# **Complete Summary**

#### **GUIDELINE TITLE**

Guidelines for diagnosis, treatment, and use of laparoscopy for surgical problems during pregnancy.

## **BIBLIOGRAPHIC SOURCE(S)**

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Guidelines for diagnosis, treatment, and use of laparoscopy for surgical problems during pregnancy. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2007 Sep. 25 p. [178 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES guidelines for laparoscopic surgery during pregnancy. Santa Monica (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2000 Oct. 4 p. [31 references]

## **COMPLETE SUMMARY CONTENT**

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

**SCOPE** 

## **DISEASE/CONDITION(S)**

Abdominal surgical emergencies in pregnant women for whom laparoscopy is indicated, including:

- Acute appendicitis
- Cholecystitis
- Intestinal obstruction

- Ovarian cysts, masses, or torsion
- Symptomatic cholelithiasis
- Adrenal tumors
- Splenic disorders
- Symptomatic hernias
- Complications of inflammatory bowel diseases
- Abdominal pain of unknown etiology

## **GUIDELINE CATEGORY**

Assessment of Therapeutic Effectiveness Management Risk Assessment Treatment

#### **CLINICAL SPECIALTY**

Gastroenterology Obstetrics and Gynecology Radiology Surgery

#### **INTENDED USERS**

Physician Assistants Physicians

# **GUIDELINE OBJECTIVE(S)**

To provide specific recommendations and guidelines to assist physicians in the diagnostic work-up and treatment of surgical problems in pregnant patients focusing on the use of laparoscopy

#### **TARGET POPULATION**

Women with a confirmed intrauterine pregnancy who require abdominal surgery that would normally be done laparoscopically

## INTERVENTIONS AND PRACTICES CONSIDERED

## **Diagnosis**

- 1. Ultrasound
- 2. Limiting doses of ionizing radiation
- 3. Computed tomography
- 4. Magnetic resonance (MR) imaging
- 5. Nuclear medicine
- 6. Cholangiography (including MR cholangiopancreatography [MRCP])
- 7. Endoscopic retrograde cholangiopancreatography (ERCP)
- 8. Intra-operative ultrasound
- 9. Intra-operative choledochoscopy

## 10. Diagnostic laparoscopy

#### **Patient Selection**

- 1. Pre-operative decision making
- 2. Use of laparoscopy during any trimester of pregnancy

# **Laparoscopic Management**

- 1. Patient positioning
- 2. Initial port placement
- 3. Insufflation pressure
- 4. Intra-operative carbon dioxide monitoring by capnography
- 5. Venous thromboembolic prophylaxis (pneumatic compression devices and early ambulation)

### **Treatments/Management**

- 1. Laparoscopic cholecystectomy
- 2. Preoperative ECRP with sphincterotomy
- 3. Laparoscopic transcystic or choledochotomy common bile duct exploration
- 4. Post-operative ECRP
- 5. Laparoscopic appendectomy
- 6. Laparoscopic solid organ resection (adrenalectomy, nephrectomy, splenectomy)
- 7. Laparoscopic removal of adnexal mass
- 8. Expectant management of adnexal mass
- 9. Laparoscopic detorsion or resection of adnexal torsion
- 10. Laparotomy

## **Peri-operative Care**

- 1. Fetal heart monitoring
- 2. Obstetrical consultation
- 3. Use of tocolytics

#### **MAJOR OUTCOMES CONSIDERED**

- Maternal and fetal morbidity and mortality
- Complication rates

## **METHODOLOGY**

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

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

Guideline developers followed established guidelines for writing Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) clinical practice guidelines, which include performing literature searches in Medline, Cochrane database, and Database of Abstracts of Reviews of Effects (DARE) and manually searching bibliographies of systematic reviews for additional references.

#### NUMBER OF SOURCE DOCUMENTS

224 articles

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

Weighting According to a Rating Scheme (Scheme Given)

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

#### **Levels of Evidence**

**Level I** - Evidence from properly conducted randomized, controlled trials

**Level II** - Evidence from controlled trials without randomization

Or

Cohort or case-control studies

Or

Multiple time series, dramatic uncontrolled experiments

**Level III** - Descriptive case series, opinions of expert panels

#### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

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

Not stated

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Recommendations are based on the current medical evidence and have been graded according to the available evidence. Where data exist for only open

surgical procedures, the guideline developers will adapt these data, and note a lower evidence and/or recommendation rating.

Each guideline is developed with a systematic approach, and includes review of the available literature and expert opinion when published data alone are insufficient to make recommendations.

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

#### **Recommendation Grades**

**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

#### **COST ANALYSIS**

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

#### METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups Internal Peer Review

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

This statement was reviewed and approved by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), September 2007. It was revised by the SAGES Guidelines Committee.

#### **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Levels of evidence (I–III) and recommendation grades (A–C) are defined at the end of the "Major Recommendations" field.

