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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Obesity surgery

Evidence-based guidelines of the European Association for Endoscopic Surgery (E.A.E.S.)

S. Sauerland,[1,2] L. Angrisani,[3] M. Belachew,[4] J. M. Chevallier,[5] F. Favretti,[6] N. Finer,[7] A. Fingerhut,[8] M. Garcia Caballero,[9] J. A. Guisado Macias,[10] R. Mittermair,[11] M. Morino,[12] S. Msika,[13] F. Rubino,[14] R. Tacchino,[15] R. Weiner,[16] E. A. M. Neugebauer[1,2]

[1] Conference Organisers on behalf of the Scientific Committee of the European Association for Endoscopic Surgery (E.A.E.S.), c/o E.A.E.S. Office, Post Office Box 335, 5500 AH Veldhoven, The Netherlands
[2] Biochemical and Experimental Division, Medical Faculty, University of Cologne, Ostmerheimer Str. 200, D 51109 Cologne, Germany
[3] S. Glovanni Bosco Hospital, University Federico II, Naples, Italy
[4] Service de Chirurgie Universitaire, CHRH, 2 rue des Trois Points, B 4500 Huy, Belgium
[5] Department of Digestive and General Surgery, Hopital Europeen G Pompidou, Paris, France
[6] Obesity Unit, Department of Medical and Surgical Sciences, University of Padova, Contra Chioare, 13, I 36100 Vicenza, Italy
[7] Wellcome Clinical Research Facility, Addenbrooke's Hospital, Hills Road, Cambridge CB2 2QQ, United Kingdom
[8] Centre Hospitalier de Poissy-Saint Germain, 10, rue du Champ Gaillard, F 78303 Poissy Cedex, France
[9] Department of Surgery, Malaga University, E 29080 Malaga, Spain
[10] Mental Health Department, Servicio Extremeno de Salud, Junta de Extremadura, C/ Jesus Rincon Jimenez n° 82, 5° D, 06010 Badajoz, Spain
[11] Department of General Surgery, University Hospital Innsbruck, Anichstr. 35, A-6020 Innsbruck, Austria
[12] Chirurgia Generale II, Department of Surgery, University of Turin, Corso A.M. Dogliotti 14, I 10126 Turin, Italy
[13] Service de Chirurgie Generale et Digestive, Hopital Louis Mourier, 78, rue des Renouillers, F 92701 Colombes, France
[14] Department of Surgery, Hopitaux Uiversitaires, BP 426 F 67091 Strasbourg, France
[15] Department of Surgery, Catholic University of Rome, Viale della Tecnica 205, I 00144 Roma, Italy
[16] Department of Surgery, Krankenhaus Sachsenhausen, Schulstr. 31, D 60594 Frankfurt a.M., Germany

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Abstract
Background: The increasing prevalence of morbid obesity together with the development of laparoscopic approaches has led to a steep rise in the number of bariatric operations. These guidelines intend to define the comparative effectivness and surrounding circumstances of the various types of obesity surgery.
Methods: A consensus panel representing the fields of general/endoscopic surgery, nutrition and epidemiology convened to agree on specific questions in obesity surgery. Databases were systematically searched for clinical trial results in order to produce evidence-based recommendations. Following two days of discussion by the experts and a plenary discussion, the final statements were issued. RecommendationsAfter the patient's multidisciplinary evaluation, obesity surgery should be considered in adults with a documented BMI greater than or equal to 35 and related comorbidity, or a BMI of at least 40. In addition to standard laboratory testing, chest radiography, electrocardiography, spirometry, and abdominal ultrasonography, the preoperative evaluation of obesity surgery patients also includes upper gastrointestinal endoscopy or radiologic evaluation with a barium meal. Psychiatric consultation and polysomnography can safely be restricted to patients with clinical symptoms on preoperative screening. Adjustable gastric banding (GB), vertical banded gastroplasty (VBG), Roux-en-Y gastric bypass (RYGB) and biliopancreatic diversion (BPD) are all effective in the treatment of morbid obesity, but differ in degree of weight loss and range of complications. The choice of procedure therefore should be tailored to the individual situation. There is evidence that a laparoscopic approach is advantageous for LAGB, VBG, and GB (and probably also for BPD). Antibiotic and antithromboembolic prophylaxis should be used routinely. Patients should be seen 3 to 8 times during the first postoperative year, 1 to 4 times during the second year and once or twice a year thereafter. Outcome assessment after surgery should include weight loss and maintainance, nutritional status, comorbidities and quality-of-life.

