# Interdisciplinary European Guidelines for Surgery for Severe (Morbid) Obesity

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### **Foreword**

In 2005, for the first time, an expert panel named "The Bariatric Scientific Collaborative Group" (BSCG), was appointed through a joint effort of the major European Scientific Societies which are active in the field of obesity management. Societies that constituted this panel were: International Federation for the Surgery of Obesity – European Chapter (IFSO-EC), European Association for the Study of Obesity (EASO), European Childhood Obesity Group (ECOG) and the International Obesity Task Force (IOTF) which was represented during the completion process by its representatives.

The BSCG was composed of officers representing the respective Scientific Societies (including four acting Presidents, two past Presidents, one Honorary President, and three Executive Directors). The panel was also balanced by the presence of many other opinion leaders in the field of obesity. The BSCG composition allowed coverage of the key disciplines in comprehensive obesity management, as well as being reflective of European geographic and ethnic diversity.

This joint BSCG Expert Panel has convened several meetings which were entirely focused on guideline creation during the past 2 years. There was a specific effort to develop and concur on clinical guidelines which reflect current knowledge, expertise and evidence-based data on treatment of morbid obesity.

### Introduction

The prevalence of obesity is increasing world-wide at an alarming rate. Obesity has reached the proportion of a global epidemic in both developed and developing countries.¹ According to data published by the International Obesity Task Force, at least 1.1 billion adults are overweight and 312 million of them are obese. Prevalence of obesity (BMI ≥30) in Europe is reported in the range of 10-20% in men and 15-25% in women, and almost half of the European population is overweight or obese (BMI. ≥25).² Overweight and obesity are associated with increased risks of type 2 diabetes, hypertension, cardiovascular disease, dyslipidemia, arthritis, non-alcoholic steatohepatitis, gallbladder disease, sleepapnea syndrome and several cancers.³

Overweight and obesity play a crucial role in the development of type 2 diabetes. The risk of diabetes attributable to overweight and obesity is 64% for men and 77% for women.<sup>4,5</sup>

Increasing body weight impairs quality of life (QoL) and reduces life expectancy. Mortality attributable to excess weight is a serious public health problem in Europe, where about 7.7% of all deaths are related to excess weight. Thus, at least one in 13 annual deaths in the EU are likely to be related to excess weight.<sup>6</sup>

The prevalence of morbid obesity (body mass index  $\geq$ 40 kg/m<sup>2</sup>) in the U.S. in 2002 was 1.8%; 60% of morbidly obese people were women, and 63% were ages 18 to 49 years.<sup>7</sup>

Mortality increases with increasing BMI. Relative risk of death at the age of 50 years among men and women with BMI >40 who have never smoked is 3.82 and 3.79 respectively.<sup>8</sup> Among severely obese young men, mortality rate is 12 times that of young normal-weight men.<sup>9</sup>

Severe obesity with its health and psychosocial consequences substantially increases not only the health costs but also the socioeconomic burden. Annual direct health-care costs of the severely obese (BMI ≥35) are three times higher than those of normal-weight subjects. <sup>10</sup> Bariatric surgery has proved to be the most effective mode of treatment for morbidly obese patients. <sup>11</sup> Recent long-term studies show, that there is a substantial reduction in mortality after bariatric surgery, as well as decreased risk of developing new health-related co-morbidities,

decreased health-care utilization and decreased direct health-care costs. 12-14 Bariatric surgery is an established and integral part of the comprehensive management of morbidly obese patients.

These Guidelines were created by an inter-disciplinary collaboration of key authorities from international medical and surgical societies (IFSO, IFSO-EC, EASO, IOTF, ECOG) in the field of obesity. The aim of the Guidelines is to provide physicians, health-care policy makers, and health-care carriers and insurance companies with essential elements of good clinical practice in the treatment of morbid obesity. Scientific data to support conclusions of this panel of experts were systematically searched in databases such as Medline (PubMed) and the Cochrane library. Searches spanned from January 1980 until December 2005, and were carried out with the help of an expert in library science, together with a clinical expert with experience in systematic reviews.

The key search words were: obesity, obesity surgery, morbid obesity, surgical treatment, bariatric surgery, morbid obesity surgery, gastroplasty, gastric bypass, Roux-en-Y, gastric banding, biliopancreatic diversion, duodenal switch, biliopancreatic bypass, obesity/morbid obesity treatment outcomes, obesity/morbid obesity follow-up, obesity/morbid obesity complications.

