Complete Summary

GUIDELINE TITLE

SAGES guideline for clinical application of laparoscopic bariatric surgery.

BIBLIOGRAPHIC SOURCE(S)

SAGES Guidelines Committee. SAGES guideline for clinical application of laparoscopic bariatric surgery. Surg Endosc 2008 Oct;22(10):2281-300. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Guidelines for the clinical application of laparoscopic bariatric surgery. Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2003 Jul. 5 p. [25 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Clinically severe obesity and/or morbid obesity

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness Evaluation
Management
Treatment

CLINICAL SPECIALTY

Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To guide surgeons applying laparoscopic techniques to the practice of bariatric surgery

Note: The document does not address credentialing of surgeons or centers, which is the focus of Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Guideline for Institutions Granting Bariatric Privileges Utilizing Laparoscopic Techniques and American Society for Metabolic and Bariatric Surgery (ASMBS) Guideline for Granting Privileges in Bariatric Surgery.

TARGET POPULATION

Morbidly obese patients who fail to respond to dietary, behavioral, nutritional, and medical therapies

Note: Body mass index (BMI) and age-based candidacy guidelines should not limit access for patients suffering with progressive or poorly controlled obesity-related comorbidities if the risk-versus-benefit analysis favors surgery.

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

- 1. Patient selection considerations
 - Body mass index (BMI)
 - Medical history/comorbidities
- 2. Preoperative workup
 - Psychological evaluation
 - Nutrition consult
 - Preoperative medical evaluation

Treatment/Management

- 1. Bariatric programs and facility
 - Multidisciplinary providers
 - Bariatric equipment
- 2. Surgical techniques and outcomes
 - Laparoscopic biliopancreatic diversion (BPD ± DS)
 - Laparoscopic roux-en-y gastric bypass (RGB)
 - Laparoscopic adjustable gastric banding (AGB)
 - Revisional surgery
 - Adjustment of gastric band

- Risk/benefit comparison of procedures
- 3. Postoperative care
 - Close, long-term follow-up, education, and support
 - Physical activity
 - Postoperative support groups

MAJOR OUTCOMES CONSIDERED

- Safety and efficacy of laparoscopic bariatric surgery
- Morbidity rates
- Mortality rates
- Quality of life

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

A broad search of the English-language literature was performed, using both electronic and physical means. The electronic search used PubMed and Cochrane Library databases. Search terms used were therefore combinations of: *obesity surgery, bariatric surgery, gastric bypass, gastroplasty, gastric band, biliopancreatic diversion, duodenal switch, sleeve gastrectomy, reoperation, revision, laparoscopic, diabetes, hypertension, hyperlipidemia, sleep apnea, nutrition, complications*. Manual reference checks of published review articles were performed to supplement the above electronic searches.

NUMBER OF SOURCE DOCUMENTS

Not stated

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 of 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

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Articles were divided and reviewed by a working group of four authors according to the protocol developed by the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Guidelines Committee, and were graded for level of evidence by the authors. Levels of evidence (and subsequent recommendations) were approved by the SAGES Guidelines Committee, the SAGES Bariatric Liaison Group and the SAGES Board of Governors.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The current recommendations are graded and linked to the evidence utilizing the definitions in appendices A and B (see "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" in this document).

Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by systematic review of available data and expert opinion.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

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

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Each guideline undergoes multidisciplinary review and is considered valid at the time of production based on data available.

The final document was approved by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Board of Governors in June, 2008, and coendorsed by the American Society for Metabolic and Bariatric Surgery (ASMBS) Board of Governors in June, 2008.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

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

Justification for Surgical Treatment of Obesity

 Weight-loss surgery is the most effective treatment for morbid obesity, producing durable weight loss, improvement or remissions of comorbid conditions, and longer life (level I, grade A).

Guidelines for Selecting Validated Bariatric Procedures

- Laparoscopic roux-en-y gastric bypass (RGB), gastric banding by vertical banded gastroplasty (VBG) or adjustable gastric band (AGB), and biliopancreatic diversion (BPD) with or without duodenal switch (±DS) are established and validated bariatric procedures that provide effective longterm weight loss and resolution of co-morbid conditions (level II, grade A).
- Laparoscopic sleeve gastrectomy (LSG) is validated as providing effective weight loss and resolution of comorbidities to 3 to 5 years (level II, grade C).