Obesity is an increasingly serious health problem in nearly all Western countries [76, 108, 320]. Although

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Correspondence to: E. A. M. Neugebauer

various preventive and conservative treatment options are available, it has been estimated that obesity-related illnesses, such as diabetes mellitus, knee osteoarthritis, systemic hypertension and heart failure, are responsible for an estimated 3% to 6% of total health care costs [6, 230, 279]. A recent study on the association between different grades of obesity and the number of life-years lost indicated that life expectancy can be up to 20 years shorter in severe obesity [104]. The consequences of obesity are by far more severe than those of smoking or alcohol [319].

Definition and classification of obesity is based primarily on the Body Mass Index (BMI), calculated as weight divided by the square of height with kg/m^2 as the unit of measurement [17]. For Caucasians, a BMI of 30 to 35 is considered as class 1 obesity, 35–40 as class 2, and over 40 as class 3. Morbid obesity is usually defined as a Body Mass Index (BMI) of over 40 or a BMI over 35 in combination with comorbidities [238]. In addition, some surgeons speak of super- and mega-obesity, if a patient's BMI exceeds 50 or 70, respectively. Alternatively, absolute or relative increases in body weight may be used to define obesity.

Given the enormous importance of morbid obesity and the limited efficacy of dietetic and pharmacological treatments, surgical treatment has become increasingly popular. The number of procedures performed has more than doubled within a few years [64, 78, 289]. This dramatic growth can be attributed in part also to the introduction of new surgical techniques, e.g. the adjustable silicone gastric band (AGB), and the rise of laparoscopic surgery. Traditionally, there are two types of operations for morbid obesity: Gastric restrictive operations (where food intake is restricted) and malabsorptive operations (where aliments are diverted from absorption via a gastrointestinal short-cut). Both types of obesity surgery are now being performed laparoscopically [38].

The aim of these guidelines is to systematically review the clinical effectiveness of the various surgical procedures and to support surgeons and other physicians in the provision of high-quality care for morbidly obese patients.

Methods

Selection of topics and experts

Considering the current controversy regarding the best surgical treatment for morbid obesity, the Scientific Committee and the Executive Board of the EAES decided to provide the surgical community with evidence-based guidelines. The aim and focus of these guidelines cover key questions regarding effective and efficient surgical treatment of obesity, including patient selection, choice of surgical technique, management of complications and follow-up.

A panel was appointed to develop clinical practice guidelines and consisted of representatives from key disciplines, i.e. surgeons specialized in obesity treatment, general surgeons, nutritionists, and epidemiologists from across Europe. Experts were selected according to scientific and clinical expertise, geographical localisation, and membership in societies pertaining to laparoscopic obesity surgery. The Obesity Management Task Force of the European Association for the Study of Obesity (EASO) was represented at the complete process by one nominated delegate (N.F.).

Guideline development started with a list of key questions, which all experts were asked to answer. In May 2004, the panel convened to review and discuss the range of answers on the basis of the scientific evidence. The nominal group process was used to develop statements that were agreeable for all or at least the majority of panel members. A preliminary position paper was compiled and presented to the audience at the EAES congress in June, 2004. All comments from the audience were discussed and a final version of the guidelines was agreed on consensually. The project was funded by the EAES. All panelists had to document and sign their relationships to commercial stakeholders in order to rule out possible conflicts of interest.

