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Interdisciplinary European guidelines on metabolic and bariatric surgery

Evropská interdisciplinární doporučení k chirurgické léčbě metabolických onemocnění a obezity

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Summary: In 2012, an expert panel composed of presidents of each of the societies, the European Chapter of the International Federation for the Surgery of Obesity (IFSO-EC), and of the European Association for the Study of Obesity (EASO), as well as of the chair of EASO Obesity Management Task Force (EASO OMTF) and other key representatives from IFSO-EC and EASO, devoted the joint Medico-Surgical Workshop of both institutions to the topic of metabolic surgery in advance of the 2013 European Congress on Obesity held in Liverpool. This meeting was prompted by the extraordinary advancement made in the field of metabolic and bariatric surgery during the past decade. It was agreed to revise and update the 2008 Interdisciplinary European Guidelines on Surgery of Severe Obesity produced by focusing in particular on the evidence gathered in relation to the effects on diabetes and the changes in the recommendations of patient eligibility criteria. The expert panel allowed the coverage of key disciplines in the comprehensive management of obesity and obesity-associated diseases, aimed specifically at updating the clinical guidelines to reflect current knowledge, expertise and evidence-based data on metabolic and bariatric surgery.

Key words: interdisciplinary – European guidelines – metabolic and bariatric surgery – IFSO-EC

Souhrn: V roce 2012 se v rámci internisticko-chirurgické pracovní skupiny před Evropským obezitologickým kongresem, konaným v roce 2013 v Liverpoolu, uskutečnilo jednání panelu odborníků, složeného z předsedů Evropské sekce Mezinárodní federace pro chirurgickou léčbu obezity (IFSO-EC), Evropské obezitologické společnosti (EASO), EASO Obesity Management Task Force (EASO OMTF) a dalších významných zástupců IFSO-EC a EASO, věnované tématu metabolické chirurgie. Podnětem k tomuto jednání byl mimořádný pokrok, kterého metabolická a bariatrická chirurgie dosáhla v uplynulém desetiletí. Účastníci se shodli na provedení revize a aktualizace Interdisciplinárních evropských závazných doporučení pro chirurgickou léčbu těžké obezity vydaných v roce 2008, zejména s ohledem na množství důkazů o antidiabetickém účinku a na změny v doporučených indikačních kritériích. Díky složení expertního panelu bylo možné obsáhnout všechny disciplíny, které jsou zásadní pro komplexní léčbu obezity a s obezitou spojených nemocí, s cílem aktualizovat klinická doporučení pro chirurgickou léčbu obezity a metabolických onemocnění na základě nejnovějších odborných zkušeností a poznatků založených na důkazech.

Key words: interdisciplinární – evropská doporučení – metabolická a bariatrická chirurgická léčba – IFSO-EC

Introduction

The term "globesity" describes the worldwide epidemic that currently affects both developed and developing countries [1–3]. In 2008, according to the World Health Organization (WHO), 1.4 billion adults, 20 years of age and older, were overweight with an estimated 500 million adults

worldwide being obese (over 200 million men and nearly 300 million women) [2–4]. In 2009–2010 in the USA, the age-adjusted prevalence of obesity was 35.5% among adult men and 35.8% among adult women [5] with the prevalence of obesity in children and adolescents being 16.9% [6]. Noteworthy, the prevalence of obesity has tripled since the 1980s in many countries of the WHO European Region with overweight and obesity affecting 50% of the population in the majority of European countries [2–4]. It has been estimated that 60% of the world's population, i.e. 3.3 billion people, could be overweight (2.2 billion) or obese (1.1 billion) by 2030 if recent trends continue [7].