## **Diagnosis and Workup**

## **Imaging Techniques**

Ultrasound

Guideline 1: Ultrasonographic imaging during pregnancy is safe and useful in identifying the etiology of acute abdominal pain in the pregnant patient (**Level II**, **Grade A**).

Risk of Ionizing Radiation

Guideline 2: Expeditious and accurate diagnosis should take precedence over concerns for ionizing radiation. Radiation dosage should be limited to 5-10 rads in the first 25 weeks of pregnancy (**Level III, Grade B**).

Computed Tomography (CT)

Guideline 3: Contemporary multi-detector CT protocols deliver a radiation dose to the fetus below detrimental levels and may be considered as an appropriate test during pregnancy depending on the clinical situation (**Level III, Grade B**).

Magnetic Resonance (MR) Imaging

Guideline 4: MR Imaging can be performed at any stage of pregnancy without the use of intravenous Gadolinium (**Level III, Grade B**).

Nuclear Medicine

Guideline 5: Nuclear Medicine administration of radio nucleotides can generally be accomplished at fetal radiation levels of exposure that are well below any known detrimental levels (**Level III, Grade C**).

Cholangiography

Guideline 6: Intra-operative and endoscopic cholangiography exposes the mother and fetus to minimal radiation and may be used selectively during pregnancy. The lower abdomen should be shielded when performing cholangiography during pregnancy to decrease the radiation exposure to the fetus (**Level III, Grade B**).

## **Surgical Techniques**

Guideline 7: Diagnostic laparoscopy is safe and effective when used selectively in the workup and treatment of acute abdominal processes in pregnancy (**Level II**, **Grade B**).

# **Patient Selection**

## **Pre-operative Decision Making**

Guideline 8: Laparoscopic treatment of acute abdominal processes has the same indications in pregnant and non-pregnant patients (**Level II, Grade B**).

## **Laparoscopy and Trimester of Pregnancy**

Guideline 9: Laparoscopy can be safely performed during any trimester of pregnancy (**Level II, Grade B**).

### **Treatment**

## **Patient Positioning**

Guideline 10: Gravid patients should be placed in the left lateral recumbent position to minimize compression of the vena cava and the aorta (**Level II**, **Grade B**).

## **Initial Port Placement**

Guideline 11: Initial access can be safely accomplished with open (Hassan), Verres needle, or optical trocar technique if the location is adjusted according to fundal height, previous incisions, and experience of the surgeon (**Level III**, **Grade B**).

#### **Insufflation Pressure**

Guideline 12: Carbon dioxide (CO<sub>2</sub>) insufflation of 10-15 mm Hg can be safely used for laparoscopy in the pregnant patient. Intra-abdominal pressure should be sufficient to allow for adequate visualization (**Level III, Grade C**).

## Intra-operative CO<sub>2</sub> Monitoring

Guideline 13: Intra-operative  $CO_2$  monitoring by capnography should be used during laparoscopy in the pregnant patient (**Level III, Grade C**).

## **Venous Thromboembolic (VTE) Prophylaxis**

Guideline 14: Intra-operative and post-operative pneumatic compression devices and early post-operative ambulation are recommended prophylaxis for deep venous thrombosis in the gravid patient (**Level III, Grade C**).

#### **Gallbladder Disease**

Guideline 15: Laparoscopic cholecystectomy is the treatment of choice in the pregnant patient with gallbladder disease regardless of trimester (**Level II**, **Grade B**).

## Choledocholithiasis

Guideline 16: Choledocholithiasis during pregnancy may be managed with preoperative endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy followed by laparoscopic cholecystectomy, intra-operative laparoscopic transcystic or choledochotomy common bile duct exploration, or post-operative ERCP depending on local resources and clinical scenario (**Level III, Grade C**).

## **Laparoscopic Appendectomy**

Guideline 17: Laparoscopic appendectomy may be performed safely in pregnant patients with suspicion of appendicitis (**Level II, Grade B**).

## **Solid Organ Resection**

Guideline 18: Laparoscopic adrenalectomy, nephrectomy and splenectomy are safe procedures in pregnant patients when indicated and standard precautions are taken (**Level III, Grade C**).

## **Adnexal Masses**

Guideline 19: Laparoscopy is safe and effective treatment in gravid patients with symptomatic cystic masses. Observation is acceptable for all other cystic lesions provided ultrasound is non-worrisome for malignancy and tumor markers are normal. Initial observation is warranted for most cystic lesions <6 cm in size (**Level III, Grade C**).

#### **Adnexal Torsion**

Guideline 20: Laparoscopy is recommended for both diagnosis and treatment of adnexal torsion unless clinical severity warrants laparotomy (**Level III, Grade C**).

#### **Peri-operative Care**

## **Fetal Heart Monitoring**

Guideline 21: Fetal heart monitoring should occur pre- and postoperatively in the setting of urgent abdominal surgery during pregnancy (**Level III, Grade B**).