Literature searches and appraisal

According to the hierarchy of research evidence, we tried to locate randomized controlled trials (RCTs, i.e. level Ib evidence) dealing with the key questions. When RCTs were of low quality or completely lacking, non-randomized controlled clinical trials (CCTs, i.e. level IIb evidence) were included. Whenever level I and II evidence was scarce, case series with comparison of pre- and postoperative status (i.e. level IV evidence) were used. However, it should be noted that for some studies our grading of evidence led to different opinions of levels than in other similar assessments [55]. Studies were downgraded whenever the intention-to-treat principle was heavily violated or randomization was obviously unconcealed and biased. For each intervention, we considered the validity and homogeneity of study results, effect sizes, safety, and economic consequences. It should be noted that not all studies can be categorized, since studies presenting epidemiogic incidences or prevalences, or proposing ideas or definitions are not amenable to evidence grading. Furthermore, one study could be assigned different levels of evidence, whenever two or more comparisons were performed within one study, some of which may be randomized while other are not.

To identify relevant studies in all languages [5], the electronic databases of Medline (PubMed) and the Cochrane Library (Issue 2, 2004) were used. Searches in Medline spanned from 1966 to May 2004 and used the following wording: "obesity/surgery"[MeSH] OR "obesity, morbid/surgery"[MeSH] OR "gastric bypass"[MeSH] OR "biliopancreatic diversion"[MeSH] OR "anastomosis, Roux en Y"[MeSH] OR "jejunoileal bypass"[MeSH] OR "biliopancreatic bypass" OR "duodenal switch" OR "gastroplasty" OR gastric band*. Restricting this search to the publication type "clinical trial" yielded 312 articles. In addition, the references of previous evidence-based guidelines on obesity therapy were screened [42, 117, 153]. Recently published systematic reviews of RCTs, CCTs, or case series (levels of evidence Ia IIb or IV, respectively) and their reference lists were also studied in detail [55, 61–63, 78, 120, 152, 220, 262]. Of note, we considered three abstracts (by Agren, van Rij, and van Woert) to be insufficient sources of information, although the Cochrane review treated them as independent RCTs [63].

All recommendations were graded according to the quality and quantity of the underlying scientific evidence, the risk-benefit balance, and the values expressed by the panelists. We attempted to respect the views of patients, although no patient directly participated in guideline formulation. The grades of recommendations ranged from A (high-quality evidence, usually from RCTs, demonstrating clear benefits) over B (medium quality evidence and/or a disputable risk-benefit ratio) to C (low quality evidence and/or unclear risks and benefits).

Results

Multidisciplinary evaluation

Before making a decision for obesity surgery, the patient must be seen by surgeon and anaesthesiologist (GoR A), and should also be seen by an expert in dietary/nutritional support (GoR B). The consultation of further specialties depends on the patient's comorbidity (GoR B).

It is beyond any doubt that all patients must be seen by a surgeon and an anaesthesiologist before surgery. While the anaesthesiologists will usually be consulted only a few days before surgery, the surgeon should see the patient at least twice prior to the decision for surgery. Alternatively, a visit with a bariatric primary care physician has been proposed (EL 5 [94]). Since obesity surgery often introduces a durable change of the gastrointestinal tract, the decision for or against surgery requires a well-informed patient. Therefore, a few weeks' time interval between the first visit and the eventual operation are desirable (EL 4 [367]). The role of other specialties in examining and preparing the patient for surgery has evolved over many years [94].

The association between psychologic health and the success of obesity surgery reinforces the role of a psychiatrist or psychologist in assessing possible candidates for surgery. The patient's preoperative motivation has been found to be a predictor of weight loss after gastric bypass (EL 2b [21, 271]), while other psychological factors have little influence on the long-term effectiveness of surgery in other studies (EL 2b [47, 82]). A few authors suggested the need of psychiatric evaluation of all morbidly obese who seek surgical treatment (EL 5 [56, 121]), because some patients were found postoperatively to develop anorexia-like syndromes, post-traumatic stress disorders, or other psychological problems leading to treatment failure (EL 4 [121, 128, 315]). A recent review by Dixon and O'Brien did recommend routine psychologic assessment, although they noted that such an assessment is common, but not standard, practice in the United States (EL 5 [82, 94]) and Europe (EL 4 [231]). This panel therefore agreed with Brolin's position that psychological evaluation is necessary only for selected patients (EL 5 [38]). It is beyond the scope of these guidelines to differentiate here between psychologists, psychiatrists, and other qualified persons.

