially influenced by most of these factors, to provide firm recommendations on the role of DL in trauma patients it is difficult.

### **3) Diagnostic Laparoscopy for Acute Abdominal Pain**

#### **Rationale for the Procedure**

In the diagnosis of non-specific acute abdominal pain Laparoscopy has been applied by multiple authors, which is defined as acute abdominal pain of less than 7 days duration after baseline examination and diagnostic tests where the diagnosis remains uncertain. The rationale for the use of DL in this setting is to prevent treatment delay and its potential for disastrous complications and at the same time to avoid unnecessary laparotomy, which is associated with relatively high morbidity rates (5-22%). Diagnostic laparoscopy offers the potential advantage of visually excluding or confirming the diagnosis of acute intra-abdominal pathology expeditiously without the need for a laparotomy.

A sizable proportion of the literature also refers to the use of DL for suspected appendicitis.

#### **Technique**

Using general anesthesia in patients with acute abdominal pain, many studies have documented the feasibility and safety of the procedure. Severe abdominal distention due to bowel obstruction usually precludes successful deployment of the technique because of inadequate working space. In addition, its use can be limited due to the presence of multiple adhesions. Conversion rates to an open procedure have ranged widely and are usually the result of intra-abdominal adhesions, inability to visualize all structures, technical difficulties, and surgeon inexperience.

For initial access, the Veress needle technique and a cut-down technique have been described. Report of Access-related complications and some authors recommend the use of the cut-down technique to prevent untoward events, especially in the case of abdominal distention or prior abdominal operations. Nevertheless, with acute abdominal pain no studies have compared these two access techniques in patients. The usual site for initial access is the periumbilical region; however, previous midline incisions may dictate the use of another “virgin” site. While most studies describe insufflation pressures of 14-15 mm Hg, due to concerns of hemodynamic compromise with higher pressures some authors have used lower levels (8-12 mm Hg). Nonetheless, no untoward effects of higher pressures have been described, and no comparative studies using different insufflation pressures exist. An angled scope is used at the periumbilical trocar site for inspection of the intra-abdominal organs, including the surface of the liver, gallbladder, stomach, intestine, pelvic organs, and visible retroperitoneal surfaces along with examination for free intraperitoneal fluid. To optimize exposure or provide therapeutic intervention additional (5-mm) trocars may be used at the discretion of the surgeon. The description of laparoscopic ultra sound is not used in this population.

#### **Indications/Symptoms:**

- After initial diagnostic workup unexplained acute abdominal pain of less than 7 days duration
- As an alternative in the management of these patients to close observation for patients with nonspecific abdominal pain which is the current practice

### **Contraindications**

- Patients with a clear indication for surgical intervention such as bowel obstruction, perforated viscous (free air), or hemodynamic instability
- Relative contraindications used by some authors include patients with prior intra-abdominal surgeries, patients with chronic pain, morbidly obese patients, pregnant patients, and patients with psychiatric disorders.

### **Risks**

- Delay to definitive treatment with potentially increased morbidity when the study is false negative
- Procedure- and anesthesia-related complications

### **Benefits**

- Reduction in the rate of negative and nontherapeutic laparotomies (with a subsequent decrease in hospitalization, morbidity, and cost after negative laparoscopy)
- Earlier diagnosis and intervention with potentially improved outcomes compared with observation
- Ability to provide therapeutic intervention

### **Diagnostic Accuracy of the Procedure**

Many studies have demonstrated high diagnostic accuracy for the procedure (70%-99%). In a level I evidence study, in more patients with non-specific abdominal pain compared with an observation group (81% vs. 36%, respectively;  $p < 0.001$ ) the diagnosis was established with early laparoscopy. In contrast, another level I study showed a small non-significant improvement in the diagnostic accuracy for acute lower abdominal pain in women of reproductive age when laparoscopy was compared with observation (85% vs. 79%, respectively;  $p = n.s.$ ). In the latter study, in the laparoscopy group, the diagnosis was established significantly faster and laparoscopy aided more accurate diagnostic judgments with clinical significance in 2/5 of the patients. Diagnostic laparoscopy has been demonstrated to change the treatment strategy in 10-58% of patients. While CT of the abdomen/pelvis was scarcely used during the preoperative workup in the majority of the reviewed papers, one study demonstrated a higher diagnostic accuracy of DL in the diagnosis of diverticulitis compared with CT of the abdomen or colonic enema.

### **Procedure-related Complications and Patient Outcomes**

In the majority of patients the procedure can be performed safely. A 0-24% morbidity and 0-4.6% mortality have been reported. The complications reported include pulmonary embolism, prolonged ileus, wound infection or hematoma, intra-abdominal abscess, pneumonia, congestive heart failure, urinary infection, acute herniations at trocar sites, intraoperative injuries to bowel or vascular structures, bladder injuries, fistulas, septic shock, myocardial infarction, and others. Since the procedure has been applied to patients with variable disease acuity and operative risk (from patients with acute abdominal pain to patients with acute abdomen and peritonitis), complications are higher in studies that include sicker patients. The majority of reported deaths have been associated with multiple organ failure secondary to sepsis.

With shorter hospital stays Diagnostic laparoscopy has been associated, especially when it is the only procedure performed. Converted procedures have similar hospital stays compared with open procedures. One level I evidence study reported similar hospital stays between an early laparoscopy group and an observation group with nonspecific abdominal pain (2 days for both groups), similar morbidity (24% vs. 31%, respectively;  $p = n.s.$ ), and similar readmission rates at a median of 21 months follow-up (29% vs. 33%, respectively;  $p = n.s.$ ). This study, however, documented higher well-being scores in patients treated with early laparoscopy at 6 weeks follow-up compared with the observation group. Another level I

evidence study that randomized patients into similar groups, also failed to show morbidity differences but demonstrated a shorter hospital stay for the laparoscopically-treated group (1.3 days vs. 2.3 days for the observation group;  $p < 0.01$ ). The re-operation rate was reported to be 7.4% in one study (for drainage of intra-abdominal abscesses, continued sepsis, or pancreatic debridement).

### **Cost-effectiveness**

No evidence exists on the cost-effectiveness of DL for non-specific acute abdominal pain.

### **Limitations of the Available Literature**

The results of the analyzed literature are difficult to combine, as there is a lack of homogeneity. Reports range from the evaluation of women of reproductive age with acute pelvic pain to patients with suspected diverticulitis and to patients with an acute abdomen and peritonitis. The diagnostic accuracy of the procedure can be substantially different depending on the examined population. It is also unknown how experience with the procedure impacts its diagnostic accuracy. Given today's reality, one important limitation of many of the available studies is the lack of preoperative, high quality imaging studies (like spiral CT scan of the abdomen and pelvis), which may have provided the diagnosis without the need for an invasive procedure.

## **4) Staging Laparoscopy for Pancreatic Adenocarcinoma**

### **Rationale for the Procedure**

Pancreatic adenocarcinoma is diagnosed in just over 30,000 patients every year in the United States and has a dismal prognosis, with an almost identical yearly death rate. Surgery is the only modality that can lead to cure; however, most patients present with inoperable disease. The overall 5-year survival is  $< 5\%$ . Patients with localized disease have a 15% 5-year survival after curative resection. In a disease with such a poor prognosis even after curative resection, it is not only important to identify patients with resectable disease but also to spare patients with incurable disease the morbidity, inconvenience, and expense of an unnecessary operation. Thus, accurate staging of pancreatic adenocarcinoma is of paramount importance. A high quality CT scan of the pancreas is considered the best initial diagnostic modality for this disease. Nevertheless, even after appropriate preoperative imaging, 11-48% of patients are found to have unresectable disease during laparotomy. For this reason, many authors have introduced SL in the treatment algorithm of pancreatic adenocarcinoma patients in an effort to decrease the number of unnecessary laparotomies.