#### **Obstetrical Consultation**

Guideline 22: Obstetric consultation can be obtained pre- and/or postoperatively based on the acuteness of the patient's disease and availability (**Level III, Grade B**).

#### **Tocolytics**

Guideline 23: Tocolytics should not be used prophylactically, but should be considered peri-operatively when signs of preterm labor are present in coordination with obstetric consultation (**Level I, Grade A**).

#### **Definitions:**

#### **Levels of Evidence**

**Level I** - Evidence from properly conducted randomized, controlled trials

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Level III - Descriptive case series, opinions of expert panels

#### **Recommendation Grades**

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## **CLINICAL ALGORITHM(S)**

None provided

#### **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

There are many advantages of laparoscopy in the pregnant patient including decreased fetal depression due to lessened postoperative narcotic requirements, lower risk of wound complications, diminished postoperative maternal hypoventilation, shorter hospital stays, and decreased risks of thromboembolic events due to early mobilization. Laparoscopy reduces the risk of uterine irritability by decreasing the need for uterine manipulation because of improved visualization. Decreased uterine irritability results in lower rates of spontaneous abortion and preterm delivery.

## **POTENTIAL HARMS**

- Significant radiation exposure may lead to chromosomal mutations, neurologic abnormalities, mental retardation, and increase the risk of childhood leukemia. Exposure of the fetus to 0.5 rad increases the risk of spontaneous abortion, major malformations, mental retardation, and childhood malignancy to one additional case in 6,000 above baseline risk.
- Endoscopic retrograde cholangiopancreatography (ERCP) has risks beyond the radiation exposure such as bleeding and pancreatitis. In non-pregnant patients, the risk of bleeding is 1.3% and risk of pancreatitis is 3.5%.
- Carbon dioxide (CO<sub>2</sub>) pneumoperitoneum may increase the risk of deep venous thrombosis by increasing venous stasis. Even insufflation of 12 mm Hg causes a statistically significant decrease in blood flow that cannot be completely reversed with intermittent pneumatic compression devices or intermittent electric calf stimulators.
- Some animal studies have confirmed fetal acidosis with associated tachycardia, hypertension and hypercapnia during CO<sub>2</sub> pneumoperitoneum. Other animal studies have demonstrated no fetal acidosis. Regardless, no long-term adverse effects have been identified. Of more interest, there is no evidence to support long term detrimental effects resulting from CO<sub>2</sub> pneumoperitoneum in humans.

## **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

- Guidelines for clinical practice are intended to indicate preferable approaches
  to medical problems as established by experts in the field. These
  recommendations will be based on existing data or a consensus of expert
  opinion when little or no data are available. Guidelines are applicable to all
  physicians who address the clinical problem(s) without regard to specialty
  training or interests, and are intended to indicate the preferable, but not
  necessarily the only acceptable approaches. Guidelines are intended to be
  flexible. Given the wide range of specifics in any health care problem, the
  surgeon must always choose the course best suited to the individual patient
  and the variables in existence at the moment of decision.
- The recommendations are considered valid at the time of guideline production based on the data available. Each guideline is scheduled for periodic review to allow incorporation of pertinent new developments in medical research knowledge, and practice.
- More information has accumulated as laparoscopy has become more common during pregnancy. However, most of the data is found in case series and retrospective reviews which limit the ability to provide absolute guidelines. Further controlled clinical studies are needed to clarify these guidelines, and revision may be necessary as new data appear.

## **IMPLEMENTATION OF THE GUIDELINE**

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

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

#### **IOM CARE NEED**

**Getting Better** 

#### **IOM DOMAIN**

Effectiveness Safety Timeliness

# **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

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#### **ADAPTATION**

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

#### **DATE RELEASED**

1996 Feb (revised 2007 Sep)

## **GUIDELINE DEVELOPER(S)**

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

# **SOURCE(S) OF FUNDING**

Society of American Gastrointestinal Endoscopic Surgeons (SAGES)

#### **GUIDELINE COMMITTEE**

Guidelines Committee

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

Not stated

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Society of American Gastrointestinal and Endoscopic Surgeons disclose potential conflicts of interest and pertinent financial relationships prior to serving as faculty for SAGES-sponsored educational events, delivering presentations at scientific meetings, etc. Additionally, members of SAGES Committees disclose their potential conflicts of interest and pertinent financial relationships annually as a condition of committee membership.

#### **GUIDELINE STATUS**

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#### **GUIDELINE AVAILABILITY**

Electronic copies: Available from the <u>Society of American Gastrointestinal</u> <u>Endoscopic Surgeons (SAGES) Web site</u>.

Print copies: Available from the Society American Gastrointestinal Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064;

Web site: www.sages.org.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

None available

#### **PATIENT RESOURCES**

None available

#### **NGC STATUS**

This NGC summary was completed by ECRI Institute on December 11, 2007. The information was verified by the guideline developer on December 19, 2007.

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