Nutrition also is a crucial aspect of obesity, both pre- and postoperatively. Therefore, most surgeons in the field believe that all patients must be evaluated, instructed, and guided by an expert in nutrition. This person may either be a physician with nutritional medicine qualification or a registered dietitian. Similarly, physical exercise should be initiated preoperatively under the guidance of a physical therapy specialist. Although there are no comparative studies on the impact of nutrition and physical exercise therapy, both are considered standard (EL 5 [94]). In addition to the nutritionist, other groups have reported routine consultation of a pneumologist or an endocrinologist (EL 4 [231, 356]).

Indications for surgery

Obesity surgery should be considered in adult patients with a documented BMI greater than or equal to 35 and related comorbidity, or a BMI of at least 40 (GoR A). All patients must fully understand and agree with postoperative care (GoR A), and must be free of general contraindications (GoR A). Adults with a BMI between 30 and 35 accompanied by substantial obesity-related comorbidity or after prolonged medical treatment should undergo obesity surgery only in the context of controlled clinical trials (GoR C). No consensus was reached on the usefulness of obesity surgery in adolescent patients.

Many studies and committees have pointed out that in morbidly obese patients "no current [conservative] treatments appear capable of producing permanent weight loss" (EL 5 [125]). So far, only one randomized trial has compared obesity surgery versus non-surgical therapy: In this trial by Andersen et al. (EL 1b [13, 14]), horizontal gastroplasty produced significantly more weight loss and maintenance of weight loss than very low calorie diet (32 kg versus 9 kg after 2 years). After more than five years, 16% of surgical patients had successfully reduced weight as compared to only 2% of diet patients.

The very large, but non-randomized Swedish Obese Subjects (SOS) study (EL 2b) compared different types of obesity surgery versus conservative treatment in a matched-pair design [158, 159]. Women and men with a BMI greater than 38 or 34, respectively, were studied over two years. They lost significantly more weight after surgical than after non-surgical treatment and this weight loss resulted in significant improvements of comorbidities, such as diabetes (from a prevalence at baseline of 19% to 10% after two years), hypertension (from 53% to 31%), sleep apnea (from 23% to 8%), dyspnea when climbing stairs (from 87% to 19%), and chest pain when climbing stairs (from 28% to 4%). The SOS study also found health-related quality-of-life (QoL) to be directly correlated with weight loss [159]. As there was a significant difference in QoL even between women with 30 to 40 kg weight loss and those with more than 40 kg weight loss, it seems as if obesity surgery should aim at the largest possible excess weight loss (EWL). If long-term EWL is less than 50%, a procedure is generally considered a treatment failure.

Traditionally, obesity surgery is considered appropriate for adult patients with either a BMI of 40 or more, or a BMI between 35 and 40 with obesity-related comorbidity. These selection criteria have been laid down in March 1991 by the National Institutes of Health Consensus Development Panel [236–238] and have subsequently been adopted by all major surgical and non-surgical societies [9, 11, 88, 148, 178, 226, 235, 313]. Even though the BMI threshold values of 40 and 35 were arbitrarily chosen, it appears wise to stick to these criteria, because the majority of surgical experience and scientific evidence relates to patients who were selected by such criteria. Off course, the risk-benefit ratio needs to be assessed critically in each individual patient (EL 2b [260]). As the short-term risks of obesity surgery clearly exceed that of conservative treatment (EL 1c [93]), it is advisable that all patients should have tried other ways of weight loss prior to surgery. In cost-effectiveness analyses, all major obesity procedures were found to give better results than conservative treatment in morbidly obese patients (EL 2b [62, 235]).

Recent reports have shown that surgical treatment is similarly effective in patients with a BMI between 25 and 35 (EL 4 [15]). According to Dixon and O'Brien, the "cut-off of BMI >35 is due for review" also in the United States, where it is currently been evaluated in a RCT [82]. Although no study so far has compared surgical and non-surgical management in patients with a BMI between 30 and 35, obesity surgery is increasingly being performed in this subgroup. Given the strength of the existing evidence, it seems too early to recommend obesity surgery even in cases with a BMI of at least 30 who suffer from substantial obesity-related comorbidity. The majority of the panel favored surgical treatment in well-selected patients with a BMI between 30 and 35 only in the context of controlled clinical trials.