### **Technique**

The feasibility of SL has been demonstrated in multiple studies with success rates ranging from 94-100%. Dense adhesions that impair inspection and examination with the ultrasound probe are the main reason for technical failures. Nevertheless, even patients with adhesions can be examined; however, the extent and yield of the examination may be compromised. Conversions to open surgery are uncommon and have been reported to occur in  $< 2\%$  of patients in a large series.

The procedure is usually performed under general anesthesia, and the majority of reports have used 15 mm Hg insufflation pressures. A thorough evaluation of peritoneal surfaces is performed. The suprahepatic and infrahepatic spaces, the surface of the bowel, the lesser sac, the root of the transverse mesocolon and small bowel, the ligament of Treitz, the paracolic gutters, and pelvis are inspected with frequent bed position changes as necessary. In addition to visual inspection, peritoneal washings can be performed, ascitic fluid, if present, sent for cytology, and biopsy specimens of lesions suspected to be malignant obtained. When no metastatic disease is identified on inspection, a detailed laparoscopic ultrasound examination can be employed during which the deep hepatic parenchyma, the portal vein, mesenteric vessels, celiac trunk, hepatic artery, the entire pancreas, and even pathologic periportal and paraaortic nodes can be evaluated and biopsied. The addition of color flow Doppler can further assist in the assessment of vascular patency.



A controversy exists in the literature about the extent of SL for pancreatic adenocarcinoma patients. Advocates of a short duration procedure that is based only on inspection of abdominal organ surfaces argue that the procedure can be performed quickly (usually within 10–20 min), can be done through one port, does not require significant expertise, minimizes the risk of potential complications by the dissection near vascular structures, and has good diagnostic accuracy. On the other hand, advocates of a more extensive procedure that includes opening the lesser sac and assessment of the vessels argue that the diagnostic accuracy of the procedure can be enhanced by detecting metastatic lesions in the lesser sac, vascular invasion by the tumor, or deep hepatic metastasis, often missed by visual inspection alone, and that it can be performed safely without a significant increase in morbidity and within a reasonable time.

It is very important, therefore, to consider these differences in the SL technique when evaluating reports of the diagnostic yield of this procedure in patients with pancreatic adenocarcinoma.

### **Indications**

- As a staging procedure for pancreatic adenocarcinoma
- For detection of imaging occult metastatic disease or unsuspected locally advanced disease in patients with resectable disease based on preoperative imaging prior to laparotomy
- For assessment prior to administration of neo-adjuvant chemoradiation
- For selection of palliative treatments in patients with locally advanced disease without evidence of metastatic disease on preoperative imaging

### **Contraindications (Absolute or Relative)**

- Known metastatic disease
- Inability to tolerate pneumoperitoneum or general anesthesia
- Multiple adhesions/prior operations

### **Risks**

- False negative studies that lead to unnecessary exploratory laparotomies and unnecessary cost
- Procedure-related complications

### **Benefits**

- Avoidance of unnecessary exploratory laparotomy with its associated higher morbidity and cost in patients with metastatic disease
- Appropriate selection of patients with true locally advanced disease and exclusion of patients with CT-occult metastatic disease from further unnecessary treatment (chemotherapy or chemoradiation) with its associated morbidity and cost
- Minimizes the delay of primary treatment (chemotherapy or chemoradiation) in the subset of patients whose disease is unresectable by avoiding laparotomy and its associated longer convalescence period

### **Diagnostic Accuracy of the Procedure**

The reported median (range) sensitivity, specificity, and accuracy of SL in detecting imaging-occult, unresectable pancreatic adenocarcinoma in the literature is 94% (range, 93-100%), 88% (range, 80-100%), and 89% (range, 87-98%), respectively (level II, III). However, the procedure misses 6% (range, 5-25) of patients whose disease is identified as unresectable during an ensuing laparotomy (level II-III). Overall, in 4-36% of patients, an unnecessary laparotomy can be avoided (level II-III).

A number of studies have also evaluated the added benefit of laparoscopic ultrasound at the time of laparoscopic staging indicating that the diagnostic accuracy of the procedure can be improved by 12-14% (level II-III). In addition, peritoneal washings have been reported to augment the yield of the procedure. Reports on the sensitivity of peritoneal washings have ranged widely (25-100%). The highest sensitivity for

peritoneal cytology has been reported in patients with a disrupted ventral pancreatic margin (when peripancreatic fatty tissue cannot be differentiated from the tumor by helical CT scan) (level III). In addition, locally advanced pancreatic cancers have a higher incidence of positive cytology (level III). Importantly, studies have reported a 7-14% incidence of positive peritoneal washings in the absence of other findings of metastatic disease during preoperative imaging and SL (level III). This incidence seems to be lower in studies that include a variety of periampullary tumors (level II).

The diagnostic yield of the procedure also depends on the histology, stage of disease, tumor size, and location. There is convincing evidence that the yield of SL is significantly higher in patients with pancreatic cancer compared with other types of periampullary tumors (level III). Furthermore, SL appears to have a higher yield in patients with locally advanced cancer compared with patients with localized disease. Identification of metastatic disease by SL in patients with locally advanced disease by high quality imaging studies has been reported in 34-37% of cases, which compares favorably with the identification rates of metastatic disease in patients with localized disease (level III).

Tumors of the pancreas body and tail are associated with a higher chance for unsuspected metastasis found at laparoscopy (level III). Larger tumors appear to be associated with a higher incidence of imaging occult metastatic disease (level III). Although the tumor size at which the risk of occult M1 disease justifies the added time and cost of laparoscopy is currently unknown, some studies have suggested that tumors > 3 cm are more likely to be associated with metastatic disease at exploration (level III). Moreover, a Ca 19-9 level <150 has been associated with a lower chance for metastatic disease and consequently a lower yield for SL (level III).

### **Procedure-related Complications and Patient Outcomes**

Procedure-related morbidity has been reported to range 0 and 4% (level II, III). Most complications are minor and consist of wound infections, bleeding at port sites, or skin emphysema. Nevertheless, complications such as myocardial infarction, pulmonary embolism, and intestinal or vascular injury during the procedure have been described. The majority of the literature reports mortality rates of 0% (level II, III); however, at least one death has been reported due to a missed colonic injury during the procedure. Although studies comparing open and laparoscopic staging are scarce, the morbidity and mortality rates reported in the literature compare favorably to reports of negative exploratory laparotomies. No studies compare a short-duration inspection-only SL with a more extended procedure.

With regard to oncologic safety, initial concerns for more port-site recurrences after laparoscopic procedures in cancer patients have not been substantiated. Multiple studies report a 0-2% incidence of port-site recurrences after SL, which is similar to the incidence after open explorations of cancer patients (level III). In one comparative study of 235 patients who had undergone exploratory laparotomy or SL, laparoscopy was not associated with increased port-site recurrences or peritoneal disease progression (level III). Furthermore, there is evidence from the Surveillance Epidemiology and End Results (SEER) database suggesting no survival differences between pancreatic cancer patients who underwent a laparoscopic procedure compared with an open surgery (level II).

Hospital length of stay after SL has been reported to range from 1 to 4 days. Level III evidence suggests that the hospital stay is shorter after laparoscopic staging compared with open staging in pancreatic cancer patients.