Guidelines for Patient Selection

- 1991 National Institute of Health (NIH) consensus guidelines provide valid but incomplete patient selection criteria for contemporary bariatric procedures including laparoscopic BPD ± DS, RGB, VBG and AGB (**level II, grade A**).
- Other well-selected patients may benefit from laparoscopic bariatric surgery by experienced surgeons:
 - BMI >60 kg/m² (level II, grade A).
 - Patients >60 years (**level II, grade B**).
- Adolescent bariatric surgery (age <18 years) has been proven effective but should be performed in an experienced center (level II, grade B). Patient selection criteria should be the same as used for adult bariatric surgery (level II, grade C).
- Individuals with BMI 30 to 35 kg/m2 may benefit from laparoscopic bariatric surgery (**level I, grade B**).

Guidelines for Bariatric Programs

- Bariatric surgery programs should include multidisciplinary providers with appropriate training and experience (**level III, grade C**).
- Institutions must accommodate the special needs of bariatric patients and their providers (**level III, grade C**).
- Participation in support groups may improve outcomes after bariatric surgery (level II, grade B).

Guidelines for Preoperative Preparation

- A psychological evaluation is commonly part of the preoperative work-up of bariatric patients (**level III, grade C**).
- Treated psychopathology does not preclude the benefits of bariatric surgery (level II, grade B).
- Preoperative weight loss may be useful to reduce liver volume and improve access for laparoscopic bariatric procedures (level II, grade B), but mandated preoperative weight loss does not affect postoperative weight loss or comorbidity improvements (level I, grade B).

Guidelines for Laparoscopic BPD \pm DS)

- In BPD, the common channel should be 60 to 100 cm, and the alimentary limb 200 to 360 cm (**level II, grade C**).
- DS diminishes the most severe complications of BPD, including dumping syndrome and peptic ulceration of the anastomosis (**level II, grade C**).
- BPD is effective in all BMI >35 kg/m² subgroups, with durable weight loss and control of comorbidities beyond 5 years (**level II, grade A**).
- Laparoscopic BPD provides equivalent weight loss, shorter hospital stay, and fewer complications than open BPD (**level III, grade C**).
- BPD may result in greater weight loss (**level II**, **grade A**) and resolution of comorbidities (**level II**, **grade B**) than other bariatric surgeries, but with the highest mortality rate (**level II**, **grade A**).
- After BPD ± DS, close nutritional surveillance and supplementation are needed (**level III, grade C**).

Guidelines for Laparoscopic Roux-en-y Gastric Bypass (RGB)

- In laparoscopic RGB, a small lesser-curvature-based pouch that excludes the gastric fundus and a 75 to 150 cm alimentary (Roux) limb are effective for most patients (**level II, grade B**).
- Alimentary limbs >150 cm may improve intermediate-term weight loss but also may increase nutritional complications (**level III, grade C**).
- Laparoscopic RGB is similar in efficacy to open RGB (**level I, grade A**) with reduced early complications and risk of hernia (**level II, grade B**).
- Long-term follow-up is recommended and may improve weight-loss outcomes (**level III, grade C**).

Guidelines for Laparoscopic Adjustable Gastric Band (AGB)

- The pars flaccida approach for laparoscopic AGB placement should be used in preference to the perigastric approach in order to decrease the incidence of gastric prolapse (**level II, grade A**).
- Laparoscopic AGB is effective in all BMI subgroups, with durable weight loss and control of comorbidities past 5 years (**level I, grade A**).
- Intermediate-term weight loss after laparoscopic AGB may be less than after laparoscopic RGB (**level I, grade A**).
- Frequent outpatient visits are suggested in the early postoperative period. Band filling should be guided by weight loss, satiety, and patient symptoms (**level III, grade C**).

