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GUIDELINES

Guidelines for institutions granting bariatric privileges utilizing laparoscopic techniques

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Principles of privileging

Preamble

The Society of American Gastrointestinal Endoscopic Surgeons (SAGES) recommends the following guidelines for privileging qualified surgeons in the performance of laparoscopic bariatric surgical procedures. The basic premise is that the surgeon must have the judgment and training to safely complete the procedure as intended, as well as have the capability of immediately proceeding to a traditional open procedure when circumstances so indicate [1–14]. Moreover, this assumes that the surgeon practices as part of a bariatric team to provide adequate preoperative care and long-term follow-up.

A. Purpose

The purpose of this statement is to outline principles and provide practical suggestions to assist healthcare institutions when granting privileges to perform bariatric procedures utilizing laparoscopy. In conjunction with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines for granting hospital privileges, implementation of these methods should help hospital staff to ensure that laparoscopic bariatric surgery is performed in a manner ensuring high-quality patient care and proper procedure utilization. The purpose of this document is not to establish the standard of care for granting privileges in laparoscopic bariatric surgery but to offer guidelines to assist credentialing committees in the evaluation of the qualifications of applicants for laparoscopic bariatric procedures.

Disclaimer: 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 due to the complexity of the healthcare environment. 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.
Guidelines are developed under the auspices of the Society of American Gastrointestinal and Endoscopic Surgeons and its various committees, and approved by the Board of Governors. Each clinical practice guideline has been systematically researched, reviewed, and revised by the guidelines committee, and reviewed by an appropriate multidisciplinary team. The recommendations are considered valid at the time of its 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.

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B. Uniformity of standards

Uniform standards should be developed that apply to all medical staff requesting privileges to perform laparoscopic bariatric surgery. Criteria must be established that are medically sound, but not unreasonably stringent, and that are universally applicable to all those wishing to obtain privileges. The goal must be the delivery of high-quality patient care. Surgical proficiency and operative outcomes should be assessed for every surgeon, and privileges should not be granted or denied based solely on the number of procedures performed [15–17]; however, it should include preoperative preparation, operative outcomes, and postoperative care [18].

C. Responsibility for privileging

The privileging structure and process remain the responsibility of the institution at which privileges are being sought. It should be the responsibility of the department of surgery, through its chief to recommend provisional/temporary privileges for individual surgeons to perform laparoscopic bariatric surgery based on training and outcomes. These recommendations should be approved by the appropriate institutional committee, board, or governing body.

D. Definitions

Must/Shall: Mandatory recommendation
Should: Highly desirable recommendation
May/Could: Optional recommendation; alternatives may be appropriate

Documented training and experience

1. Case list that must specify the applicant's role (primary surgeon, co-surgeon, first assistant, chief resident, junior resident, or observer). Complications, outcomes, and conversion to traditional techniques should be included. The applicant must specify if these details are not known.
2. Summary letter from preceptor and/or program director and/or chief of surgery (should state if applicant can independently and competently perform the procedure in question).

Privileging

The process whereby a specific scope and content of patient care services (that is, clinical privileges) are authorized for a health care practitioner by a health care organization based on evaluation of the individual's credentials and performance.

Competence or competency

A determination of an individual's capability to perform up to defined expectations.

Credentials

Documented evidence of licensure, education, training, experience, or other qualifications.

Complete procedural conduct

Competency of the applicant and/or institution regarding patient selection, peri-procedural care, conduct of the operation, technical skill, and equipment necessary to safely complete a bariatric surgical procedure using laparoscopic techniques, and the ability to proceed immediately with the traditional open procedure.

Laparoscopy

Specialized areas within the field of surgery, which require unique knowledge and set of skills related to the equipment, physiology, and operative technique, whether the procedure is performed inside or outside of the traditional operating room.

Categories of bariatric surgical procedures

For the purposes of this document, bariatric surgery will be divided into two broad categories: (1) those operations that include transection of GI tract (e.g., laparoscopic Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy, etc.) and those that do not required transection of GI tract (e.g., laparoscopic gastric band).

Formal course

This is a limited period of instruction that should offer category I Continuing Medical Education (CME) credits that meet American Medical Association (AMA) standards. The course should be taught by instructors with appropriate clinical experience and have a curriculum that includes didactic instruction as well as hands on experience utilizing inanimate and/or animate models. Other teaching aids may include video review and interactive computer programs. The curriculum should include an appropriate number of opportunities for the applicant to observe, assist, and serve as primary operator for the procedure for which privileges are being sought. The course director and/or

instructor should provide a written assessment of the participant's mastery of course objectives. Documentation for certain courses consisting of only didactic instruction may consist of verification of attendance. A formal course alone is not appropriate training to begin performing a procedure independently.