In patients with locally advanced disease, SL has been reported to be superior to exploratory laparotomy, as it decreases length of hospital stay, increases the number of patients who receive chemotherapy, and shortens the time to initiation of such treatment (level III).

### **Cost-effectiveness**

Although high quality evidence on the cost effectiveness of SL is lacking, the literature suggests that SL is more cost-effective than open exploration when it is the only procedure required (i.e., in patients with unsuspected metastatic disease identified during SL) (level II). This is a consequence of decreased patient length of stays. On the other hand, the cost-effectiveness of SL when applied in the diagnostic algorithm of

all pancreatic cancer patients appears to be linked directly to the yield of the procedure in identifying patients with imaging occult disease. In a cost utility analysis of the most effective management strategy for pancreatic cancer patients, at least a 30% yield was needed for SL to be more cost-effective than open exploration (level III).

### **Literature Controversies**

The main controversy regarding SL is whether it should be used routinely or selectively in patients with pancreatic adenocarcinoma deemed resectable on preoperative imaging. Proponents for the routine use of SL cite the high incidence of imaging occult metastatic disease found during laparoscopic examination of the abdominal cavity that leads to avoidance of unnecessary operations and thus benefits patients. Proponents for the selective use of SL argue that when high quality imaging is used, only a small percentage of patients benefit from SL, and under these circumstances the procedure is not cost-effective. As discussed in the technique section, there is also a controversy about whether to perform a limited or extended procedure.

### **Limitations of the Available Literature**

The quality of the available studies on SL for patients with pancreas cancer is limited; no level I evidence exists. Furthermore, population-based data are very limited, as the majority of studies are single institution reports from highly specialized centers, making generalizations difficult and allowing institutional and personal biases to be introduced into the results.

In addition, reported data are not uniform across studies, making their analysis difficult. A number of studies assess the role of laparoscopy indirectly without having ever performed a single laparoscopic staging procedure (referred to as 'phantom' studies by some authors) and assume that only visible metastatic disease would have been detected at the time of laparoscopy, ignoring the value of laparoscopic ultrasound and cytology. Other studies do not clearly report the quality of preoperative imaging, the criteria used to define resectability, and the number of R0 resections. Importantly, studies often evaluate inhomogeneous patient samples, including patients with localized and locally advanced pancreatic cancers, with periampullary and other non-pancreatic cancers or even with benign disease and do not report results separately. Moreover, the information on the cost-effectiveness of the procedure is limited, and there are no studies that assess the quality of life of patients undergoing SL compared with patients undergoing open exploration.

## **5) Staging Laparoscopy for Gastric Cancer**

### **Rationale for the Procedure**

Since many patients with gastric cancer present with locally advanced or metastatic disease, accurate staging of gastric cancer aids in the appropriate treatment selection for both cure and palliation. Palliative resection may be indicated for gastric cancer causing obstruction, hemorrhage, or perforation; however, surgical resection alone for patients with advanced disease has not been shown to improve survival. Studies regarding neoadjuvant protocols for locally advanced gastric cancers are ongoing which makes accurate staging imperative. Moreover, even after many preoperative radiologic tests (CT scan, endoscopic and transabdominal ultrasound, and PET scan) for staging of gastric tumors, a proportion of patients are found to have unsuspected, unresectable disease at exploration. Thus, SL may aid in the more accurate staging of gastric cancers and guide appropriate treatment without the morbidity associated with exploratory laparotomy.

### **Technique**

The patient is placed in the supine position, and pneumoperitoneum is established. A 30-degree laparoscope through an umbilical port is recommended. If present, ascitic fluid is aspirated and sent for cytology. In the absence of ascites, 200 cc of normal saline can be instilled into the peritoneal cavity and aspirated from the pelvis and bilateral sub-diaphragmatic spaces for cytologic examination. Full inspection

of the peritoneal cavity helps evaluate for peritoneal or liver metastases. Laparoscopic ultrasound may aid in the detection of deep hepatic lesions. If no metastatic disease is discovered, then the left lateral lobe of the liver is elevated to expose the entire stomach. The perigastric nodes along the greater and lesser curvature are inspected and biopsied if needed. In addition, the porta hepatic and gastrohepatic ligaments are inspected carefully. Next, the gastric tumor itself is inspected for extra-serosal invasion and infiltration into surrounding structures. If the tumor is posterior, then the lesser sac must be accessed to gain appropriate visualization.

### **Indications**

- Patients with T3 or T4 gastric cancer without evidence of lymph node or distant metastases on high quality preoperative imaging

### **Contraindications (Absolute and Relative)**

- Gastric cancers complicated by obstruction, hemorrhage, or perforation in need of palliative surgery
- Patients with early stage gastric cancer (T1 or T2) should proceed to surgical resection without SL.
- Severe upper abdominal adhesions from prior surgery that may preclude the procedure

### **Risks**

- Procedure- and anesthesia-related complications
- False negative studies that lead to unnecessary laparotomy
- Delay in definitive treatment when the procedure does not coincide with planned laparotomy
- Unnecessary cost if procedure has a very low yield
- Potential adverse oncologic effects of the procedure

### **Benefits**

Accurate preoperative staging determines the most appropriate therapy for gastric cancer. Staging laparoscopy can identify patients with locally advanced disease and metastasis that may be best treated with neoadjuvant or palliative chemotherapy rather than surgical resection. These patients may potentially be spared the risks and complications of a non-therapeutic laparotomy and may have a shorter convalescence period with earlier start of chemotherapy.

### **Diagnostic Accuracy of the Procedure**

Staging laparoscopy can identify unsuspected metastatic disease in 13-57% of patients despite negative preoperative imaging studies (level II, III). Accuracy has been reported to range from 89-100% in different series (level II, III). In addition, exploratory laparotomy has been avoided in 17-40% of cases (level II, III). Compared with CT scan and ultrasound, SL is more sensitive (96%) for detecting hepatic metastasis compared with both CT (52%) and ultrasound (37%) (Level III). Similarly, sensitivity is also better for detecting peritoneal metastasis (laparoscopy 69%, ultrasound 23%, CT 8%) (Level III). The additional value of laparoscopic ultrasound has not yet been determined. Peritoneal washings positive for cancer cells have been demonstrated to correlate with the extent of disease (T1/T2: 0%, T3/T4: 10%, and M+: 59%) (Level III).

### **Procedure-related Complications and Patient Outcomes**

Reported complications are rare and include bleeding, infection, and visceral injury. No mortality has been reported. Although there are no direct comparisons between SL and exploratory laparotomy for gastric cancer staging, the average length of stay after SL has been reported to be 1-2 days, which compares favorably with stays after exploratory laparotomy for other indications. No study has assessed the benefit of SL in shortening the time to adjuvant therapy compared with exploratory laparotomy. No adverse oncologic effects of SL for gastric cancer have been reported.

## **Cost-effectiveness**

There are no available data on the cost-effectiveness of staging laparoscopy for gastric cancer.

## **Limitations of the Available Literature**

The quality of the available literature for staging laparoscopy in gastric cancer is limited, since no level I evidence exists. In addition, studies differ in their technique and use of laparoscopic ultrasound and peritoneal washings. Many reports do not clearly state preoperative imaging or postoperative pathology. The impact of the surgeon's expertise in the diagnostic accuracy of the procedure is unknown. The reported data are not consistent across studies, making their analysis difficult.

