

GUIDELINES

For Bariatric & Metabolic Surgery
Saudi Arabia 2019

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Message from SASMBS

"Patient safety along with achieving the best outcome is the most important goal of medical services."

"It can be achieved by establishing clinical pathways and guidelines proven in several studies and evidence-based medicine to minimize preventable complications, morbidity, and mortality. Does it also improve the outcome?"

Bariatric and Metabolic Surgery is one of the surgical subspecialties growing rapidly in the last few years.

"As in any surgery, it has its own risks and preventable complications."

In Saudi Arabia, both obesity and diabetes are considered epidemics, which resulted in a high demand for such specialty and the need for a well-trained specialized surgeon to practice under high standard protocol and guidelines from bariatric surgery centers and national registry.

As part of SASMBS mission, to ensure safe standard patient care in this field, a group of expert physicians and surgeons has been selected to review and update the guidelines implemented in all centers.

Thanks to all the members of "The Review Committee" for their help, support, and efforts.

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PURPOSE

These guidelines intended to assure provision of the highest levels of safety and quality of bariatric services in licensed health facilities of Saudi Arabia. These guidelines are a resource for establishing Bariatric Surgery Unit policy and procedures. Bariatric services are authorized by the Ministry of Health (MOH).

OBJECTIVE

To bring the services of bariatric and metabolic surgeries in KSA to the highest attainable level.

APPLICABILITY

Saudi Arabia licensed healthcare professionals and health facilities providing bariatric services under the jurisdiction of the MOH.

Obesity is a disease in which fat has accumulated to the extent that health is impaired. A measurement used to assess health risks is the Body Mass Index (BMI= weight (kg)/height (m) squared)

DEFINITIONS

Bariatric surgery is a gastrointestinal surgery performed to help obese patients achieve significant, sustained weight loss, with improvement/resolution of related comorbidities

❖ BMI classification (kg/m²):

Normal range 18.50– 24.99 Overweight 25.00– 29.99 Obesity class I 30.00– 34.99

Obesity class II 35.00– 39.99 "Asian 32.5 - 37.5"

Obesity class III ≥ 40.00 "Asian ≥37.5"

Super Obesity ≥ 50.00

Comorbid factors:

These are defined as medical conditions triggered or generated by excess body weight or morbid obesity.

- The most common comorbid factors are as follows:
- Diabetes type 2
- Hypertension
- Sleep apnea
- Gastrointestinal reflux disease "GERD"
- Joint degenerative disorders
- Psychosocial disturbances
- Infertility

Chapter 1.1: STANDARD ONE: HEALTH FACILITY REQUIREMENTS

- 1.1.1 Bariatric surgeries shall be performed only in general hospital settings or specialized surgical hospitals with a fully equipped intensive care unit (ICU).
- 1.1.2 Hospitals shall maintain a minimum of 50 bariatric surgeries per annum, including primary, revision, and emergency bariatric surgeries.
- 1.1.3 Hospitals performing bariatric surgery must present an annual report about the service(registry).
- 1.1.4 Day Surgical Centers (DSC) with appropriate equipment and critical support care requirements may provide bariatric services to stable patients with no comorbidities who are likely to be discharged within the day with low preoperative risk score and low risk of adverse events from an esthesia.
- 1.1.5 DSC shall maintain a minimum of 50 bariatric procedures per annum.
- 1.1.6 DSC providing bariatric services shall have a signed written patient transfer agreement with a nearby hospital to transfer patients in case of emergency that fully meets the requirements for bariatric patients.
- 1.1.7 The health care facility providing bariatric service should have supporting service specifications to provide suitable medical, surgical, diagnostic, and emergency care with appropriate equipment and instruments.
- 1.1.8 The size of instruments selected should meet the type of patients treated, including but not limited to blood pressure cuffs, staplers, retractors, long instruments, sequential compression, and device sleeves. Single-use instruments should not be re-sterilized.
- 1.1.9 Bariatric surgeries shall be restricted according to weight limits of the existing equipment.
- 1.1.10 Lifting and transfer equipment should be suitable to facilitate and accommodate obese patients.