In spite of excess weight being considered the fifth leading risk for worldwide deaths according to the WHO, it has not been possible to successfully curb the obesity epidemic with more than 40 million children under the age of 5 being overweight in 2010 [3]. Moreover, severe obesity (i.e. a body mass index – BMI > 35 kg/m^2) represents a quickly growing segment of the epidemic in which the negative effects on health and disability are especially marked. In addition, obesity not only disproportionately affects the disadvantaged segments of the population, but these groups experience the most relevant increases in obesity prevalence. In the USA, individuals with a BMI > 35 kg/m^2 represent 15% of the adult population [5]. Excess weight drastically elevates a person's risk of developing a number of non-communicable diseases, like diabetes, hypertension, stroke, dyslipidaemia, sleep apnoea, cancer, non-alcoholic steatohepatitis and other serious co-morbidities. The WHO emphasizes that 44% of the type 2 diabetes mellitus (T2DM) burden, 23% of the ischaemic heart disease burden and around 7–41% of certain cancer burdens are attributable to overweight and obesity [3,4]. In the majority of European countries, overweight and obesity are responsible for about 80% of cases of T2DM, 35% of ischaemic heart disease and 55% of hypertensive disease among adults [4]. In addition, a range of debilitating conditions such as osteoarthritis, respiratory difficulties, gallbladder disease, infertility and psychosocial problems, among others, which lead to reduced life expectancy, quality of life and disability, are extremely costly in terms of both absence from work and use of health resources [2,4,8,9]. Noteworthy, the lifespan of severely obese individuals is decreased by an estimated 5 to 20 years depending on gender, age and race [10].

At present, approximately 65% of the world's population inhabits countries where overweight and obesity kill more people than underweight [2–4]. The WHO highlights that obesity is responsible for 10–13% of deaths in different parts of the region [2–4]. A systematic analysis with pooled data from 19 prospective studies adjusted for age, study, physical activity, alcohol consumption, education, and marital status, comprising 1.46 million white adults and over 160,000 deaths, showed that overall for men and women combined, for every five unit increase in BMI, a 31% increase in risk of death was observed [11]. A recent meta-analysis focusing on all-cause mortality with the inclusion of nearly three million people (and encompassing 270,000 deaths) reported that relative to normal weight all grades of obesity (i.e. a BMI > 30 kg/m^2) and grades 2 and 3 obesity (i.e. a BMI 35–40 and > 40 kg/m^2, resp.) were associated with significantly higher all-cause mortality [12].

Bariatric surgery has proven to be the most effective mode of treatment of the morbidly obese patients. Recent long-term studies provide evidence of a substantial reduction of mortality in bariatric surgery patients, as well as decreased risk of developing new health-related co-morbidities, together with decreased health care utilization and drop in direct health care costs [10,13].

Bariatric surgery is an established and integral part of the comprehensive management of morbidly obese patients. These guidelines were created through the interdisciplinary effort of key opinion leaders from international medical and surgical societies (International Federation for the Surgery of Obesity (IFSO), International Federation for the Surgery of Obesity – European Chapter (IFSO-EC), European Association for the Study of Obesity (EASO)) [14]. The aim of the guidelines is to provide physicians, health care practitioners, health care policy makers and health care providers and insurance companies with essential elements of good clinical practice in the treatment of obesity.

Scientific evidence level (EL) 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 May 2013 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, gastric plication, intestinal bypass, Roux-en-Y, gastric banding, biliopancreatic diversion (BPD), duodenal switch, biliopancreatic bypass, obesity/morbid obesity treatment outcomes, obesity/morbid obesity follow-up, obesity/morbid obesity complications, nutrition and psychology. Some of the EL data were also retrieved from the following publications [15–19].

The recommendations of the panel are supported by the best available evidence, which includes all EL (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 EL:

- 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 experience/principles case reports.

Indications for bariatric surgery

Bariatric surgery is indicated to patients in age groups from 18 to 60 years having the following characteristics:

1. with BMI ≥ 40 kg/m^2 (EL A–C [14,19–38]);
2. with BMI 35–40 kg/m^2 with co-morbidities in which surgically induced weight loss is expected to improve the disorder (such as metabolic disorders, cardiorespiratory disease, severe joint disease, obesity-related severe psychological problems) (EL A, B, D [39–44]);
3. BMI criterion may be the current BMI or previously maximum attained 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 programme but started to gain weight again, even if the required minimum indication weight for surgery has not yet been attained again. To be considered for surgery, patients should have failed to lose weight or to maintain long-term weight loss, despite appropriate surgical and/or non-surgical comprehensive medical care (EL B, D) [21,38].
   c) Consideration should be given to reducing the BMI threshold by 2.5 for individuals of Asian genetic background and to the balance between genetic and environmental/dietary factors.

Patients should have shown their compliance withscheduled medical appointments.