## **6) Staging Laparoscopy for Esophageal Tumors**

### **Rationale for the Procedure**

The overall prognosis for patients with esophageal cancer is poor. Many patients with esophageal cancer present at an advanced stage with lymph node or even distant metastases. Patients with advanced cancer commonly undergo preoperative chemotherapy and radiation in an attempt to improve survival. Thus, the value of precise staging is important to separate patients with an early stage tumor who are candidates for immediate curative resection from those who need neoadjuvant therapy. The most common radiologic tests used to confirm the stage of the tumor are CT scan, endoscopic ultrasound, and PET scan. Staging laparoscopy may aid in more accurate staging of esophageal cancers to guide the most appropriate treatment and avoid non-therapeutic laparotomy.

### **Technique**

The patient is placed in the supine position, and pneumoperitoneum is established. A 30-degree laparoscope is recommended for optimal visualization. Additional ports in the left upper quadrant and epigastric area can be placed as needed. Full inspection of the peritoneal cavity helps evaluate for peritoneal or liver metastases. If no distant disease is discovered, then the left lateral lobe of the liver is elevated to expose the gastroesophageal junction, and the patient is placed in steep reverse Trendelenburg position. The tumor is inspected for extension into the surrounding area. Lymph nodes in the gastrohepatic ligament or celiac axis suspected to be malignant are biopsied. An optional laparoscopic feeding jejunostomy can be placed when neoadjuvant therapy is planned.

In addition, combined thoracoscopic/laparoscopic staging has been described to improve staging for esophageal cancer by increasing the number of positive lymph nodes identified compared with conventional staging (level II). Specifically for the thoracoscopic evaluation, the patient is in full, left lateral decubitus position with single-lung ventilation. Two to three thoracic trocars are placed, and the mediastinal pleura overlying the esophagus is incised to identify and biopsy lymph nodes as needed.

### **Indications**

Staging laparoscopy should be used for patients with esophageal cancer who are potential candidates for curative surgical resection based on a negative preoperative staging for lymph node or distant metastases. Furthermore, the procedure can be used for the placement of enteral feeding access in patients when a percutaneous endoscopic gastrostomy cannot be undertaken, and the patients are candidates for neoadjuvant chemotherapy.

### **Contraindications**

The primary contraindication is known metastatic disease. In addition, dense intra-abdominal adhesions, particularly in the upper abdomen, from prior surgery may be a relative contraindication.

### **Risks**

- Procedure- and anesthesia-related complication
- False negative studies that lead to unnecessary laparotomy
- Delay in definitive treatment when the procedure does not coincide with planned laparotomy
- Unnecessary cost if procedure has a very low yield
- Potential adverse oncologic effects of the procedure

### **Benefits**

Accurate preoperative staging can identify patients with an early stage cancer in whom curative resection is possible. The patients with distant or lymph node metastasis are best treated with chemotherapy and radiation as neo-adjuvant therapy or even palliation. Since patients undergoing SL may have a faster postoperative recovery than those undergoing exploratory laparotomy, the time interval to adjuvant therapy may be shorter. In addition, laparoscopic feeding jejunostomy can be placed during SL when neo-adjuvant therapy is anticipated.

### **Diagnostic Accuracy of the Procedure**

When all preoperative imaging indicates no metastatic disease, SL with or without laparoscopic ultrasound has a sensitivity of 71% in finding peritoneal metastases, 78% for nodal metastases, and 86% for liver metastases (level II). This compares with ultrasound sensitivities of 14%, 11%, 86%, respectively, and CT scan sensitivities of 14%, 55%, 71%, respectively (level II). The accuracy has been reported to be 75-80% (level III). However, several reports indicate that only 0.08-10% of patients actually had a change in their management based on the results of laparoscopy (level II-III). In the hands of a skilled thoracic surgeon, combined thoracoscopic and laparoscopic staging can be performed over 70% of the time. When compared with final pathologic staging, thoracoscopic and laparoscopic staging has a sensitivity of 64%, specificity of 60%, and accuracy of 60% (level II).

### **Procedure-related Complications and Patient Outcomes**

After SL complications are low, and no mortality has been reported. Complications include bleeding, infection and esophageal injury during inspection, and the risks associated with anesthesia. One report documented perforation at the feeding jejunostomy tube site as well as pulmonary edema due to unexpected aortic valve stenosis.

The assumed benefit of earlier time to adjuvant therapy for patients with metastatic disease has not specifically been measured in the literature. However, after SL the average length of stay is only 1-3 days, which compares favorably with open exploration. There have been no reported adverse oncologic effects of SL for esophageal cancer.

### **Cost-effectiveness**

A trial comparing CT scan, endoscopic ultrasound-fine needle aspiration, PET, combined thoracoscopy and laparoscopy, and combinations of these has shown that the combination of PET scan with endoscopic ultrasound-fine needle aspiration is the most cost-effective (level II).

### **Limitations of the Available Literature**

Regarding the studies staging laparoscopy for esophageal cancer patients are limited and no level I evidence exists. There are a small number of reports from highly specialized centers, which may make the reproducibility of their results difficult. In addition, studies differ in their technique and intended hypotheses. The impact of surgeon's expertise on the diagnostic accuracy of the procedure is unknown. Given the inconsistency of the reported data, the overall analysis of SL in esophageal cancer is difficult.

## **7) Staging Laparoscopy for Colorectal Cancer**

## **Rationale for the Procedure**

In the primary treatment of colorectal cancer, since surgical resection, SL is seldom used and palliation are typically indicated to prevent bleeding, obstruction, and perforation even in patients with advanced disease. However, patients who have liver metastases from a primary colorectal cancer may be candidates for curative resection when there is no other extrahepatic disease, and when all of the disease in the liver is resectable. Thus, SL for these patients can provide more accurate identification of all hepatic lesions, including size, number, and location, than non-invasive imaging.

## **Technique**

Before the establishment of pneumoperitoneum, the patient is placed in the supine position. Through an umbilical port, a 30-degree laparoscope is recommended for optimal visualization of the entire abdominal cavity. Additional ports can be placed in the right anterior axillary line and epigastric area as needed. A standard laparoscopic ultrasound probe is often used to systematically examine the entire liver, identifying all lesions suspected to be malignant. The ultrasound examination should also include the porta hepatitis and celiac lymph nodes. Ultrasound-guided biopsy of peritoneal, lymph node, and unsuspected liver lesions should be obtained.

## **Indications**

1. Patients with resectable liver metastases from colorectal cancer but with no evidence of extra-hepatic disease on non-invasive imaging

## **Contraindications**

1. Patients with known extra-hepatic metastatic disease or unresectable hepatic disease

Dense intra-abdominal adhesions from prior surgery particularly surrounding the liver may be a relative contraindication.

## **Risks**

1. Procedure- or anesthesia-related complications
2. Potential adverse oncologic effects of the procedure
3. False negative examinations that lead to unnecessary laparotomies
4. Unnecessary patient morbidity and cost if the procedure has a very low yield

## **Benefits**

Staging laparoscopy and laparoscopic ultrasound can identify patients with unsuspected extra-hepatic metastatic disease. The identification of these patients may spare them the morbidity of a non-therapeutic open laparotomy and treatment plans may be altered. As with other intra-abdominal cancers, SL may lead to decreased hospital costs, shorter length of stay, and earlier time to adjuvant therapy compared with open exploration without resection.