 Weight capacities of equipment and furniture used shall be documented based on the manufacturer's specifications, and this information shall be readily available to relevant staff. Essential equipment and furniture may include but not limited to:
 - Bariatric wheelchairs
 - Patients' chairs, seats, and beds
 - Gowns, weighing scales, and stretchers
 - Floor-mounted or floor-supported toilets and shower rooms
- 1.1.12 Health facilities providing bariatric surgeries for morbidly obese patients (having a BMI of ≥40 kg/m2 for Caucasians and 37.5 kg/m2 for Asians) shall meet specific design standards and space requirements to accommodate such patients.

Chapter 1.2: Doorway and corridor widths

- 1.2.1. Toaccommodate bariatric wheelchairs, 1.2m doorway openings are required.
- 1.2.2. Where the passage of bariatric stretchers is needed, doorways should be 1.5 m minimum.
- 1.2.3. Wider door standards should be provided in the diagnostic and treatment rooms, inpatient rooms, and surgical suites and other areas where a bariatric patient is treated.

Chapter 1.3: Lobbies and waiting areas

- 1.3.1. Up to 10%–20% of general seating should be designed for bariatric patients. Provide at least 20% in emergency departments and up to 50% in cardiac and bariatric units with steel-reinforced furniture to support a minimum of 250 kg.
- 1.3.2. Appropriately sized elements with adequate capacity for obese patients should be interspersed with more traditional furnishings to avoid confining bariatric patients to specific areas in the waiting environment.

Chapter 1.4: Bariatric patient room

- 1.4.1. The number of patient rooms provided should be determined in accordance with the functional program.
- 1.4.2. More space is needed for the bariatric inpatient rooms to accommodate larger equipment needed for bariatric patients.
- 1.4.3. Rooms are preferred to be located near the elevators to provide a clear path of travel.

Chapter 1.5: Bathrooms

- 1.5.1. Shall be sized to allow for staff assistance on two sides of the patient at the toilet and shower.
- 1.5.2. Dispensers shall be flush-mounted to aid clearance and safety.
- 1.5.3. Opt for open showers with a floor drain.
- 1.5.4. Bigger shower stalls with sufficient opening and space to feature heavy-duty wall-mounted grab bars that hold at least 250 kg.

Chapter 2: STANDARD TWO: HEALTHCARE PROFESSIONAL REQUIREMENTS

Center providing bariatric surgery services must have at least one full time actively practicing, credentialed bariatric and metabolic surgeon:

- 2.1. The Institution's credential body is responsible to privilege surgeons to perform bariatric surgeries according to Saudi commission for health specialties accreditation policy
- 2.2. All bariatric services shall be led by a consultant.
- 2.3. For each admitted patient, the health facility should designate a Most Responsible Physician (MRP), who should be ultimately responsible for the admission, management, and discharge of bariatric patients.
- 2.4. Part time and visiting bariatric surgeons shall not be permitted to perform bariatric surgeries in a health facility without a full-time licensed physician with bariatric privileges.
- 2.5. Any health facility providing bariatric services should have a dedicated multidisciplinary healthcare professional team with experience in bariatric patient management. The team should consist of licensed anesthesiologist, nurses, psychologists, gastroenterologist, clinical dieticians, Interventional radiologist, cardiologist, pulmonologist, endocrinologist and physiotherapist.
- 2.6. All healthcare professionals shall be trained to use the equipment and be capable of moving obese patients without causing injury to the patient orthemselves.
- 2.7. Physicians performing bariatric surgeries shall be responsible for demonstrating defined experience and exposure to the discipline's unique cognitive, technical, and administrative challenges.
- 2.8. Physicians performing bariatric surgeries shall be suitably trained and assessed as competent to perform them and competent to recognize and treat related complications.
- 2.9. Physicians performing bariatric surgeries shall have a clear and documented process to record patient details in their health records as follows:
 - Patient selection criteria
 - Preoperative assessment and counseling
 - Early/acute postoperative care (immediate care at 1–4 days) and upon discharge.
- 2.10. Postoperative management follow-ups are conducted at 3, 6 and 12 months and then as per the patient's condition. This includes, but not limited to:
 - Weight loss assessment
 - Physical activity advice and support
 - Management of dietary and nutritional deficiencies
 - Bone density measurement, assessment of lipid and glucose levels and medication review to be considered based on patient needs& type of the procedure
 - Management of postoperative complications

Chapter 3: Guidelines

Chapter 3.1: SURGICAL INDICATIONS

The general indications used for laparoscopic bariatric procedures are as follows and should be clearly documented in each patient's chart.