Bariatric surgery and T2DM

T2DM can be viewed as a reversible disease. Bariatric surgery is clearly confirmed to be beneficial in T2DM remission. Bariatric surgery contributes to improved beta cell function in patients with BMI > 35 kg/m^2 (EL A) [45–47]. Note that throughout the guidelines there are different HbA_{1c} cut-offs stated in certain sections/paragraphs. However, different cut-offs are pertinent to statements outlining different treatment outcomes, for example success of post-bariatric improvement of T2DM patients vs. "partial" or "complete" remission in T2DM patients, etc.).

Surgically induced improvement of T2DM may be considered effective if:

- post-operative insulin dose ≤ 25% of the pre-operative one;
- post-operative oral antidiabetic treatment dose ≤ 50% of the pre-operative one;
- post-operative reduction in HbA_{1c} > 0.5% within 3 months or reaching < 7.0%;
- patients with BMI ≥ 30 and < 35 kg/m^2 with T2DM may be considered for bariatric surgery on an individual basis, as thereis evidence-based data supporting bariatric surgery benefits in regard to T2DM remission or improvement (EL A–D) [48–60].

However there is not yet available large enough number of high evidence level data to unquestionably support a clear, long-term benefit, especially for merely and self-standing surgical treatment/control of glycaemia, dyslipidaemia and/or other metabolic diseases.

Bariatric surgery in children/adolescents

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

In adolescents with severe obesity, bariatric surgery can be considered if the patient (EL C, D) [61–68]:

1. has a BMI > 40 kg/m^2 (or 99.5th percentile for respective age) and at least one co-morbidity;
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 post-operative multidisciplinary treatment programme in a unit with specialist pediatric support (nursing, anaesthesia, psychology, post-operative care);
6. can access surgery in a unit with specialist pediatric support (nursing, anaesthesia, psychology, post-operative care).

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

Bariatric surgery in those aged above 60

The proof of a favourable 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 quality of life, even though surgery is unlikely to increase lifespan [69].

Contraindications specific for bariatric surgery

The containdications for bariatric surgery are:

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, personality and eating 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.

Specific exclusion criteria for bariatric surgery in the treatment of T2DM

Specific exclusion criteria for bariatric surgery in the treatment of T2DM are:

1. secondary diabetes,
2. antibodies positive (anti-GAD or ICA) or C-peptide < 1 ng/mL or unresponsive to mixed meal challenge.

Patient pre-operative evaluation

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 (EL B–D [16,40,70–77]): physician, surgeon, anaesthetist, psychologist or psychiatrist, nutritionist and/or dietitian, nurse practitioner/social worker.

Patients indicated for bariatric surgery should undergo routine pre-operative assessment as for any other major abdominal surgery.

Pre-operative management should include assessment of general health and nutritional status as follows:

- 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 programmes;
- 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 of lifestyle modification, including behavioural changes and follow-up compliance.

In addition to the routine pre-operative assessment as for any other major abdominal surgery, the patient should undergo further assessment for (depending on the planned bariatric procedure and clinical status of the patient) (EL A–D) [16,77–91]:

- sleep apnoea syndrome and pulmonary function;
- metabolic and endocrine disorders, lipids, TSH, etc.;
- gastro-oesophageal disorders (*Helicobacter pylori*, etc.);
- bone density;
- body composition,
- resting energy expenditure.

Psychological support

Pre-operative phase

Psychological assessment of behavioural, nutritional, familial and personality factors should be an integral part of the patient's pre-operative evaluation (EL C) [92–98].

The purpose of the psychosocial evaluation for weight loss surgery is not merely diagnostic, but to enhance the safety and efficacy of surgical treatment by identifying areas of potential vulnerability, challenges and strengths, to create an individually tailored treatment plan.

Pre-operative psychological evaluation should always include assessment of psychopatology such as personality examination as well as asessment of his/her expectation/motivation, diet history, lifestyle (i.e. nutritional behaviour, physical activity habits, life conditions) and social support network. Pre-operative evaluation enables identification of interventions that can enhance long-term compliance and weight maintenance (i.e. crisis intervention, psychological support, psychotherapy, etc.) (EL D) [99]. The goal is to enhance patients motivation and ability to comply with nutritional, behavioural and psychosocial changes before and after bariatric surgery. Pre-operative examination leverages psychological support in case of patient's psychological disorder relapse post-operatively (depression, anxiety, etc.) (EL C, D) [100–103].