## **Diagnostic Accuracy of the Procedure**

Comparative studies of open intra-operative ultrasound compared with laparoscopic ultrasound and preoperative CT scanning for colorectal metastases have shown that the yield is best with open intra-operative ultrasound, followed by laparoscopic ultrasound (98% yield; detected one lesion less than open intra-operative ultrasound), and CT scan 78% yield (level II). Moreover, in the detection of nodal metastases, SL and laparoscopic ultrasound have better sensitivity than imaging studies (94% laparoscopic ultrasound vs. 18% imaging preoperatively) (level II). The combination of SL and laparoscopic ultrasound has been reported to detect unresectable disease in 25%-42% of patients in whom preoperative radiological testing showed potentially curable disease (II, III). The use of laparoscopic ultrasound further identifies

unresectable disease, which is not identified with laparoscopic inspection alone (level II). In addition, the findings of the procedure have altered the management in 33-48% of patients (level II). The Clinical Risk Score (CRS) system was developed to predict which patients will most likely benefit from SL. This system uses five preoperative criteria, which are independent factors of prognosis. Each factor is assigned one point: 1) more than one hepatic tumor, 2) disease-free interval less than 12 months (time of discovery of primary colon cancer to discovery of liver metastases), 3) lymph node-positive colon cancer, 4) CEA greater than 200 ng/mL within 1 month of surgery, and 5) size of largest hepatic tumor greater than 5 cm. If the CRS is greater than 2, then the yield of SL is higher.

### **Procedure-related Complications and Patient Outcomes**

- the general complications associated with laparoscopy and bleeding, infection, bowel injury, bile leak

In general, low rate of morbidity and mortality are found; however, complications have been reported to be as high as 28% including pneumonia and myocardial infarction (level III). Compared with open laparotomy, hospital length of stay has been demonstrated to be significantly lower for SL (5.8 days vs. 1.2 days) (level II). No adverse oncologic effects have been described.

### **Cost-effectiveness**

A 55% reduction in total hospital charges with the most savings in room and board charges has been reported after SL compared with open exploration (level II).

### **Limitations of the Available Literature**

The quality and amount of the available literature for staging laparoscopy in colorectal cancer liver metastasis is limited, since no level I evidence exists. While most studies use laparoscopic ultrasound to establish resectability, institutions differ in their technique and expertise. The impact of surgeon's expertise in the diagnostic accuracy of the procedure is unknown. To provide firm recommendations on the basis of limited available evidence impairs our ability.

## **8) Staging Laparoscopy for Primary Hepatic Tumors**

### **Rationale for the Procedure**

The prognosis of patients with hepatocellular carcinoma (HCC) may be improved with the appropriate selection of treatment, which depends on the accurate identification of all hepatic lesions, including size, number, and location. Non-therapeutic laparotomy and its associated morbidity may be prevented by the detection of unresectable disease with SL. Since peritoneal disease is uncommon with HCC, surface laparoscopy may be less valuable compared with laparoscopic ultrasound.

### **Technique**

Before the establishment of pneumoperitoneum, patient is placed in the supine position. A 30-degree laparoscope through an umbilical port is recommended for optimal visualization of the entire liver. Additional ports can be placed in the right anterior axillary line and epigastric area as needed. A standard laparoscopic ultrasound probe is used to systematically examine the entire liver identifying all lesions suspected to be malignant. Ultrasound-guided core biopsy should be used for suspicious lesions that are unresectable or preclude curative resection. Biopsy of resectable lesions need not be performed.

### **Indications**

- Patients with primary hepatic tumors who are candidates for curative resection based on preoperative identification of size and location of disease with adequate hepatic reserve



## **Contraindications**

- Patients with known unresectable hepatic disease such as major vessel or organ invasion are not candidates for surgery

In addition, dense intra-abdominal adhesions, particularly surrounding the liver, from prior surgery may be considered a relative contraindication to SL and laparoscopic ultrasound.

## **Risks**

- Procedure- or anesthesia-related complications
- Unnecessary patient morbidity in cases of a low yield procedure
- Potential adverse oncologic effects of the procedure
- False negative examinations that lead to unnecessary laparotomy

## **Benefits**

The appropriate identification of patients who have unresectable disease by SL with laparoscopic ultrasound will potentially spare these patients a non-therapeutic laparotomy with its associated morbidity and may alter treatment plans. Additional benefits include decreased patient morbidity, hospital stay and costs, and earlier time to adjuvant treatment.

## **Diagnostic Accuracy of the Procedure**

The identification of hepatic tumors using tri-phasic CT scan is less sensitive than laparoscopic ultrasound in correlation studies and is highly dependent on tumor size: 0-1 cm (71%), 1-2 cm (84%), 2-3 cm (96%), and greater than 3 cm (100%) (Level II). Laparoscopic ultrasound can detect 9.5% more tumors than CT alone, most of which are less than 1 cm (level II). Staging laparoscopy correctly identifies 63-67% of patients with unresectable disease (level II, III). The most common reasons that SL missed unresectable disease were vascular invasion, lymph node metastases, and adjacent organ invasion. With the combination of SL and laparoscopic ultrasound, 16-25% of patients may avoid open laparotomy (level II, III).

## **Procedure-related Complications and Patient Outcomes**

Procedure-related complications are uncommon, and no mortality has been reported. Bleeding, infection, bowel injury, bile leak, and anesthesia-related complications may occur. Compared with open exploration, patients undergoing SL with laparoscopic ultrasound have been reported to have shorter hospital stay (9 vs. 2.2 - 5 days, respectively) and earlier time to adjuvant therapy (23 vs. 6 days, respectively) (level II, III). No adverse oncologic effects of the procedure have been described.

## **Cost-effectiveness**

A 60% drop in hospital charges for patients undergoing SL compared with open laparotomy has been described (level II).

## **Limitations of the Available Literature**

In primary hepatic tumors the quality and amount of the available literature for staging laparoscopy is limited, and no level I evidence exists. The designs of these studies differ. Some compare SL with laparoscopic ultrasound to preoperative imaging while others compare it to exploratory laparotomy. There is also inconsistency in the type of preoperative imaging and the specific CT scan techniques used. In addition, the impact of each surgeon's expertise in laparoscopic ultrasound on the diagnostic accuracy of the procedure remains unknown.

## **9) Staging Laparoscopy for Biliary Tract Tumors**

### **Rationale for the Procedure**

Two main categories of Biliary tract tumors: gallbladder cancers and cholangiocarcinomas. The two groups differ in their patterns of spread and in prognosis. Gallbladder cancer tends to grow more rapidly and has earlier dissemination which makes SL a more useful tool in this setting. In contrast, cholangiocarcinomas tend to be more locally invasive, decreasing the yield of SL. Preoperative imaging to determine resectability of biliary tract cancers often includes ultrasound, CT scan, direct cholangiography (PTC or ERCP), and/or MRCP. These radiologic preoperative studies are used to evaluate the extent of tumor within the biliary tree, vascular invasion, hepatic lobar atrophy, and metastatic disease.

Many gallbladder cancers are incidental findings during or after laparoscopic cholecystectomy. For patients with T2 lesions or greater, liver resection is indicated as a secondary procedure, therefore obviating the need for SL.

### **Technique**

The patient is placed in the supine position, and pneumoperitoneum is established. A 30-degree laparoscope through an umbilical port is recommended for optimal visualization of the entire abdominal cavity. Additional ports can be placed in the right anterior axillary line and epigastric area as needed. Careful and thorough inspection of the peritoneum, pelvis, liver surfaces, porta hepatitis, gastrohepatic ligament, and omentum should be made. A standard laparoscopic ultrasound probe may improve the yield of finding lesions in the liver and lymph node metastasis in the porta and celiac nodal areas. Biopsy specimens of peritoneal metastases, nodes suspected to be malignant, or hepatic lesions should be obtained to determine the extent of disease.