A complex issue in the NIH selection criteria is the proper definition of comorbidities, which warrant obesity surgery due to their seriousness and potential alleviation through weight loss. Comorbidities may be divided in medical, physical and psychological categories. In this respect, medical conditions such as sleep apnea and other hypoventilation syndromes (EL 4 [57, 114]), type II diabetes mellitus (EL 4 [190, 251, 261, 263, 265, 282, 328]), obesity-related cardiomyopathy and hypertension [31, 53, 103, 273, 318, 328], hyperlipidemia (EL 4 [231, 251]), asthma (EL 4 [251]), pseudotumor cerebri (EL 4 [216, 324]), knee osteoarthritis (EL 4 [114]), low back pain (EL 4 [215]), female urinary incontinence (EL 4 [45, 114]) and infertility (EL 4 [113, 204, 360]) are well-documented indications for obesity surgery, because clinical evidence has convincingly proven that weight-loss allows prevention, relevant improvement, or even remission of these conditions. The metabolic effect of obesity surgery in diabetic patients is especially noteworthy, since it goes beyond weight reduction alone (EL 4 [161, 263, 282]; EL 5 [283]). Gastroesophageal reflux, however, was found unresponsive to obesity surgery in some studies (EL 2b [107, 255]), whereas others found an association (EL 4 [81, 114, 149, 251, 311]). Of course, these results varied with the type of surgery.

Physical, social, and psychological problems are important factors in the quality-of-life of obese persons. Although such problems are difficult to communicate and to quantify, they play a leading role in deciding on conservative or surgical treatment of obesity. Various validated instruments are available to assess quality-of-life (QoL) in obese patients [171], but it should be added that most of these QoL questionnaires were validated by their responsiveness to weight loss, so by definition a procedure that produces weight loss will produce improved QOL. The literature is replete with before-and-after-studies (EL 4) about the positive changes in patients' quality-of-life (QoL) caused by bariatric surgery [135, 347]. This allows us to focus here exclusively on studies with a non-surgical control group. Arcila et al., for example, demonstrated significant improvements in various QoL domains after VBG and RYGB as compared to conservative therapy (EL 2b [19]). In a recent study from Switzerland (EL 2b), obesity surgery proved better than conservative treatment in patients with and without severe psychosocial stress [43]. It can be concluded that deliberation on obesity treatment options must incorporate an assessment of the patient's current physical, social, and psychological status as well as the expected effects of therapy on this status. Therefore, psychological counseling, even superficial, as a screening tool is desirable in all patients before surgery.

Various contraindications must also be taken into account, although most have not been derived from firm clinical evidence. As patients' non-compliance with follow-up schedules can lead to potentially life-threatening complications [26], all candidates for obesity surgery must hold a realistic view of the operation and the necessity for lifelong aftercare (EL 1c). Severe mental or cognitive retardation and malignant hyperphagia are therefore generally considered absolute contraindications, because such patients will be unable to eat and exercise as required postoperatively (EL 5 [82, 121]). On the other hand, minor arid major mental and personality disorders are highly prevalent in morbidly obese patients, but they were not found to be valid predictors of successful therapy (EL 2b [34, 291]). Eating disorders are no general contraindication, even if they are not amenable to psychological and dietary counseling (EL 4 [203]). Nevertheless, such disorders must be known when selecting the type of surgery.

Psychiatric disorders (psychotic, personality, or affective disorders, alcoholism and/or drug abuse, mental retardation, and eating disorders, especially bulimia nervosa, and binge eating disorder), lack of social support, persistent ambivalence to surgery, and marital dysfunction are factors which must be evaluated in particular before surgery. A substantial percentage of bariatric surgery patients suffer from binge eating disorders or binge eating symptoms. The effect of bariatric surgery on the outcome of binge eating symptoms largely depends on the type of operation. In general, the indication for surgery depends on the severity of the mental disorder and its response to psychopharmacological treatment. Repeated assessment of the patient may end in a postponement or cancelling of the operation. Surgery is contraindicated only in the cases of severe mental disease not responding to treatment (EL 4 [56, 203, 336]).