Pre-operative evaluation should detect potential psychological contraindications to surgery, such as severe eating disorders and others highlighted in chapter 'Contraindications Specific for Bariatric Surgery' (see above).

Post-operative psychological support

Eating pathologies, such as binge eating disorder, increase risk of lower

weight loss and weight regain after some bariatric procedures (EL C) [104–109]. Presence of two and more psychiatric/mental disorders increases the risk of inadequate weight loss both after purely food restrictive as well as after metabolic type of procedures (EL B) [110–114].

Pre-operative identification of psychological risk factors associated with lower post-operative compliance, inadequate weight loss, alcohol or drug dependencies, eating pathologies and others should lead to post-operative interventions through implementing a self-monitoring strategy in higher risk patients.

Surgical techniques overview

In the past several years, better understanding of substantial metabolic changes induced by different surgical interventions to the alimentary tract was achieved. Therefore, the former classification of operations according to their influence on food ingestion, defined as limiting stomach capacity (restrictive), limiting absorption of nutrients (malabsorptive) or combined procedures does not appropriately reflect the current level of knowledge about early and weight independent metabolic effects of these operations. Nowadays, most of the standard surgical interventions are being mostly referred to as metabolic operations. The focus when treating obese patients is gradually shifting from the primary goal of weight loss outcomes to the metabolic effects of the operations (EL A–D) [115–127].

Standard bariatric and metabolic procedures that are currently available for patients requiring weight loss and/or metaboliccontrol are as follows:

- adjustable gastric banding (AGB),
- sleeve gastrectomy (SG),
- Roux-en-Y gastric bypass (RYGB),
- BPD,
- BPD/duodenal switch (BPD/DS).

Recent procedures

Recent procedures in which long-term outcome data is not yet available include:

- Laparoscopic gastric plication (LGP) in which infolding of the greater curvature of the stomach leads to tubularizing the stomach through intraluminal tissue fold. The current evidence on LGP for severe obesity raises no major safety concerns in short-to-medium term but more evidence is needed about the long-term efficacy of the procedure (EL B) [128–133].
- The "omega loop gastric bypass" involves laparoscopic construction of elongated gastric pouch and a loop gastric bypass with distal diversion. Omega loop gastric bypass is so far controversial for its potential long--term risks. Most of the evidence on the omega gastric bypass comes from descriptive reports and case series, and more evidence-based data is needed to enable appropriate evaluation ofsafety and efficacy of the procedure.

Procedures that are under investigation

Single anastomosis duodeno-ileal bypass with SG is a modified DS operation. This procedure is performed so far only in the Framework of Clinical Trials, and no wider spread of the procedure is recommended until evidence-based data are available [134].

A strictly "investigational" approach is recommended for different "intestinal interposition" operations.

Endoluminal innovative procedures

The currently explored endoluminal novel procedural techniques, devices and technologies are in various stages of technical development and are an experimental or clinical application for both the primary or revisional treatment of obesity. These novel technologies have no evidence-based data support yet and should be limited to clinical trials conducted under ethical guidelines and under institutional review board approvals only.

However, it is expected that some of the investigational procedures will impact the future decision making in the treatment of obesity.

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 a specific bariatric/metabolic procedure with no evidence in favour of any particular procedure.

A laparoscopic technique should be considered as the preferable approach to the operation, providing no contraindications for the laparoscopic approach are present (EL A) [135].

Among others, pre-operative factors that could influence the choice of the type of operation are:

- BMI,
- age,
- gender,
- body fat distribution,
- T2DM – duration of T2DM, pre-operative levels of HbA_{1c}, multi-drug anti--diabetic treatment, fasting C-peptide levels,
- dyslipidaemia,
- low IQ,
- significant hiatal hernia,
- gastroesophageal reflux disease,
- patient's expectations/realistic goals
- presence of eating disorders
- presence of long-term treatment for a coexisting disease or condition for which absorption and pharmacokinetics are of major concern.

The expected average impact on improvement of metabolic status, improvement or remission of T2DM, weight loss and weight maintenance is increasing with the following procedures in the following order: AGB, LSG, RYGB, 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–D) [17,30,136–160].

The early weight independent metabolic effects on HbA_{1c}, LDL-cholesterol, blood pressure, prevention and reduced cardiovascular risks of some of the procedures were already demonstrated in several studies; however, the exact mechanism of action of different surgical interventions has to be explored in detail and is not completely defined yet (EL A–D) [49–52,161].