Some of the evidence level data were retrieved as well from following publications: Commonwealth of Massachusetts Betsy Lehman Center for Patient Safety and Medical Error Reduction Expert Panel on Weight Loss Surgery, <sup>15</sup> Obesity Surgery evidence-based guidelines of the European Association for Endoscopic Surgery (EAES), <sup>16</sup> Maggard's et al Meta-analysis: Surgical Treatment of Obesity, <sup>17</sup>, and Recommendations Regarding Obesity Surgery. <sup>18</sup>

The panel's recommendations are supported by the best available evidence, which includes all evidence levels (Randomized controlled trials - RCTs, systematic reviews of cohort studies, observational "outcomes" studies, and expert opinion). To grade the quality of evidence, the panel adopted the "Oxford Centre for Evidence-based Medicine classification system" based on levels of evidence and "grades of recommendations" according to the study designs and critical appraisal of prevention, diagnosis, prognosis, therapy, and harm studies. The Oxford classification system has four Levels of Evidence (EL):

• Level A: consistent Randomised Controlled

- Clinical Trial, Cohort Study, All or None, Clinical Decision Rule validated in different populations.
- Level B: consistent Retrospective Cohort, Exploratory Cohort, Ecological Study, Outcomes Research, Case-Control Study; or extrapolations from level A studies.
- Level C: Case-series Study or extrapolations from level B studies.
- Level D: Expert opinion without explicit critical appraisal, or based on physiology, bench research or first principles.

### Indications for Bariatric Surgery

Patients aged 18-60 years:

- 1) with BMI  $\geq$ 40 kg/m<sup>2</sup>;
- 2) with BMI 35-40 kg/m<sup>2</sup> with co-morbidity in which surgically-induced weight loss is expected to improve the disorder (eg. metabolic disorders, cardio-respiratory disease, severe joint disease, obesity-related severe psychological problems); (EL: A, B, D. Ref. 19-37)
- 3) BMI criterion may be current BMI or a documented previous BMI of this severity. Note that:
- a. weight loss as a result of intensified treatment prior to surgery (patients that reach a body weight below the required BMI for surgery) is NOT a contraindication for the planned bariatric surgery;
- b. bariatric surgery is indicated in patients who exhibited a substantial weight loss in a conservative treatment program but started to regain weight.

In order to be considered for surgery, patients must have failed to lose weight or to maintain long-term weight loss, despite appropriate non-surgical medical care.(EL: B, D. Ref. 20, 37) Patients must have shown compliance with medical appointments.

### **Bariatric Surgery in the Adolescent**

Bariatric surgery in children and adolescents could be considered in centres which have extensive experience with such treatment in adults and are able to offer a true multi-disciplinary approach that involves paediatric skills relating to surgery, dietetics and psychological management.

In adolescents with severe obesity, bariatric sur-

gery can be considered if the patient:

- 1) has a BMI >40 (or 99.5th percentile for respective age) and at least one co-morbidity;
- 2) has failed at least 6-12 months of organized weight-reducing attempts in a specialized centre;
- 3) shows skeletal and developmental maturity;
- 4) is able to commit to comprehensive medical and psychological evaluation before and after surgery;
- 5) is willing to participate in a postoperative multidisciplinary treatment program;
- 6) can access surgery in a unit with specialist paediatric support (nursing, anaesthesia, psychology, postoperative care). (EL: C, D. Ref. 38-45)

Bariatric surgery can be considered in genetic syndromes, such as Prader-Willi syndrome, only after careful consideration of an expert medical, paediatric and surgical team.

### **Bariatric Surgery above Age 60**

The indication for bariatric surgery above age 60 years should be considered on an individual basis. Proof of a favourable risk:benefit ratio must be demonstrated in elderly or ill patients, before surgery is contemplated in such individuals

In elderly patients, the primary objective of surgery is to improve QoL, even though surgery may be unlikely to increase life-span. (Ref. 46)

### **Contra-indications Specific to Bariatric Surgery**

- 1) Absence of periods of identifiable medical management;
- 2) A patient who is unable to participate in prolonged medical follow-up;
- 3) Non-stabilized psychotic disorders, severe depression and personality disorders, unless specifically advised by a psychiatrist experienced in obesity;
- 4) Alcohol abuse and/or drug dependencies;
- 5) Diseases threatening life in the short-term;
- 6) Patients who are unable to care for themselves and have no long-term family or social support that will warrant such care.

