

# CLINICAL GUIDELINES

## Inter-disciplinary European guidelines on surgery of severe obesity

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In 2005, for the first time in European history, an extraordinary Expert panel named 'The BSCG' (Bariatric Scientific Collaborative Group), was appointed through joint effort of the major European Scientific Societies which are active in the field of obesity management. Societies that constituted this panel were: IFSO – International Federation for the Surgery of Obesity, IFSO-EC – International Federation for the Surgery of Obesity – European Chapter, EASO – European Association for Study of Obesity, ECOG – European Childhood Obesity Group, together with the IOTF (International Obesity Task Force) which was represented during the completion process by its representative. The BSCG was composed not only of the top officers representing the respective Scientific Societies (four acting presidents, two past presidents, one honorary president, two executive directors), but was balanced with the presence of many other key opinion leaders in the field of obesity. The BSCG composition allowed the coverage of key disciplines in comprehensive obesity management, as well as reflecting European geographical and ethnic diversity. This joint BSCG expert panel convened several meetings which were entirely focused on guidelines creation, during the past two years. There was a specific effort to develop clinical guidelines, which will reflect current knowledge, expertise and evidence based data on morbid obesity treatment.

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### Introduction

The prevalence of obesity is increasing world-wide at an alarming rate and represents a global epidemic in both developed and developing countries.<sup>1</sup>

According to the 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

(body mass index (BMI)  $\geq 30$ ) in Europe is reported in the range 10–20% in men and 15–25% in women and almost a half of the European population is overweight or obese (BMI  $\geq 25$ ).<sup>2</sup>

Overweight and obesity are associated with increased risks of type 2 diabetes, hypertension, cardiovascular disease, dyslipidaemia, arthritis, non-alcoholic steatohepatitis, gall-bladder disease, sleep-apnoea syndrome and several cancers.<sup>3</sup>

Overweight and obesity play a crucial role in the development of type 2 diabetes. The risk fraction of type 2 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 and reduces life expectancy. Mortality attributable to excess weight

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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 (BMI > or = 40 kg/m<sup>2</sup>) in the US in 2002 was 1.8%; 60% of morbidly obese people were women, and 63% were in the ages range 18–49 years.<sup>7</sup>

Premature mortality increases with increasing BMI. Relative risk of death at the age of 50 years among men and women with BMI ≥ 40 who had 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 disease, 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 of the morbidly obese patients.<sup>11</sup> Recent long-term studies show that there is a substantial reduction of mortality in bariatric surgery patients, as well as decreased risk of developing new health-related co-morbidities, and health-care utilization and direct health-care costs.<sup>12–14</sup>

Bariatric surgery is an established and integral part of the comprehensive management of morbidly obese patients.

These guidelines were created through the inter-disciplinary effort of key opinion leaders 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 evidence level data to support conclusions of this panel of experts were systematically obtained from 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, gastropasty, 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 was also retrieved from the 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 *et al.*'s 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 '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:

- Level A: consistent RCT, 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 in age groups from 18 to 60 years.

1. With BMI ≥ 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 (such as metabolic disorders, cardio-respiratory disease, severe joint disease, obesity related severe psychological problems) etc. EL A, B, D<sup>19–37</sup>
3. BMI criterion may be the current BMI or a documented previous BMI of this severity. Note that
  - (a) Weight loss as a result of intensified treatment before surgery (patients who 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 gain weight again.

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.<sup>20,37</sup>

Patients must have shown their compliance with medical appointments.

## Bariatric surgery in (children)/adolescent

Indication for bariatric surgery in adolescents and children could be considered in centers with extensive experience of such treatment in adults and who are able to offer a true multidisciplinary approach, which involves paediatric skills relating to surgery, dietetics and psychological management.

In adolescents with severe obesity, bariatric surgery can be considered if the patient

1. Has a BMI >40 (or 99.5<sup>o</sup> percentile for respective age) and at least one comorbidity
2. Has followed at least 6 months of organized weight reducing attempts in a specialized centre
3. Shows skeletal and developmental maturity
4. Is capable 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<sup>38-45</sup>)

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

### Bariatric surgery in those aged above 60

Indication for bariatric surgery should be considered individually.

The Proof of a favorable risk benefit 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 is unlikely to increase lifespan.<sup>46</sup>

### Contraindications specific for bariatric surgery

1. Absence of a period of identifiable medical management
2. 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

### Patient pre-operative evaluation

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

- Physician
- Surgeon

- Anesthetist
- Psychologist or psychiatrist
- Nutritionist and/or dietitian
- Nurse practitioner / social worker

(EL B,C, D<sup>16,20,47-54</sup>)

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

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 on the benefits, consequences and risks of the surgical options and the necessity of lifelong 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 behavior modification of life style and of follow-up

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

- Sleep apnea syndrome and pulmonary function
- Metabolic and endocrine disorders
- Gastro-esophageal disorders (Helicobacter)
- Body composition (densitometric assessment)
- Bone density
- Indirect calorimetry

(EL A,B,C,D<sup>16,55-69</sup>)

### Surgical techniques overview

Definition

- Food limitation operations
  - Restrictive procedures
    - Vertical-banded gastroplasty (VBG)
    - Gastric sleeve resection
    - Gastric banding
      - Adjustable (AGB)
      - Non-adjustable Gastric bypass (GBP) Proximal
      - Long/limb
- Operations limiting absorption of nutrients
  - 'Energy' absorption limiting operations

- Biliopancreatic diversion (BPD)
- Combined operations
  - Biliopancreatic diversion with duodenal switch (BPD DS)
  - Distal gastric bypass (common limb 100 cm or less)

A laparoscopic technique should be considered as the first treatment choice in bariatric surgery, unless specific contraindications for laparoscopic operation are present.