Guidelines for Revisional Bariatric Surgery

- Prior to elective procedures, anatomy should be defined by review of available records, plus radiographic and/or endoscopic assessment (level II, grade B).
- Laparoscopic revisional procedures may be performed safely, but with more complications than primary bariatric procedures, therefore the relative risks and benefits of laparoscopy should be considered on a case-by-case basis (level III, grade C).

Definitions:

Levels of Evidence

Level I	Evidence from properly conducted randomized, controlled trials
Level II	Evidence from controlled trials without randomization
	Or
	Cohort of case-control studies
	Or
	Multiple time series, dramatic uncontrolled experiments
Level III	Descriptive case series, opinions of expert panels

Grades of Recommendation

	Based on high-level (level I or II), well-performed studies with uniform interpretation and conclusions by the expert panel
	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

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 the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Surgically induced weight loss is associated with resolution or improvement of comorbid diseases in 75% to 100% of patients, and reduced mortality compared with medically treated patients.

POTENTIAL HARMS

There is a risk of complications and death from surgery. For specific surgical complications of laparoscopic biliopancreatic diversion (BFD), laparoscopic Rouxen-Y gastric bypass (RGB), and laparoscopic adjustable gastric banding (AGB) see the original guideline document "Complications" sections.

CONTRAINDICATIONS

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Relative contraindications for bariatric surgery include severe heart failure, unstable coronary artery disease, end-stage lung disease, active cancer diagnosis/treatment, cirrhosis with portal hypertension, uncontrolled drug or alcohol dependency, and severely impaired intellectual capacity. Crohn's disease may be a relative contraindication to Roux-en-Y gastric bypass (RGB) and biliopancreatic diversion (BPD), and is listed by the manufacturer as a contraindication to the LAP-BAND® system.

Laparoscopic surgery may be difficult or impossible in patients with giant ventral hernias, severe intra-abdominal adhesions, large liver, high body mass index (BMI) with central obesity or physiological intolerance of pneumoperitoneum.

Surgeons performing bariatric surgery should possess the necessary skills to perform open bariatric surgery in the event it becomes necessary to convert to an open procedure.

QUALIFYING STATEMENTS

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- From Society of American Gastrointestinal and Endoscopic Surgeons (SAGES): Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by systematic review of available data and expert opinion. Recommendations are not intended to be exclusive given the complexity of the health care environment. These guidelines are intended to be flexible and should be applied with consideration of the unique needs of individual patients and the evolving medical literature. These guidelines are applicable to all physicians who are credentialed appropriately and who address the clinical situation in question, regardless of specialty.
- From American Society for Metabolic and Bariatric Surgery (ASMBS): Guidelines are not intended to provide inflexible rules or requirements of practice and are not intended, nor should they be used, to state or establish a local, regional, or national legal standard of care. Ultimately, there are various appropriate treatment modalities for each patient, and the surgeon must use judgment in selecting from among feasible treatment options. ASMBS cautions against the use of quidelines in litigation in which the clinical decisions of a physician are called into question. The ultimate judgment regarding appropriateness of any specific procedure or course of action must be made by the physician in light of all the circumstances presented. Thus, an approach that differs from this guideline, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious physician may responsibly adopt a course of action different from that set forth in the quideline when, in the reasonable judgment of the physician, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology. All that should be expected is that the physician will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient, in order to deliver effective and safe medical care. The sole purpose of this quideline is to assist practitioners in achieving this objective.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations Patient Resources For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

SAGES Guidelines Committee. SAGES guideline for clinical application of laparoscopic bariatric surgery. Surg Endosc 2008 Oct;22(10):2281-300. PubMed

ADAPTATION

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

DATE RELEASED

2003 Jul (revised 2008 Oct)

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

SAGES 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 (SAGES) 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.

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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 of 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

The following is available:

• Patient information for laparoscopic surgery for severe obesity from SAGES. Available in English and Spanish from the <u>Society of American Gastrointestinal</u> Endoscopic Surgeons (SAGES) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on March 22, 2004. The information was verified by the guideline developer on April 27, 2004. This information was

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