Women of reproductive age, who wish to have children after surgery, should not be denied an operation, because the course of pregnancy and the health of the baby are usually unaffected by previous obesity surgery (EL 2b [79, 113, 202, 205, 309, 350]). Still, postoperative contraception is recommended for about 12 months, after which weight should usually be stabilized. In patients with LABG (laparoscopic adjustable gastric banding), the band can be deflated in case of pregnancy (EL 4 [344]). Finally, liver cirrhosis should not hinder elegibility for obesity surgery (EL 4 [26, 65]).

Before reaching skeletal maturity children should definitely not be offered obesity surgery, but recent pilot studies (EL 4) on adolescents (12 to 19 years old) suggested that surgery in this age group is as effective as it is in adults [32, 52, 85, 146, 317, 327]. Since about 80% of obese adolescents will remain obese into adulthood, some surgeons have offered surgery to well selected non-adult patients. However, the total number of patients aged between 12 and 18 is small, thus precluding any recommendation on performing surgery in adolescents. Recently, a threshold BMI of 40 (with severe comorbidities) or 50 (with less severe comorbidities) has been proposed for consideration of obesity surgery in adolescents (EL 5 [147]). In this panel, however, there was no consensus on the selection of adolescents for surgery. The balance of the risks and benefits of surgery must be also considered critically at the other end of the age scale. Findings in patients aged between 55 and 70 documented beneficial effects of surgery on weight and some comorbidities (EL 4 [193, 229]). In patients over 60 or 65 years, however, obesity-related comorbidity has usually become more complicated and less reversible (EL 5 [32, 82, 231]). In consequence, the risks of surgery may be no worthwhile (EL 2b [93, 339]), although a fixed age limit can not be recommended.

Preoperative diagnostics

As for any other major abdominal surgical procedures, all patients should be evalated for their medical history (GoR A) and undergo laboratory tests (GoR B). Despite the lack of sound evidence in the obese, chest radiography, electrocardiography, spirometry, and abdominal ultrasonography may be recommended for the evaluation of obesity-related comorbidity (GoR C). Polysomnography (GoR C) should be done in patients with high risk of sleep apnea. In centers where psychiatric consultation or psychological assessment is not routine, psychological screening should be performed (GoR C). Upper gastrointestinal endoscopy or upper GI series is advisable for all bariatric procedures (GoR C), but is strongly recommended for gastric bypass patients (GoR B).

In the preoperative work-up, as outlined above, patients with apparent psychosocial problems should be seen also by a psychologist or psychiatrist. In the morbidly obese, psychosocial problems are usually associated with an increased motivation for weight loss, which in turn is predictive of the success of surgery (EL 2b [253, 271, 336]). Socioeconomic problems are also highly prevalent [188]. To assess these connections, all patients should be evaluated for psychologic health, quality-of-life, possible personality disorders, social relationships, motivation, expectations and compliance. Many centers use self-developed questionnaires for this purpose (EL 4 [271, 291, 315]). The psychiatric assessment of morbid obesity should include a brief explanation and description of the assessment process, a clinical interview (ideally at least three months before surgery), and psychological testing of eating behaviour, quality of life, psychopathology, and personality (EL 5 [95]). The clinical interview should cover the patient's previous weight loss attempts and treatments, eating patterns, eating disorders symptoms, psysical activity, attitudes and expectation regarding treatment, psychiatric history, mental and marital status.

Published evidence on the technical preoperative evaluation of obese patients stems largely from case series and general gastrointestinal surgery standards, which were adopted to obesity surgery. Standard investigations are electrocardiography, chest radiography and laboratory tests (EL5 [94, 312]). According to Naef et al. (EL 4), laboratory testing should include a full blood count, liver, kidney (EL 4 [162]), coagulation and thyroid parameters, thyroid hormone stimulating test, a lipid profile, a oral glucose screening test (only in patients not known to be diabetic), and an analysis of arterial blood gas [231]. Urinalysis is also a standard procedure [94].