### **Indications**

- Known or suspected gallbladder cancer without evidence of unresectable or metastatic disease
- Stage T2 or T3 hilar cholangiocarcinoma without evidence of unresectable or metastatic disease determined by preoperative imaging

### **Contraindications**

- Known metastatic or unresectable disease
- Known stage T1 disease found incidentally may potentially be treated with cholecystectomy alone.

Dense intra-abdominal adhesions from prior surgery, particularly surrounding the porta hepatitis, may be considered a relative contraindication

### **Risks**

1. Procedure- or anesthesia-related complications
2. Potential adverse oncologic effects of the procedure
3. False negative examinations that lead to unnecessary laparotomy
4. Unnecessary patient morbidity in cases of a low yielding procedure

### **Benefits**

Staging laparoscopy may spare patients a laparotomy for incurable disease with an associated decreased morbidity and pain, faster recovery, and earlier time to adjuvant treatment.

### **Diagnostic Accuracy of the Procedure**

Staging laparoscopy can detect peritoneal or superficial liver metastases (23%), which are often not detected by preoperative imaging (level III). For gallbladder cancer, the overall yield for detecting unresectable disease using SL has been reported to be 48%, with a diagnostic accuracy of 58% (level II). In cholangiocarcinoma, as many as 9%-42% of patients may avoid laparotomy with an accuracy of 42-53% (level II, III) The sensitivity and negative predictive value of SL for detecting unresectable disease have been reported to be 60% and 52%, respectively (level II). The yield of SL for gallbladder cancer is slightly higher than for cancers of the biliary tree because of the higher incidence of peritoneal and liver metastases associated with gallbladder cancer. One study suggests that the yield for cholangiocarcinoma may be improved if SL is limited to patients with higher stage primary tumors on preoperative imaging (T2 and T3), since there are few patients with stage T1 disease who are deemed unresectable (9%) by laparoscopy. The additional benefit of laparoscopic ultrasound in improving the diagnostic yield of the procedure has been inconsistent in the literature (0-41%) (level II, III).

### **Procedure-related Complications and Patient Outcomes**

The reported incidence of complications is low with no mortality. Potential risks include bleeding, infection, and bile leak, particularly if liver biopsy is performed. Additional risks include those associated with surgical laparoscopy in general and risks associated with anesthesia. The assumed benefit of earlier time to adjuvant therapy for patients with metastatic disease has not been addressed in the literature. However, the average length of stay after SL is 2-3 days, which compares favorably with laparotomy (level II). There have been no reported adverse oncologic effects of SL for biliary cancer.

### **Cost-effectiveness**

There are no data in the literature addressing the cost-effectiveness of the procedure.

### **Limitations of the Available Literature**

The reported literature for staging laparoscopy in biliary tract cancer patients is limited, and no level I evidence exists. From highly specialized centers there are a small number of reports with variations in technique. In addition, some studies span a period of 7-10 years, which likely affects the quality of preoperative imaging as well as laparoscopic technique at the beginning and end of the study. The impact of surgeon's expertise in the diagnostic accuracy of the procedure is unknown. To provide strong recommendations these shortcomings of the literature limits our ability.

## **10) Staging Laparoscopy for Lymphoma**

### **Rationale for the Procedure**

Hodgkin's lymphoma originates in one nodal group and spreads in a stepwise manner to contiguous nodal groups. Staging laparoscopy may be useful in determining the stage and location of the disease, as this may affect decisions regarding treatment, particularly the administration of chemotherapy.

In contrast, for non-Hodgkin lymphoma, the exact extent of the disease has less impact on the treatment course, and therefore, SL in non-Hodgkin lymphoma is less frequently performed. The primary indication for SL in non-Hodgkin lymphoma is for tissue diagnosis through biopsy of intra-abdominal lymph nodes in the absence of peripheral lymphadenopathy.

### **Technique**

Patients are commonly placed at a 45-degree angle, left decubitus position. A laparoscopic hand-assisted technique is often used, especially when splenectomy is planned. The steps of SL are similar to the traditional open procedure:

1. Inspection for gross abnormalities

2. Core liver biopsy of each hepatic lobe and wedge biopsy of left lateral liver segment
3. Laparoscopic ultrasound to search for hepatic lesions
4. Splenectomy with removal of organ intact
5. Lymph node sampling of the following areas: iliac, celiac, portal, mesenteric, and peri-aortic
6. Lymph node excision of abnormal nodes identified on preoperative testing with application of clips at those excision areas
7. Oophoropexy posterior to the uterus

### **Indications**

- Tissue diagnosis and biopsy of intra-abdominal lymphadenopathy in the absence of peripheral lymphadenopathy, especially for non-Hodgkin's lymphoma cases and when core needle biopsy has been non-diagnostic
- Accurate staging in Hodgkin's lymphoma when staging affects decisions for appropriate treatment or prognosis
- Restaging after treatment or when recurrence is suspected

### **Contraindications**

There have been no specific contraindications reported for SL in lymphoma. However, dense intra-abdominal adhesions from prior surgery may be considered a relative contraindication.

### **Risks**

- Procedure- or anesthesia-related complications
- Potential adverse oncologic effects of the procedure

### **Benefits**

To confirm the diagnosis of non-Hodgkin lymphoma staging laparoscopy may spare patients the morbidity of an unnecessary laparotomy and provide tissue or allow the surgical staging of Hodgkin lymphoma. Staging laparoscopy can also be used for patients who need laparoscopic splenectomy as treatment and may lead to less pain, faster recovery, and earlier time to definitive treatment.

### **Diagnostic Accuracy of the Procedure**

Data on the accuracy of the procedure come mainly from feasibility studies (level III) and are sparse. Compared with percutaneous biopsy, laparoscopic biopsy was demonstrated to have superior sensitivity (87% vs. 100%, respectively), specificity (93% vs. 100%, respectively), and accuracy (33% vs. 83%, respectively) (level III).

### **Procedure-related Complications and Patient Outcomes**

Published morbidity ranges widely (1-20%) and includes complications such as small bowel perforation, abscess, pancreatitis, bleeding, and pneumonia. Conversion to laparotomy has been reported to occur in 5-17% of the cases. No mortality has been reported. The presumed benefit of earlier time to adjuvant therapy has not been addressed in the literature. On the other hand, length of stay after DL has been reported to vary between 1 and 4 days. No adverse oncologic effects have been reported for the procedure.

### **Cost-effectiveness**

No cost-effectiveness data exist.

### **Limitations of the Available Literature**

For staging laparoscopy in lymphoma the quality of the available literature is primarily limited to retrospective reviews. In addition, quite small number of studies is available. Furthermore, some studies compare the accuracy of the procedure with historical controls for open surgery, which increases the bias of the results. Surgical technique differs according to the institution and surgeon experience.

## **11) Diagnostic Laparoscopy for Pelvic Pain and Endometriosis**

### **Rationale for the Procedure**

Chronic pelvic pain is typically defined as pelvic pain lasting more than 6 months and is a complex disorder with multiple etiologies. It influences many women and can severely impair their quality of life and lead to frequent visits to gynecologists. The etiology of chronic pelvic pain is frequently obscure despite the use of many diagnostic tests. For direct visualization of the pelvis Diagnostic laparoscopy is an excellent tool and may help identify the etiology of the patients' pain. The procedure facilitates therapeutic intervention and may help ameliorate the morbidity of an open exploration.

### **Technique**

The procedure can be employed under general anesthesia or conscious sedation. The latter approach must be used with the technique of conscious pain mapping during which the patient can respond to intra-peritoneal manipulations that may identify the source of pain. Smaller trocars and lower pneumoperitoneum pressures should be used with this technique to decrease the operative pain.