Better understanding of various mechanisms of action of these operations may contribute to personalized treatment and more precise assignment of different procedures to individual patients [162].

The procedures should be performed at interdisciplinary obesity management centres with appropriately trained staffand adequate equipment (see above).

In all situations, the bariatric surgeon's experience is a key issue. It is not advisable to practise 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) [30,163–169].

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

Follow-up

Morbid obesity is a lifelong 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 (surgical 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 longterm 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 patient compliance with long-term follow-up.

Patients attending support groups after bariatric/metabolic surgery show enhanced weight loss and other treatment outcomes, specifically in RYGB and gastric banding (EL C). Patients should be repeatedly educated about staged meal progression dependent on the time elapsed after surgery and based on the type of surgical procedure they underwent (EL A–D) [168–176]. Patients should also be informed that an excessive number and size of meals will probably result in lower weight loss.

They should be advised on the general importance of:

- adequate protein intake in order to prevent excessive lean body mass loss;
- avoidance of ingestion of concentrated sweets to prevent dumping syndrome, especially after RYGB and BPD;
- preferable use of crushed and/or rapid release medication (EL B, D) [177,178];
- the health benefits of regular physical activity/exercise that may need specific advice.

In case of T2DM patients, use of anti-diabetic medication and/or insulin should be with no delays adjusted post-operatively to minimize risks of hypoglycaemia.

Criteria for assessment of the effect of bariatric surgery on remission of T2DM

Criteria for assessment of the effect of bariatric surgery on remission of T2DM [58] are:

- partial remission – hyperglycaemia below diagnostic thresholds for diabetes (HbA_{1c} > 6%, but < 6.5%, FPG 100–125 mg/dL), at least 1-year duration, no active pharmacological therapy or ongoing procedures;
- complete remission – normal glycaemic measures (HbA_{1c} normal range (< 6%), FPG < 100 mg/dL), at least 1-year duration, no active pharmacological therapy or ongoing procedures;
- prolonged remission – complete remission of at least 5-year duration.

Criteria for assessment of effect of bariatric surgery on optimization of metabolic status

Criteria for assessment of effect of bariatric surgery on optimization of metabolic status and some other comorbid conditions [58] are:

- HbA_{1c} ≤ 6 %,
- no hypoglycaemia,
- total cholesterol < 4 mmol/L,
- LDL cholesterol < 2 mmol/L,
- triglycerides < 2.2 mmol/L,
- blood pressure < 135/85 mm Hg,
- > 15% weight loss, or lowering of HbA_{1c} by > 20%,
- LDL < 2.3 mmol/L and blood pressure < 135/85 mm Hg with reduced medication from preoperated status.

In cases of postprandial hypoglycaemic symptoms, evidence for lowered blood glucose concurrent with symptoms should be looked for; patients should first be advised on dietary changes (low carbohydrate diets, regular meal times); second-line drug treatment may be considered, such as acarbose, calcium (Ca) channel antagonists, diazoxide and octreotide (EL C) [179–183].

Special care

Special care must be taken for the following:

- the possible nutritional deficiencies, such as vitamin, protein and other micronutrients;

- adjustments of medical treatments, specifically treatment of obesity-related co-morbidities, such as diabetes and hypertension, and avoidance of some types of pharmacotherapy (e. g. non-steroidal and steroidal anti-inflamatory drugs), prevention of deep vein thrombosis and/or pulmonary embolism is recommended for all bariatric patients through low molecular weight heparin subcutaneous administration, leveraged with use of T.E.D. stockings, early post-operative ambulating and intra- and post-operative use of sequential compression devices (EL B–D) [184–187];
- early detection and adequate treatment of gastrointestinal (GI) leaks in suspected patients (newly sustained tachycardia > 120 pulses/min for at least 6 hours, fever, tachypnea, newly established signs of hypoxia, increasing pain, elevated C reactive protein) through UGI X-ray or CT studies; surgical revision (laparoscopy or laparotomy) may be considered and is justified in case of highly clinically suspicious cases, despite non-presence of some of the symptoms and/or even in negative upper GI studies (EL C) [188–191].

All patients after bariatric procedures require regular lifelong qualified surveillance.

Patients must have access to 24-hour emergency service provided by the operating centre.