### **Preoperative Evaluation of the Patient**

A decision to offer surgery should follow a comprehensive interdisciplinary assessment. The core team providing such assessment should optimally consist of the following specialists, experienced in obesity management and bariatric surgery:

- physician
- surgeon
- · anaesthetist
- psychologist or psychiatrist
- nutritionist and/or dietitian
- nurse practitioner / social worker

Patients indicated for bariatric surgery should undergo routine preoperative assessment as for any other major abdominal surgery.

(EL: B, C, D. Ref. 16, 20, 47-54)

Preoperative management should include:

- Assessment of general health and nutritional status (see below);
- Explanation of the dietary changes that are required after surgery;
- Optimizing treatment of co-morbidities to reduce the risks of the surgical procedure;
- Assessment of patient motivation and willingness to adhere to follow-up programs;
- Ensuring that the patient is fully informed of the benefits, consequences and risks of the surgical options and the necessity of life-long follow-up;
- Ensuring that the patient understands the potential (limited) outcomes of surgery;
- Ensuring that the patient can give truly informed consent including a statement on risks of the surgery and acceptance of behaviour modification of lifestyle and of follow-up.

In addition to the routine preoperative assessment as for any other major abdominal surgery, the patient may undergo further assessment (depending on the planned bariatric operation and the patient s clinical status):

- Sleep apnoea syndrome and pulmonary function;
- Metabolic and endocrine disorders;
- Gastro-oesophageal disorders (*Helicobacter*);
- Body composition (densitometric assessment);
- Bone density;
- Indirect calorimetry.

(EL: A, B, C, D. Ref. 16, 55-69)

### **Overview of Surgical Techniques**

### Definition

- Food limitation (restrictive) operations
- Vertical banded gastroplasty (VBG)
- Gastric sleeve resection
- · Gastric banding
  - adjustable (AGB)
  - non-adjustable
- Gastric bypass (GBP)
  - proximal
  - long-limb
- Operations limiting absorption of nutrients and energy
- Biliopancreatic diversion (BPD)
- Combined operations
- Biliopancreatic diversion with duodenal switch (BPD-DS)
- Distal gastric bypass (common limb ≤100 cm) Laparoscopic technique should be considered as the first treatment choice in bariatric surgery, unless specific contraindications to a laparoscopic operation are present.

# Assigning a Patient to a Particular Bariatric Procedure

At this moment, there are no sufficient evidencebased data to suggest how to assign a patient to any particular bariatric procedure. Among others, preoperative factors that could influence the choice of the type of operation are:

- BMI
- Age
- Gender
- Body fat distribution
- Type 2 diabetes mellitus
- Dyslipidaemia
- Binge eating disorders (BED)
- Low IO
- Significant hiatal hernia
- Gastro-oesophageal reflux disease
- Patient's expectations/realistic goals

The expected average weight loss and weight maintenance increases with the following procedures: AGB, VBG, GBP, BPD-DS, BPD.

On the contrary, the surgical complexity and potential surgical and long-term metabolic risks of procedures decrease in reverse order. (EL: A, B, C, D. Ref. 17, 71-95)

The procedures should be performed in interdisciplinary obesity management centres with appropriately trained staff and adequate equipment (see below). In all situations, the bariatric surgeon's experience is a key issue. It is not advisable to practice bariatric techniques on an occasional basis.

If the patient is expected to benefit more from a particular procedure not available in a specific centre, he/she should be referred to a centre/surgeon with adequate bariatric experience in that procedure. (EL: B, D. Ref. 20, 96-103) As a result of successful bariatric treatment, further treatment (such as plastic / reconstructive surgery) may be required.

### Follow-up

Morbid obesity is a life-long disease. The treating physician, together with the treating surgeon, are responsible for the treatment of co-morbidities before the operation and for the follow-up after the operation. Complementary follow-up pathways (surgery and medical) should be provided to all patients, ideally in part through interdisciplinary joint clinics. The surgeon is responsible for all possible short- and long-term events directly related to the operation. The medical physician will be responsible for the long-term post-surgery followup and management of the obesity and obesity-related diseases and operation-related non-surgical consequences. Treatment outcome is significantly dependent, among other factors, on patient compliance with long-term follow-up.

During the rapid weight loss, special care must be taken for:

- Possible deficiencies, such as vitamin, protein, other micronutrients;
- Adjustments of medical treatment of the obesity-related morbidities, such as diabetes, hypertension, etc.

All patients after bariatric procedures require regular life-long qualified surveillance. Patients must have access to a 24-hour emergency service provided by the operating centre. The patient must take life-long responsibility for adhering to the follow-up rules.