- 3.1.1. Average range: 14 to 65 years (<14 years have their own guidelines, elderlies above 65 managed according their general conditions).
- 3.1.2. Patients must have a BMI of 40 kg/m² (37.5 kg/m² for Asians) or 35 kg/m² (32.5 kg/m² for Asians) if one or more comorbid factors are documented.
- 3.1.3. Patients should undergo a standard bariatric-social and nutritional detailed history.
- 3.1.4. Patients must have undergone a basic Medical evaluation.
- 3.1.5. Have a long/repeated history of failed nonsurgical weight loss regimens.
- 3.1.6. Understand the risks, benefits, and impact of the procedure and willing to comply with pre- and postoperative instructions.

Chapter 3.2: Selection Criteria

- 3.2.1. Surgical candidate: The trigger point used by most bariatric surgeons is the BMI value at which the risks of potential complications from the bariatric procedure itself equal the risks generated by the excess weight. This trigger point is a BMI of 40 kg/m² (37.5 kg/m² for Asians), but this value is lowered if a comorbid condition is identified. Consequently, a bariatric surgical procedure is indicated for the following conditions:
 - Morbid obesity with BMI \ge 35 kg/m² (Asian \ge 32.5).
 - History of repeated conservative treatment failures.
 - No history of significant psychiatric disorders.

3.2.2. Exclusion Criteria:

- Alcohol drug abuse
- Uncontrolled psychiatric illnesses
- Lack of comprehensive risk-benefit ratio

Chapter 3.3: Bariatric Surgeon

- 3.3.1. A surgeon privileged according to the Saudi commission for health specialties accreditation criteria.
- 3.3.2. Annual submission of bariatric procedures performed by the surgeon to SASMBS registry.

Chapter 3.4: Granting Bariatric Surgery Privileges

- 3.4.1 The medical director or the chairman of BSU of the health facility is responsible for the following:
- ❖ Granting privileges to full-time, part-time, and/or visiting physicians to perform bariatric surgeries in the health facility. The medical director should ensure that the physician has the appropriate certification, training, and experience to perform the bespoke procedures.
- Ensuring that the healthcare professionals involved in providing bariatric services are adequately qualified and well trained to provide such services.
- **Stablishing bariatric surgery unit policy and procedure.**
- 3.4.2. This privileging document shall be kept in the physician's personal file and provided for MOH/SASMBS review whenever required.
- 3.4.3. The credentialing and privileging committee or the medical director may suspend/revoke privileges at any time, as per the health facility policy, and the action shall be validated with appropriate documented reasons.



Chapter 4: Procedures

Chapter 4.1: Bariatric Surgery Procedures

The following are endorsed by SASMBS

- 1. Laparoscopic Adjustable Gastric Banding (LABG)
- 2. Laparoscopic Sleeve Gastrostomy
- 3. Roux- En -Y Gastric Bypass
- 4. Mini Gastric Bypass/One anastomosis Gastric bypass.
- 5. Biliopancreatic Diversion (BPD) Duodenal Switch
- 6. Single anastomosis duedonoileal bypass (SADI)
- 7. Biliopancreatic Diversion (BPD) Scopinaro

Other Procedures will be subjected to the evaluation and review by SASMBS according to the available data.

Chapter 4.2: Revisional Bariatric Procedures

- 1. Removal of Gastric Banding
- 2. Conversion of Gastric Banding to R-Y Gastric Bypass, Sleeve, BPD, BPB-DS
- 3. Conversion of Vertical Banded Gastroplasty (VBG) to R-Y Bypass/sleeve/MGBP/BPD
- 4. Revision of gastric bypass or sleeve Gastrectomy to other procedures

Chapter 5: Pre-evaluation

Chapter 5.1: First visit in the bariatric clinic

Full detailed informative history and physical examination including special additional attention to:

- Previous ways of weight reduction and exercise reasons of failure.
- Type and style of eating sweets and candies.
- Psychic state and mentality of the patient.
- ❖ Any hormonal therapy or disease.
- History of medical illness, e.g., DM, HTN, sleeps apnea, joint pains, and cardiac conditions.
- History of previous surgeries especially abdominal laparoscopies.