Minimum requirements for granting privileges

Completion of formal residency training in general surgery and being a part of a team that is dedicated to the long-term follow-up of the bariatric surgical patient are mandatory for all candidates.

- Candidates who fall into Category B must accomplish F3 and also must accomplish F2 or F4.
- Candidates who fall into Category C must accomplish F1 and may/could accomplish F2.
- Candidates who fall into Category D must accomplish F2, F3, and F4.
- Candidates who fall into Category E must accomplish F3, should accomplish F4 and may/could accomplish F2.

Please see attached algorithm (Fig. 1) and Table 1.

A. Formal residency training in general surgery

Prerequisite training must include satisfactory completion of an accredited surgical residency program, with subsequent certification by the American Board of Surgery, or its equivalent, as required by the institution.

B. Formal training in open bariatric surgery

For surgeons who successfully completed a residency and/or fellowship program that incorporated a structured experience in open bariatric surgery, the applicant's program director, and if desired other faculty members, should supply the appropriate documentation of training.

C. Formal training in laparoscopic bariatric surgery

For surgeons who successfully completed a residency and/or fellowship program that incorporated a structured experience in laparoscopic bariatric surgery, the applicant's program director, and if desired other faculty members, should supply the appropriate documentation of training [19, 20].

D. No formal residency training in laparoscopic or open bariatric surgery

For those surgeons without residency and/or fellowship training, which included structured experience in laparoscopic and/or open bariatric surgery, or without documented prior experience in these areas, a structured training curriculum is required.

E. Experienced advanced laparoscopic surgeon

For those surgeons who have extensive experience with intracorporeal and extracorporeal suturing, stapling, tissue dissection, and energy device usage, a formal course for the specific category of bariatric procedure for which privileges are being sought is required.

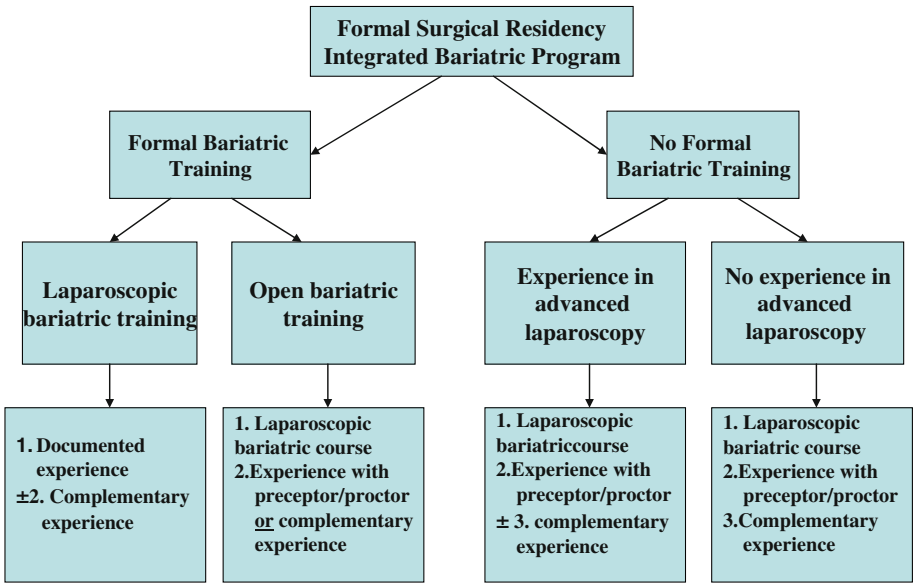

Fig. 1 Laparoscopic bariatric privileges guidelines algorithm

Table 1 Requirements for laparoscopic bariatric surgery privileges

Type of bariatric experience	Documented experience	Laparoscopic bariatric course	Experience with preceptor/proctor		Complementary experience
Laparoscopic bariatric training	+	−	−		±
Open bariatric training	−	+	+	or	+
Experience in advanced laparoscopy	−	+	+		±
No formal bariatric training	−	+	+		+

F. Practical experience

1. Applicant's experience—Documented training experience that includes an appropriate volume of cases (open and/or laparoscopic) in the category of bariatric surgical procedure for which privileges are being considered (transection versus non-transection, "Definitions" section above). The chief of surgery should determine the adequacy of this experience based on the number of procedures, the role of the applicant during the procedure, and the outcome of these procedures.
2. Complementary experience—Two surgeons (applicant and an experienced laparoscopic or bariatric surgeon) supporting one another who demonstrate combined expertise in the complete procedural conduct. (Must include one surgeon skilled in laparoscopy and in the traditional open technique for the specific category of bariatric procedure for which privileges are being sought.)
3. Applicant must complete a formal course for the specific category of bariatric procedure for which privileges are being sought.
4. Experience with preceptor and/or proctor—The specific role and qualifications of the preceptor and/or proctor, if required, must be determined by the institution. Criteria of competency for each procedure should be established in advance and should include evaluation of: familiarity with instrumentation and equipment, competence in their use, appropriateness of patient selection, clarity of dissection, safety, successful completion of the procedure, technical complications, and documented outcomes (mortality and morbidity to include anastomotic leak, DVT/PTE, open conversion, and others as determined by the credentialing committee). The chief of surgery in conjunction with the specific specialty chief should establish the criteria where appropriate. It is essential that proctoring be provided in an unbiased, confidential, and objective manner.