Ultrasonography of the abdomen is usually done to detect cholecysto- or choledocholithiasis. Being a non-invasive and cheap procedure, abdominal sonography seems to be advisable as a part of the routine preoperative work-up. Even those centers where intraoperative ultrasound is performed, use preoperative ultrasonography as a screening tool.

Specifically important to obese patients is the evaluation of pulmonary function and obstructive sleep apnea. Sugerman and colleagues first described the high prevalence of pulmonary obstructive diseases in morbidly obese patients (EL 4 [322, 323]). To prevent postoperative hypoventilation, it has been recommended that all patients be assessed spirometrically as part of the preoperative work-up and supplied with the necessary therapy (EL 4 [217, 231]; EL 5 [312]). In multivariate analysis, a forced expiratory volume (FEV_1) under 80% and an abnormal electrocardiogram were predictive of postoperative intensive care admission (EL 2b [124]). Hypoventilation syndromes were also found to be predictive of thrombembolic complications and anastomotic leakage (EL 2b [93, 285]). American obesity clinics recently recommended routine polysomnography, because sleep apnea was detected in 77% to 88% of their patients (EL 4 [109, 252]) and was predictive of postoperative complications in other studies. Other groups use the Epworth sleepiness scale or similar instruments to screen for patients who will require polysomnography (EL 4 [299]). Various studies have found a higher preoperative prevalence of pulmonary problems with increasing BMI (EL 2b [214]). One study, however, failed to confirm the predictive value of both, BMI and Epworth sleepiness scale, in the prediction of obstructive breathing disorders (EL 2b [109]). In summary, the threshold for ordering polysomnography should be low and all superobese patients should probably be tested routinely (EL 5 [94]).

Disputable is the evaluation of the upper gastrointestinal (GI) tract by endoscopy, barium meal, both, or none of the two technologies. In the study by Sharaf et al., routine radiologic assessment of the upper GI tract before bariatric surgery led to clinically important findings in only 5.3% of patients (EL 4 [302]). In only six of 814 patients (0.9%), as reported by Ghassemian et al., X-ray examination of the GI tract demonstrated relevant abnormality, and not a single operation had to be delayed due to the results of the GI tract series (EL 4 [122]). Using esophageal manometry, two recent case series found abnormalities in only 13 to 20% of patients and being without clinical consequences (EL 4 [169, 186]). Jaffin et al., however, described that esophageal disorders were highly prevalent (61%) and associated with postoperative results (EL 4 [150]). Other groups also have advocated routine upper GI tract series before gastric banding, because hiatal hernia may cause band slippage (EL 4 [115, 127]). Endoscopy, however, offers the advantage of visualizing esophageal and gastric mucosa (EL 4 [115, 337]), thus detecting gastritis, reflux, or ulcerations. This may be of special value before any operation with exclusion of the stomach (EL 5 [312]). To make a compromise, this panel advises to perform either upper GI series or endoscopy in all patients. Given the higher prevalence of reflux after VBG (EL 4 [24, 164, 259, 301]), preoperative GI evaluation seems to be of special importance in VBG patients.

Choice of Procedure

Adjustable gastric banding (AGB), vertical banded gastroplasty (VBG), Roux-en-Y gastric bypass (RYGB) and biliopancreatic diversion (BPD) are all effective in the treatment of morbid obesity (GoR B). All four types of procedures should be explained to the patient (GoR C). In terms of weight loss, BPD is superior to RYGB (GoR B), RYGB is superior to VBG (GoR A), and VBG is superior to AGB (GoR A). There is an increased risk of perioperative complications in procedures requiring stapling and anastomoses (GoR A). The reoperation rate is higher for adjustable gastric banding and Mason (but not MacLean) VBG (GoR A). As positive and negative effects differ among the procedures, the choice of procedure should be tailored to the patient's BMI, perioperative risk, metabolic situation, comorbidities and preference as well as to the surgeon's expertise (GoR C). Intragastric balloon, sleeve gastrectomy, and gastric pacemaker are options (GoR C), which require further evaluation.