Chapter 5.2: Full explanation of the different surgical modalities

Special attention to the side effects, expected morbidities, mortality, and benefits for each surgery.

- ❖ Band surgery needs the cooperation of the patients and total diet modification.
- ❖ Biliopancreatic diversion surgery patients are liable to late metabolic syndromes and deficiencies; therefore, long-term follow-up and replacement are mandatory.
- * RYGB is not without complications; therefore, commitment to supplement is essential.
- Sleeve gastrostomy is associated with higher incidence of leak and possible weight regain.

Chapter 5.3: Required investigations for all bariatric cases

5-3.1. The following investigations are requested before undergoing surgery:

- Hepatitis screening
- Complete Blood Count
- Serum electrolytes
- ❖ Fasting blood sugar, HbA1c
- Renal function test
- Liver Function Test (LFT)
- Calcium profile
- ❖ Vitamin D level, ± (PTH)
- Coagulation Profile
- Serum lipid profile
- TSH
- . H. pylori and eradication treatment

5.3.2. Second preoperative visit in the bariatric clinic:

- ❖ All questions raised by the patient are answered by the professional team
- All results of investigations are revised, and any hormonal abnormality with expected endocrine disease is referred to family medicine doctor or endocrinologist.
- ❖ Any vitamin deficiencies found should be treated.
- ❖ Patients with anemia and blood diseases are referred to a hematologist.
- ❖ *H. pylori* -positive patients receive the triple treatment preoperatively.
- Appropriate treatment for each case and consultation from other subspecialties if needed are done in preparation for the surgery.

Chapter 5.4: Preoperative Screening

- a) Endocrine:
 - Lipid profile
 - * TSH
 - Fertility assessment in females
 - Surgical candidates should minimize the risk of pregnancy for 12 months postoperatively
 - All women should be counseled on contraception
- b) Cardiology:
 - **ECG** for patients aged above 40 years.
 - Cardiology referral depending on patient's clinical assessment.
 - ❖ All patients with known CVD need a cardiology referral.
- c) Pulmonary:
 - CXR for patient aged above 40 years depending on clinical finding.
 - All patients need to stop smoking foratleast6 weeks before the surgery.
- d) Gastroenterology:
 - All patients should be evaluated for the presence of gastrointestinal symptoms and treated if present before surgery
- e) Psychiatric patients should be referred if:
 - With history of psychiatric diseases
 - On psychiatric medications
 - With recent admission to psychiatric ward
- f) Nutrition:
 - Nutritional education for healthy weight reduction before and after Surgery

Chapter 6: Surgical and Pre-surgical Care

Chapter 6.1: On Admission

- Informed consent.
- NPO after midnight.
- ❖ UFH/Enoxaparin 40 mg subcutaneously prior to surgery (12 h before the surgery OR upon induction of anesthesia on the day of admission).
- Prophylactic antibiotics on induction of anesthesia.
- Proton pump inhibitor.
- Llastic stockings or Pneumatic Decompression Device (full mobilization).

Chapter 6.2: Postoperative Orders

- ❖ The patient is kept NPO with adequate IVF, usually 150–200 ml RLS/h.
- ❖ Antibiotics and omeprazole are continued until discharge.
- ❖ UFH 5000 TID/Enoxaparin 40 mg BID after 8 hours of surgery.
- Prophylaxes against DVT by mechanical devices are continued.
- On postoperative day 1, the gastrografin study is performed, and then patients can start oral fluid intake.