In case severe GI symptoms are present and persistent (such as abdominal pain, nausea, vomiting, change in stools, etc.) endoscopy and/or CT may be considered as the first diagnostic/therapeutic option in order to evaluate potential presence of intestinal disease(s), bacterial overgrowth, ulcer disease, anastomotic problems, obstruction due to foreign body, etc. 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 effects.

Adjustable gastric banding

Follow-up during the first year should be at least every 3 months, starting 1 month post-operatively until a clinically satisfactory rate of weight loss is achieved, if necessary with repeated band fills. Thereafter, follow-up should be at intervals of no more than 1 year.

Follow-up should be carried out by the interdisciplinary team and should include dietary change/behavioural modification/physical activity interventions and encouragement as well as pharmacology support and surgical revision if appropriate.

Metabolic and nutritional status should be regularly monitored to prevent vitamin and mineral 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.

Roux-en-Y gastric bypass

Check-up 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 (+HbA_{1c} in diabetics), liver function tests, renal function, vitamin B_1, B_9 (folates), B_{12}, 25(OH)vitamin D_3, ferritin, parathormone, albumin, Hb, Ca^{2+}, checks, as well as basic blood cells, haemoglobin and electrolytes tests.

As a result of these tests, it may be necessary to correct deficits by first oral supplementation or even parenteral administration of vitamins and micronutrients.

In case of secondary lactose intolerance, supplement with oral lactase is advised.

In case of early dumping syndrome, hydration before meals is advised and the use of corn starch and/or low glycaemic index food supplements considered.

In case of late dumping syndrome, hypoglycaemia should be considered and the patient assessed and advised accordingly.

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

Biliopancreatic diversion

1. Check-up after 1 month, followed by minimal follow-up every 3 months after the operation in the first post-operative year, every 6 months in the second year, and annually thereafter.
2. Lab tests are necessary to evaluate the evolution of metabolic and nutritional status and to adapt supplementation and drug treatment accordingly.
3. Blood tests at 1, 4 and 12 months, thereafter annually, should be done for the following:
   - liver function tests (GPT, γ-GT),
   - complete blood cell count, complete blood electrolytes tests,

- minimal nutritional parameters should be vitamin B_{12}, 25(OH) vitamin D_3, parathormone, bone alkaline phosphatase, ferritin, Ca, pre-albumin, albumin, transferrin, creatinine, prothrombin time, etc.

4. Urine examination.
5. Lifelong daily vitamin and micronutrient supplementation (vitamins should be administered in a water-soluble form):
   - vitamins A, D, E and K,
   - Ca supplementation (preferably in food, Ca citrate, recommended total intake 2 g/day).
6. Minimum advised protein intake of approximately 90 g/day.
7. In addition, supplement of vitamins and micronutrients should compensate for their possible reduced intake and absorption and according to lab values.
8. In a preventive regimen, the supplementation can be administered orally.
9. For correction of deficits, the supplementation can be administered parenterally, except for Ca.
10. Proton pump inhibitors/histamine 2 receptor antagonists for the entire first post-operative 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–D) [192–219].

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 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 considered (EL B–D) [220–233].

Conclusion

All those who, on behalf of the scientific societies IFSO, IFSO-EC and EASO partially rewrote and updated the former 2008 Interdisciplinary European guidelines on surgery of severe obesity realize that they have touched only basic issues of bariatric and metabolic surgery.

There are many other areas in this field that were deliberately left open or were not up-dated at this point. Among such areas are definitions of centres of excellence, bariatric surgeon's qualification and acceptance of the disease/reimbursement issues. These issues will be subject of the societies future work. The authors hope that these guidelines will improve both medical and surgical care of severely obese patients and will contribute to better outcomes and increased patient safety in the long term.

Disclaimer

The consensus material in this document is a clinical guideline. It is therefore intended to promote and guide good clinical practice. It should not be construed as a substitute for or as taking precedence over the duty of a clinician to conscientiously apply his/her knowledge and clinical skill to the best interests of a given patient [234,235].

It may thus be fully correct to offer or agree treatment out with this guidance. Clinicians may wish to document that they appraised patients clearly when proposing such treatment.

In applying this guidance, clinicians are advised in each case to consider the strength of evidence for any given part of it.

IFSO-EC and EASO are committed to promoting reliance on operationalized and controlled data.

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