### Assigning a patient to a particular bariatric procedure

At this moment, there is insufficient evidence-based 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:

- BMI
- Age
- Gender
- Body fat distribution
- Type 2 diabetes mellitus
- Dyslipidemia
- Binge eating disorders (BED)
- Low IQ
- Significant hiatal hernia
- GERD
- Patient's expectations/realistic goals

The expected average weight loss and weight maintenance is increasing 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<sup>17,70-95</sup>)

The procedures should be performed at inter-disciplinary obesity management centers with appropriately trained staff and adequate equipment (see above).

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 center/surgeon with adequate bariatric experience in that procedure. (EL B, D<sup>20,96-103</sup>).

As a result of successful bariatric treatment, further treatment (such as plastic/reconstructive surgery) might be required.

### Follow-up

Morbid obesity is a life-long disease. The treating physician and 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 inter-disciplinary 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 follow-up and management of obesity and obesity-related diseases and operation-related non-surgical consequences.

Treatment outcome is significantly dependent, among other factors, on patients compliance with long-term follow-up.

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

- The possible deficiencies, such as vitamin, protein, and other micronutrients
- Adjustments of medical treatment of the obesity-related morbidities such as diabetes, and hypertension.

All patients after bariatric procedures require regular lifelong qualified surveillance.

Patients must have access to 24 h emergency service provided by the operating center.

The patient takes lifelong 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 exact type of the received implant (if applicable) together with description of possible serious adverse effect.

- Adjustable gastric band
  - Follow-up during the first year should at least be every 3 months, starting 1 month postoperatively until a clinically satisfactory rate of weight loss is achieved, if necessary with repeated bandfills. Thereafter follow-up should be at intervals of no more than 1 year
  - 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 weight loss and the type of the implant
    - first inflation according to the type of the band
    - as a medical/clinical decision
    - by trained medical or paramedical staff with adequate experience (such as surgeon, medical physician, nurse practitioner, dedicated radiologist)
  - supplement of vitamins and micronutrients should compensate for their possible reduced intake

- VBG, non-adjustable gastric banding, and other pure gastric restriction operations
  - Similar recommendations as for adjustable gastric banding, except there will be no band adjustments
- Gastric bypass
  - Checkup after 1 month, minimal follow-up every 3 months for the first year, every 6 months for the second year and annually thereafter
  - Vitamin and micronutrient supplements (oral) should routinely be prescribed to compensate for their possible reduced intake and absorption. However, in addition,
  - Laboratory tests to evaluate the metabolic and nutritional status should also be carried out annually to include
    - fasting glucose (+HbA1c in diabetics), liver function test, renal function, vitamin B<sub>12</sub>,<sup>25</sup> (OH) vitamin D<sub>3</sub>, ferritin, Ca, parathormone, albumin, Hb, Mg<sup>2+</sup>, Ca<sup>2+</sup>, zinc checks
  - As a result of these test, it may be necessary to correct deficits by parenteral administration of vitamins and micronutrients
  - In case of secondary lactose intolerance, supplement with oral lactase
  - In case of early dumping syndrome, hydration before meals is advised and the use of corn starch supplements considered.
  - In case of late dumping syndrome hypoglycaemia should be considered and the patient advised accordingly.

### Minimal requirements and recommendations for follow-up after operations limiting absorption of nutrients:

- Biliopancreatic diversion
  - Checkup after 1 month, followed by minimal followup every 3 months after the operation in the first post-operative year, every 6 months in the second year, and annually thereafter
  - Lab tests are necessary to evaluate the evolution 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,  $\alpha$ GT)
    - complete blood cell count
    - minimal nutritional parameters should be vitamin B<sub>12</sub>,<sup>25</sup> (OH) vitamin D<sub>3</sub>, PTH, bone alkaline phosphatase, ferritin, Ca, albumin, transferrin, creatinine, prothrombin time (PPT)
    - urine examination
  - Lifelong daily vitamin and micronutrient supplementation (vitamins should be administered in a water-soluble form)
  - Vitamin A, D, E and K

- Calcium supplementation (preferably in Ca citrate, recommended total intake 2 g/day)
- Minimum advised protein intake of approximately 90 g/day
- Supplement of vitamins and micronutrients should compensate for their possible reduced intake and according to lab 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 excessive bloating, flatulence and/or foul-smelling stools, the recommended treatments are oral neomycin or metronidazole or pancreatic enzymes (EL A, B, C, D<sup>104–131</sup>)

### Failed treatment

To reinforce adherence to lifestyle changes and weight loss maintenance after bariatric surgery, regular contacts and lifelong follow-up with the obesity management center 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<sup>132–145</sup>).

### Conclusion

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

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