Chapter 6.3: Discharge Medication Order

- One week appointment for stitch removal
- ❖ Fluid diet for 1 month (According to Dietician's advice)
- ❖ VTE Prophylaxis according to patient's BMI: a. BMI (40 – 49 .99kg/m2): Enoxaparin 40 mg SC BID for 2 weeks
 - b. BMI ≥ 50 kg/m2: Enoxaparin 40 mg SC BID for 4 weeks
- Calcium
- ❖ Vitamin D3
- Ferrous sulfate daily
- Multivitamin tab daily
- ❖ PPI for 2-8 weeks
- Thiamine PO daily

Chapter 6.4: Postoperative visit in OPD

- 6.4.1. First visit (postoperative days 7–8)
- Full demographic history and physical examination
- Wound examination
- ❖ DVT and PE are common complications at this time
- 6.4.2. Second Visit (postoperative day 30).
- 6.4.3. Three-month interval visits for the next 2 years: Special attention should be made on expected complications, such as ulcers, bowel obstructions, and Gall bladder stones.
- Requested the usual follow-up laboratory tests and adjustment of refill medications according to the results.



6.4.4. Repeated every three (3) month visit:

- **❖** CBC
- Electrolytes
- Glucose, lipid profile
- ❖ Iron, ferritin
- ❖ Vitamin B12
- Liver function tests
- **❖** Vitamin D
- Optional (PTH, thiamine, RBC)

6.4.5. Life-long postoperative management:

- Maintenance of weight loss
- ❖ Failure to lose or regain of weight should be promptly evaluated
- Maladaptive eating habits and nutritional deficiencies



Chapter 7: Non-surgical treatment

- 7.1. Class I obesity with a BMI of 30–35 kg/m² (Asian, 27.5–32.5 kg/m²): safety and efficacy are two important factors when considering a treatment method in clinical practice.
- 7.2. Lifestyle modification programs to improve eating habits and physical activities are considered as the first option for weight control in Class I obesity and overweight.
- 7.3. Pharmacotherapy is also indicated to augment weight loss by referring to endocrine guidelines.
- 7.4. Liraglutide (GLP -1) agonist can be used for the management of Class I and Class II obesity and is also effective in downgrading morbidly obese patients preoperatively and weight regain in post-bariatric surgeries.
- 7.5. Endoscopic intraluminal procedures include:
 - Intragastric balloon



Disclosure Documents

Patients planning to undergo a bariatric surgical procedure should be educated about the procedure and its risks and benefits. They should understand that the procedure is non-physiological and demands lifelong behavioral life style modifications.

The procedure, as described above, helps to select the right (and motivated) patients to undergo bariatric surgery. It is essential for the surgeon to accurately disclose the surgical risks of the proposed procedure.

Patient should understand & accept that the surgical intervention has its own mortality, morbidity rate, etc. as well as the expected long-term side effects, and impact of the postoperative outcomes.

A detailed comparison to other available bariatric procedures should also be provided. In turn, the patient should reiterate his or her commitment to a lifelong follow-up and monitoring. Lastly, extensive written documentation or disclosure documents should be given to the patient. All patients should understand and accept lifelong follow-up according to the protocol and strict compliance with dietary supplement and vitamins.

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APPENDICES

Appendix I

BARIATRIC PATIENT CARE PATHWAY IN THE OUTPATIENT CLINIC:

PATIENTS REFERRED TO THE CLINIC FROM:

- 1. FAMILY MEDICINE
- 2. INTERNAL MEDICINE
- OTHER SPECIALTY
- 4. DIETICIAN

The patient is previously qualified for bariatric surgery according to:

- Identified departmental guidelines
- ❖ HISTORY AND PHYSICAL EXAMINATION
- Taking vital signs
- ❖ Weighing and calculating BMI: Discussing of excess weight, target weight, and/or expected weight loss goals
- Reviewing medications and allergies
- Teaching
- ❖ Answering patient's questions
- * When risk factors were identified, patients are referred to (according to the indication):
- ❖ FAMILY MEDICINE
- ❖ KNOWN CASE OF COMORBIDITY: DM, HT,HYPO-, AND HYPERTHYROIDISM PREOPERATIVELY

FOR CONTROL

- Six months postoperatively, patients were scheduled for follow-up at the ENDOCRINE AND ASTHMA CLINIC(pre- referral test)
- Echocardiogram (if required)
- Medication adjustments
- Hormonal test

Psychiatric indications:

- History of depression
- Patients with medications
- Unstable behavior
- ❖ History of mental Illness within 12 months on admission

CLINICAL DIETICIAN:

- Dietary and nutritional evaluation and teaching
- Screening for possible eating disorders
- Failure to control weight with non-surgical measures documented as "Dietary concerns and required changes."
- Diabetes education and information

Appendix II

ANESTHESIA CLINIC

After a full investigation

- Triglycerides
- Hematology
- Vitamins
- Urine
- Radiology
- Cardiology
- Electrocardiogram
- Evaluation and prophylaxis according to DVT protocols
- Blood donation
- CBC (includes diff), platelet count, PT, PIT, INR, HbA1c, ferritin, pregnancy
- Chest X-ray, and pulmonary function test
- ❖ All smokers must quit smoking 8 weeks prior to surgery and remain nonsmoker postoperatively

SURGERY SCHEDULING

Scheduling information includes:

- A Patient weight, height, and BMI
- Special needs identified (e.g., SICU, allergies, fears)
- Surgical procedure to be performed and time estimates
- Surgical approach (laparoscopic versus open)
- Special equipment, instrumentation, or product needs(e.g., gastric bands)

PREOPERATIVE TEACHING AND INFORMED CONSENT: NPO status

after midnight the day before the surgery.

PREADMISSION TEACHING AND TESTING

The surgical team interviews the patient usually 7–10 days before the procedure and makes initial assessments to support the needs of the entire preoperative patient care.

The surgical team should:

- Verify patient identification according to hospital policy
- ❖ Assess vital signs, allergies, and laboratory and test results
- Confirm height, weight, and BMI measurements
- Review relevant history and current medications
- Measure patient body width (hip-whist ratio)
- Identify special needs for ambulation, toileting, etc.
- ❖ Note the special bariatric equipment needs. THE DAY OF SURGERY
- ❖ The patient arrives at the agreed time INTRAOPERATIVECARE
- The preoperative or pre-anesthesia nurse identifies the patient according to the hospital policy and implements the preoperative bariatric orders. Fluids (Lactated Ringers, 1,000 mL) are started as soon as the IV is placed Preoperative antibiotics and anticoagulant therapy is also started.

INTRAOPERATIVE CARE

- Time out after induction of anesthesia
- The circulating and scrub responsibilities are defined by hospital policy for laparoscopic surgery
- Adjustable gastric band and other procedures resource map and bariatric instrument
- Tray: All laparoscopic procedures must be recorded
- Integrated video camera head laparoscope(s)
- ❖ Camera box as the light source with a light cord or video/multimedia image recorder
- Bariatric grade insufflator device and 2 tubing with C02 filter and warming capabilities
- Bariatric custom drape packs
- Electrosurgical unit (ESU).
- Pressure bag for irrigation
- Implants (adjustable lap band) and accessories
- Medications: irrigation, antibiotic and local anesthetic agents, and blood products (autologous or blood bank) accessible and verified
- * Major abdominal tray appropriate for open surgery.
- Operative reports should be simultaneously dictated and recorded postoperatively.

Appendix III

BARIATRIC PATIENT CHECK LIST:

The patient is previously qualified for bariatric surgery according: Departmental Bariatric Surgery guidelines

Detailed history and physical examination DVT Risk Score

Patients were referred to:

Internal Medicine preoperative evaluation clinics Anesthesia Clinic

Psychiatric Evaluation

Clinical dieticians

Preoperative laboratory/radiology

Surgical booking form completed and sent with BMI Preoperative teaching and informed consent with complications/risks/benefits/medication

Pre-admission teaching and testing, according to Bariatric Surgery Guidelines Day of Surgery, medication given according to Bariatric Surgery

Guidelines Patient assessment and removal of drain as indicated Patient education before discharge on diet and life time discharge medications according to Bariatric Surgery Guidelines

Morning Medications

MULTIVITAMINS, 1 DAILY

THIAMINE IOO mg, 1 DAILY

Afternoon Medications Calcium Carbonate once

Bedtime Medications FERROUS SULFATE ONCE

Continue previous medications for comorbidity as indicated at the

follow-up nursing clinic 10 days after clip removal at the obesity clinic OPD consultation should be performed 1 month after the surgery and then every 3 months with laboratory examinations and weight loss progress postoperatively according to Bariatric Surgery Guideline.