The patient is placed in the lithotomy position. The initial access site is usually peri-umbilical. Additional trocars can be placed in the left lower or right lower quadrant. A manipulator can be placed on the cervix and a rectal probe can be used if necessary for further retraction; these instruments are usually not used during conscious sedation.

During the procedure, identified adhesions are divided, and lesions suspected to be endometriosis should be biopsied and classified. In the absence of visible endometriosis lesions, random biopsies may demonstrate endometriosis in 30% of patients with typical symptoms. Should be sampled out free peritoneal fluid and examined for the presence of endometriosis. Endometriosis lesions can then be fulgurated or removed.

### **Indications**

- Chronic pelvic pain of unknown etiology after appropriate noninvasive workup

### **Contraindications**

- Procedure intolerance
- Known dense pelvic adhesions that may make an accurate evaluation of pelvic pathology impossible or may impede safe abdominal access

### **Risks**

- Procedure- or anesthesia-related complications

### **Benefits**

- Possibility for immediate therapeutic intervention
- Potential improvement in the patient's quality of life
- Potential identification of the source of the chronic pelvic pain

### **Diagnostic Accuracy of the Procedure**

Diagnostic laparoscopy has been demonstrated to identify endometriosis, adhesions, or other abnormalities of the appendix and ovaries as the source of chronic pelvic pain.

In patients with clinical suspicion of endometriosis, DL has been shown to confirm the diagnosis in 78-84% of patients (level III). Random peritoneal biopsies and peritoneal fluid cytology have been shown to improve the diagnosis of endometriosis by 20% (level III). In addition, up to 22% of patients with findings of endometriosis during DL have had previous nondiagnostic laparoscopy (level III). The diagnosis of endometriosis is more likely when multiple complex pigmented lesions are observed during DL.

For pelvic inflammatory disease, the visual accuracy of DL alone was found to be 78% (sensitivity 27% and specificity 92%) (level III). In the same study, the diagnostic accuracy of the procedure was significantly higher for more experienced laparoscopists. Pain mapping identified a direct source for the pain in 80% of patients with adhesions but was inconsistent in patients with endometriosis.

### **Procedure-related Complications and Patient Outcomes**

Procedure-related complications include bowel injuries, bleeding, urologic injuries, vaginal cuff wounds, peritonitis, and pelvic pain. In a large multi-center French study (n=30,000), diagnostic and therapeutic laparoscopy were found to be associated with a 3.3 per 100,000 mortality and a 4.6 per 1,000 morbidity risk (level II). Complications requiring conversion to laparotomy occurred in 3.2 per 1,000 patients. The risk of complications was related to the complexity of surgery and the experience of the laparoscopist. One in four intra-operative complications was missed during the procedure.

For laparoscopic pain mapping, under conscious sedation, one study showed 48 of 50 women had improvement (level II).

### **Cost effectiveness**

There are no available data on the cost effectiveness of DL for chronic pelvic pain.

### **Limitations of the Available Literature**

Due to the limitation of the quality of the available literature, as almost all of the available studies are retrospective studies from single institutions. Furthermore, there is a paucity of data on long-term outcomes and little data on cost-effectiveness and quality of life.

## **12) Diagnostic Laparoscopy in Primary and Secondary Infertility**

### **Rationale for Procedure**

Laparoscopy is typically the final step of a workup for infertility and is used to avoid open surgery. Diagnostic laparoscopy can be used as an adjunct to salpingography to help diagnose causes of infertility. Lesions that may not be seen with salpingography and are viewed better with laparoscopy include endometriosis and adhesions.

### **Technique**

The lithotomy position is employed so that cervical manipulation can be used. Standard prone positioning is used, when cervical manipulation is not needed. A primary trocar site is placed in the periumbilical region, and additional trocars are placed in the right and or left lower quadrants as needed. To check for patency, Methylene blue or other dye can be injected into the fallopian tube. Peritoneal fluid can be obtained to check for endometriosis. Endometriosis observed should be biopsied and classified with tools such as the American Society for Reproductive Medicine Guidelines. Adhesions can be identified and classified as mild, moderate, or severe. Pathology affecting the fallopian tube can be classified as mild (a superficial vascular pattern suggesting congestion or inflammation and/or minimal kinking, and/or minimal

fibrosis), moderate (salpingitis, isthmica, nodosum, distal phimosis, high degrees of vascular change, fibrosis, ampullary dilation after visualization with chromotubation), or severe (obstruction of the tube proximally or distally). Treatment of identified pathology can be initiated at this time.

### **Indications**

- Infertility particularly after normal hysterosalpingography

### **Contraindications**

- Inability to tolerate general anesthesia or significant pelvic adhesions that may preclude safe access or visualization

### **Risks**

- Procedure- and anesthesia-related complications

### **Benefits**

- Possible therapeutic intervention
- Identification of the reason for infertility
- Confirmation of lack of pathology may also be important for further treatment options

### **Diagnostic Accuracy of the Procedure**

The diagnostic yield of the procedure for infertile women after negative hysterosalpingography has been described to range between 21 and 68% (level III). Identified pathology includes intrinsic tubal disease (3-24%), peritubal adhesions (18-43%), and endometriosis (up to 43%). To have a higher yield in secondary infertility the procedure has been described (54%) compared with primary infertility (22%) (Level III). Furthermore, DL has been shown to alter treatment decisions in at least 8% of patients (level III) and may lead to earlier intervention with assisted reproductive technology.

### **Procedure-related Complications and Patient Outcomes**

Procedure-related complications include bowel injuries, bleeding, urologic injuries, vaginal cuff wounds, peritonitis, and pelvic pain. In a large multi-center French study (n=30,000), diagnostic and therapeutic laparoscopy were found to be associated with a 3.3 per 100,000 mortality and a 4.6 per 1,000 morbidity risk (level II). Complications requiring conversion to laparotomy occurred in 3.2 per 1,000 patients. The risk of complications was related to the complexity of surgery and the experience of the laparoscopist. During the procedure one in four intra-operative complications was missed.

After laparoscopy up to 45% of patients may become pregnant within 1 year, many without *in vitro* fertilization (level III). While bilateral tubal occlusion on laparoscopic inspection usually signifies the need for *in vitro* fertilization, pregnancies in patients with this pathology have been described.

### **Cost Effectiveness**

There are no available data on the cost effectiveness of DL for infertility.

### **Limitations/shortcomings**

The quality of the available literature is limited, from single institutions, as all of the available studies are retrospective studies. Furthermore, there is a paucity of data on long-term outcomes and pregnancy rates and no data on cost-effectiveness and quality of life. In addition, there is no consistency in the reporting of

pregnancy success after laparoscopy, as some studies consider the use of *in vitro* fertilization a success and others a failure.

### **13) Laparoscopy for Non-palpable Testicle**

#### **Rationale for the Procedure and/or General Comments**

Laparoscopy has been used since 1976 for the evaluation of the non-palpable testis in pediatric patients. The rationale for the procedure has been to decrease the morbidity of open standard surgical exploration for the non-palpable testicle. Moreover, therapeutic interventions such as orchiopexy and orchiectomy are also feasible using this technique.