# Minimal Requirements for Follow-up after Food Limitation Operations

The patient should be provided with written information about the procedure and the exact type of

received implant (if applicable), together with a description of possible serious adverse effects.

### · Adjustable gastric band

- Follow-up during the 1st year should be at least every 3 months, starting 1 month postoperatively, until a clinically satisfactory rate of weight loss is achieved, if necessary with repeated band fills. Thereafter, follow-up should be not less than at yearly intervals;
- Metabolic and nutritional status should be regularly monitored to prevent vitamin deficiencies and allow appropriate supplementation, as well as to monitor response to surgery and weight loss and adjust concomitant drug treatment;
  - Band adjustments should be performed
    - according to the individual patient's weight loss and the type of implant;
    - first inflation according to the type of band;
    - as a medical/clinical decision;
    - by trained medical or paramedical staff with adequate experience (such as surgeon, medical physician, nurse practitioner, dedicated radiologist);
- Supplementation of vitamins and micronutrients should compensate for their possible reduced intake;

## • VBG, non-adjustable gastric banding, and other pure gastric restrictive operations

- Similar recommendations as for adjustable gastric banding, except there will be no band adjustments
  Gastric bypass
- check-up after 1 month, minimal follow-up to be every 3 months the first year, every 6 months the second year, and annually thereafter;
- Vitamin and micronutrient supplements (oral) should be routinely prescribed to compensate for their possible reduced intake and absorption;
- Laboratory tests to evaluate the metabolic and nutritional status should be carried out annually to include fasting glucose (HbA1c in diabetics), liver function tests, renal function, vitamin B<sub>12</sub>, 25-(OH) vitamin D3, ferritin, calcium, parathyroid hormone, albumin, Hb, Mg<sup>++</sup>, zinc;
- As a result of these tests, it may be necessary to correct deficits by parenteral administration of vitamins and micronutrients;
- In the case of secondary lactose intolerance, replace with oral lactase;

- In the case of early dumping syndrome, hydratation before meals is advised and the use of corn-starch supplements considered;
- In the case of late dumping syndrome, hypoglycaemia should be considered and the patient advised accordingly.

### Minimal Requirements for Follow-up after Operations Limiting Absorption of Nutrients

### · Biliopancreatic diversion

- Check-up after 1 month, followed by minimal follow-up every 3 months after the operation in the first postoperative year, every 6 months in the second year, and annually thereafter;
- Laboratory tests are necessary to evaluate the course of metabolic and nutritional status and to adapt supplementation and drug treatment accordingly;
- Blood tests at 1, 4 and 12 months, thereafter annually
- liver function tests (GPT, γGT);
- complete blood cell count;
- minimal nutritional parameters should be vitamin B<sub>12</sub>, 25-(OH) vitamin D3, PTH, bone alkaline phosphatase, ferritin, Ca, albumin, transferrin, creatinine, protrombin time (PTT);
- urine examination;
- Life long daily vitamin and micronutrient supplementation (vitamins should be administered in a water-soluble form). Vitamins A, D, E, K;
- Ca supplementation (preferably in Ca citrate, recommended total intake 2 grams/day);
- Minimum advised protein intake of ~90 grams per day;
- Supplement of vitamins and micronutrients should compensate for their possible reduced intake and according to laboratory values
  - in a preventive regimen, the supplementation can be administered orally;
  - for correction of deficits, the supplementation should be administered parenterally, except for Ca;
- PPI/H2 blockers for the entire first postoperative year.

In case of excess bloating, flatulence and/or foul-smelling stools, the recommended treatments are oral neomycin or metronidazole or pancreatic enzymes. (EL: A, B, C, D. Ref. 18, 104-131)

### Failed treatment

To reinforce adherence to lifestyle changes and weight loss maintenance after bariatric surgery, regular contacts and life-long follow-up with the obesity management centre are usually required. Scientific evidence reveals that a certain number of bariatric patients will fail to lose weight, or to maintain weight loss. If medically indicated and if such a patient is willing, further bariatric surgery should be undertaken. (EL: B, C, D. Ref. 132-145)

### Conclusion

The BSCG members who created the Guidelines realize that they have only touched upon basic points of treatment of morbid obesity. There are many other areas in this field which were deliberately left open. Among such areas are definitions of Centres of Excellence, the bariatric surgeon's qualifications, and acceptance of the disease/reimbursement issues. These issues will be the subject of the future work of the BSCG. The authors trust that these Guidelines will improve both, medical and surgical care of morbidly obese individuals and will contribute to better outcomes and increased patient safety.

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