G. Follow-up

It is necessary to document that the surgeon is working with an integrated program for the care of the morbidly obese patient that provides ancillary services, such as specialized nursing care, dietary instruction, counseling, support groups, exercise training, and psychological assistance as needed. Document that there is a process in place to minimize, monitor, and manage short-term and long-term complications, as well as to provide follow-up for all patients is required [21–25].

Institutional support

Bariatric procedures require a significant amount of supporting infrastructure (both equipment and staff training), which is vital for the complete procedural conduct of bariatric procedures. It is incumbent on the institution and surgeon to have this infrastructure in place before initiating a program. Appropriate support aspects are delineated in the Bulletin of ACS, Vol. 85, No. 9, Sept. 2000.

Many laparoscopic bariatric operations require the presence of two skilled surgeons for their safe and efficient performance. To conform to these requirements, the surgeon should choose a skilled first assistant, and the surgeon and the institution should use the assistant when required. Guidelines for the first assistant are given in the SAGES Statement on First Assistant [12].

It is strongly advised that the institution and/or surgeon seek certification as a Center of Excellence in bariatric surgery as designated by the governing body of their choosing. This is important to ensure that the institutional and programmatic support is adequate for bariatric surgery.

Maintenance of privileges

A. Provisional privileges

Once competence has been determined, a period of provisional privileges may be appropriate. The timeframe and/or number of cases required during this period should be determined by the chief of surgery and/or the appropriate institutional committee, board, or governing body.

B. Monitoring of performance

Once privileges have been granted, performance should be monitored through existing quality assurance mechanisms at the institution. These mechanisms may be modified as appropriate and should evaluate outcomes (mortality and morbidity to include anastomotic leak, DVT/PTE, open conversion and others as determined by the credentialing committee) as well as competency in the complete procedural conduct [26, 27].

C. Continuing medical education

Continuing medical education related to bariatric surgery should be required as part of the periodic renewal of privileges. Attendance at appropriate local, national, or international meetings and courses is encouraged to satisfy these requirements. It is highly recommended that the surgeon join and maintain membership in the appropriate surgical organizations (SAGES, ASMBS, ACS, IFSO, etc.) that have specific interest in laparoscopic bariatric surgery to remain current and committed to bariatric surgery.

D. Renewal

An appropriate level of continuing clinical activity should be required. This should include review of quality assurance data, as well as appropriate CME activity, in addition to existing mechanisms at the institution designed for this purpose. It is recommended that the local facility review the surgeon's outcome data within 6 months of initiation of a new program and at regular intervals thereafter, to evaluate patient safety comparable to published outcome benchmarks, such as mortality, anastomotic leaks, DVT/PTE, strictures, marginal ulcers, etc. If outcomes do not approach published outcome benchmarks, then serious consideration should be given to requiring remedial training, continued close supervision by an experienced bariatric surgeon, or denial/failure of renewal of privileges to perform laparoscopic bariatric surgery.

E. Denial of privileges

Institutions denying, withdrawing, or restricting privileges should have an appropriate mechanism for appeal in place. The procedural details of this should be developed by the institution and must satisfy the institution's bylaws and JCAHO recommendations.

F. Privileges for relocating surgeons

For the bariatric surgeon who is relocating to another hospital, thorough documentation of past experience with outcomes must be obtained and reviewed by the institution at the new location. Documentation of the criteria used by the former facility and credentials given to fulfill these requirements also should be presented to the new facility. Acceptable current credentials also must be presented to the new institution.

Conflicts of interest Dr. Ronald H. Clements is a consultant for Olympus, was on a review panel for Covidien, and was on an advisory committee for Cardinal Healthcare/Snowden-Pencer. Dr. Julio A. Teixeira was a consultant for Novare and for Ethicon Endoscopy, was on the advisory committee for Allergan Inc., and was a speaker/teacher for Covidien. Dr. Robert D. Fanelli is a board member of New Wave Surgical Corporation, received honoraria from Ethicon Endo-Surgery for speaking/teaching, received honoraria from Boston Scientific Corporation, Inc for speaking/teaching, and was an independent contractor for Cook Surgical, Inc. Drs. David Provost, William S. Richardson, and Alan A. Saber have no conflicts of interest or financial ties to disclosure.

Appendix

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For additional information, visit: http://sages.org/publications/guidelines/guidelines.php

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