#### **Technique**

Under general anesthesia in the operating room, a second manual palpation is performed to check for testes in the inguinal canal or scrotum. If none is found, the patient is prepped and draped in the usual manner. The primary port is inserted in the periumbilical region. For manipulation a 5-mm port is placed in the contra-lateral lower abdominal quadrant. A second port can be used for laparoscopic clipping and division of testicular vessels where necessary for the first part of the two-part staged Fowler-Stevens orchiopexy. During this part of the procedure, the testicle is identified and its relation to the spermatic vessels and internal inguinal ring ascertained. A testicle that is normal size for the patient's age should be salvaged, whereas a testicle that is non-viable should be removed. If no testicle is identified on laparoscopy and blind ending spermatic vessels are seen, the testicle has atrophied and the procedure is terminated. If no testicle is identified, no spermatic vessels are seen, and only the vas deferens is seen going into the inguinal canal, in search of the undescended testicle the laparoscopic dissection must continue higher in the retroperitoneum. The second stage of the procedure is usually performed approximately 6 months later through a high groin incision mobilizing the testicle into the scrotum.

#### **Indications**

- Identification of a non-palpable testis on physical exam

#### **Contraindications**

- Inability to tolerate the procedure
- Dense abdominal adhesions that may preclude safe access and/or dissection

#### **Risks**

- Procedure- and anesthesia-related complications

#### **Benefits**

- Decreased morbidity, less pain, and earlier recovery compared with open exploration

#### **Diagnostic Accuracy of the Procedure**

Diagnostic laparoscopy identifies the location of a nonpalpable testis with 99-100% accuracy (level III). The procedure reliably demonstrates whether the testicle is present intra-abdominally or whether the vas and the vessels enter the internal inguinal ring. When laparoscopy is applied only for diagnosis, it can still prevent unnecessary abdominal explorations in 13-18% of patients (level III). Inguinal exploration alone may identify up to 34% of testicles and obviate laparoscopy; however, no good predictors exist (III). Laparoscopy by a skilled laparoscopist enables therapeutic intervention (orchidopexy or orchiectomy), minimizes the need for open explorations, and preserves the benefits of the minimally invasive approach.



Importantly, physical examination under anesthesia prior to laparoscopy may identify up to 18% of non-palpable testicles in the groin (level III). There are little data comparing laparoscopic and open exploration.

### **Procedure-related Complications and Patient Outcomes**

Procedure-related complications have been described to occur in 0-3.2% of patients, the most severe being a bowel injury.

Laparoscopic-assisted orchidopexy has been associated with 0-2.2% testicular atrophy and 97% success rates. This compares favorably with the one-stage Fowler-Stephens orchidopexy (with a 22% atrophy and 74% success rate) and the two-stage Fowler-Stephens orchidopexy (with a 10% atrophy and 88% success rate) (level III). It has been hypothesized that laparoscopic orchidopexy may decrease the rate of testicular atrophy by preserving the vascular supply as it can be performed usually in one stage.

### **Cost-effectiveness**

There are no available data on the cost-effectiveness of the procedure.

### **Limitations of the Available Literature**

The quality of the available literature for laparoscopy in the management of non-palpable testis is limited to level III evidence. No studies compare the open and laparoscopic approach with regard to patient morbidity, and there is inconsistency in the use of preoperative localization studies before laparoscopy.

## **14) Diagnostic Laparoscopy for Liver Diseases**

### **Rationale for the Procedure**

Liver disease amenable to laparoscopic exploration can be categorized into three main categories: discrete masses (metastatic cancer, hepatoma, or benign masses), diffuse diseases (HIV-related liver function abnormalities, hepatomegaly with or without splenomegaly, unexplained portal hypertension, and cirrhosis), and disease processes possibly related to the liver (ascites, abnormal liver function tests, or fever of unknown origin). Diagnostic laparoscopy may play a role as an adjunct to other diagnostic tests, especially when the diagnosis is in question or to grade the severity of disease.

### **Technique**

Preoperatively coagulopathy should be corrected to the extent possible. The procedure is usually performed under general anesthesia; however, conscious sedation has also been described. The first trocar is usually placed in the periumbilical area paying attention to avoid potential varices. The position of other trocars is based on the liver lesions under evaluation or potential biopsy sites. A wedge biopsy can be taken with a cupped forceps through a 10-mm trocar at the umbilicus with a second 5-mm trocar below the liver edge to accommodate the camera. The same trocar can then be used to coagulate the biopsy site. For liver exploration, two 5-mm trocars in addition to the umbilical trocar may be used for tissue manipulation. Percutaneous needle biopsy specimens may be obtained under direct visualization and to confirm hemostasis. Hemostasis may be obtained with direct compression or coagulation. Laparoscopic ultrasound may be used to identify discrete liver lesions, confirm appropriate biopsy method, and avoid venous structures. The procedure is feasible in at least 98% of high risk patients, and biopsies are possible in 93-95% of patients (level III). Ninety-seven percent of laparoscopic liver biopsies are an adequate size for diagnostic histological evaluation (level III).

### **Indications**

- Grading of severity of illness particularly in cases of cirrhosis
- Evaluation of liver diseases after nondiagnostic radiologic examination

- Staging of hepatoma (?)
- Biopsy in patients with coagulopathy or for lesions difficult to access percutaneously

### **Contraindications**

- Inability to tolerate anesthesia or the procedure

### **Risks**

- Procedure- and anesthesia-related complications

### **Benefits**

- Avoid open surgery and its associated morbidity, less pain, quicker recovery

### **Diagnostic Accuracy of the Procedure**

The procedure leads to the correct diagnosis in 91% of patients and requires biopsy in most cases (level III). The sensitivity and specificity of the procedure have been reported at 100% and 97%, respectively for the diagnosis of liver cirrhosis (level III).

The diagnostic yield of the procedure depends on the disease process (chronic liver disease 98%, cancer 85%, ascites 82%, abnormal liver function tests 91%, HIV-related abnormal liver function tests 81%, and hepatomegaly, splenomegaly, unexplained portal hypertension, fever of unknown origin, or cholestasis 74%).

The visual inspection of the liver alone without biopsy has been reported to be 96% sensitive and 100% specific for detecting fatty infiltration or non-alcoholic steato-hepatitis (level III). Furthermore, it has been suggested that the visual diagnosis of cirrhosis is more accurate than the histological diagnosis, in patients with chronic hepatitis C infection, at least for the prediction of treatment success with interferon-alfa.

### **Procedure-related Complications and Patient Outcomes**

Major complications have been described in 0.45% of patients and include bowel perforation, bleeding from the biopsy site, hemobilia, and splenic laceration. Minor complications occur in 1.7% of cases and include ascitic fluid leakage, abdominal wall hematoma, and postoperative fever.

### **Cost effectiveness**

There are no available data on the cost effectiveness of DL for liver disease

### **Limitations of the Available Literature**

The quality of the available literature is limited, as almost all of the available studies are retrospective studies from single institutions. Furthermore, there is a paucity of data on long-term outcomes and little data on cost-effectiveness and quality of life. There are also no direct comparisons with regard to complications and outcomes between percutaneous, laparoscopic, and open biopsy of the liver.

## **15) Other**

Diagnostic laparoscopy has been applied to many clinical conditions in addition to the ones included in these guidelines. Nevertheless, the available literature for such conditions is scarce, consists mainly of case reports, and is therefore not included in the guidelines.

The use of DL has also been applied outside the operating room. In addition to bedside laparoscopy under conscious sedation and local anesthesia in the ICU or “awake” laparoscopy under local anesthesia in the emergency department described in this review, DL has been applied as an office procedure. This application of DL is rare in the United States with limited available evidences.

The new natural orifice transluminal endoscopic surgery is an alternative technique for the performance of DL that may be important in the near future. This procedure will likely be included in future versions of these guidelines when additional, more convincing evidence has accumulated.