Since obesity surgery has various competing aims, such as weight loss, adjustability, reversibility, and safety, it is difficult to draw universally valid conclusions about the optimal bariatric procedure. For all types of surgery, there is overwhelming evidence from case series on safety, efficacy, and effectiveness in terms of weight loss, but much less data are available on the comparative evaluation of different bariatric procedures. Therefore, the decision must be taken with the patient's individual situation and the surgeon's expertise in mind. A profound knowledge of the different malabsorptive and gastric restrictive procedures and their pathophysiologic consequences is indispensable.

Biliopancreatic diversion (BPD) was invented by Scopinaro (EL 5 [294, 296]; EL 4 [295]) and later modified by Marceau et al., who added a duodenal switch (EL 4 [136, 200, 201]). BPD with duodenal switch and sleeve gastrectomy was found to be superior (EL 2b [267]), which allows us to leave the original BPD procedure unmentioned in the following considerations. In the long-term after BPD, patients typically loose between 65% and 75% of their excess body weight (EL 4 [267, 293]).

Roux-en-Y gastric bypass (RYGB) was first described by Mason and Ito [207, 208]. Numerous technical modifications have been proposed relating to gastric pouch construction, gastro-jejunal anastomosis, and length of alimentary and biliopancreatic limbs. RYGB usually results in 60% to 70% EWL [75, 101, 138, 173, 222, 273], but the procedure is much better accepted in the United States (about 70% of all procedures) as compared to Europe [332].

Gastroplasty was first performed horizontally ("gastric partition"), but in 1982 Mason introduced the vertical banded gastroplasty (VBG), which was quickly adopted by surgeons [206]. In this procedure a gastric pouch of about 10 to 20 ml is created. By using a mesh band or a silastic ring, the gastric pouch outlet can be calibrated and reinforced. Postoperative weight reductions range between 55% and 65% nadir EWL (EL 4 [199, 224, 232, 277, 325]).

In gastric banding, a ring is placed around the gastric cardia. A small pouch is created, thus limiting food intake. Modern gastric bands have an inflatable reservoir to adjust the size of the remaining passage [30, 175]. With the introduction of laparoscopic adjustable gastric banding (LAGB), the procedure has gained worldwide popularity. Being a gastric restrictive procedure, weight loss is less in gastric banding compared to other procedures and usually reaches only 45% to 55% (EL 4 [49, 67, 83, 249, 250, 330, 342, 367]). Technical details of all four procedures will be discussed in a separate chapter below.

The randomized studies in this field are summarized in Fig. 1. In the following, we will discuss key findings of these studies comparing biliopancreatic diversion, gastric bypass, gastroplasty, and gastric banding.

Several randomized studies have compared gastric bypass versus horizontal or vertical gastroplasties. As horizontal gastroplasty has been abandoned since the 1980 s, we will only briefly discuss the four RCTs evaluating this technique. Laws first showed that gastric partitioning produces less weight loss than RYGB (EL 1b [179]). Other groups (Pories et al. [264], Lechner et al. [181, 182], and Hall et al. [129]) have confirmed this finding (EL 1b). Finally, Naslund et al. (EL 1b [233, 234]) found that nearly all of their gastric bypass patients lost more than 25 kg within the first postoperative year, compared to only 18 of 28 gastroplasty patients ($p < 0.01$). The 1987 publication by Andersen et al. (EL 1b [12]) finally brought horizontal gastroplasty to an end.

Four RCTs compared open RYGB and open vertical banded gastroplasty. In an often-quoted study (EL 1b), Sugerman et al. [326] compared three-year results between 20 RYGB and 20 VBG patients. In terms of EWL after one year, RYGB was found to be superior over VBG (68% versus 43%), but postoperative complications, for instance vitamine B_{12} deficiency and vomiting due to stoma stenosis, were more common after RYGB. In the three-armed study from Adelaide, which was already cited above, Hall et al. [129] compared the 3-year success rates defined as $> 50\%$ EWL. Successful treatment was observed in 67% of patients after RYGB, 48% after vertical gastroplasty, and 17% after gastric partition. The RCT by Howard et al. [143] was able to report long-term data. Again, EWL was clearly better in the RYGB than in the VBG cohort. MacLean et al. [196, 198] confirmed these results.

VBG and gastric banding have been compared in three trials (all EL 1b), but the trials used different surgical approaches (Fig. 1). One trial compared both

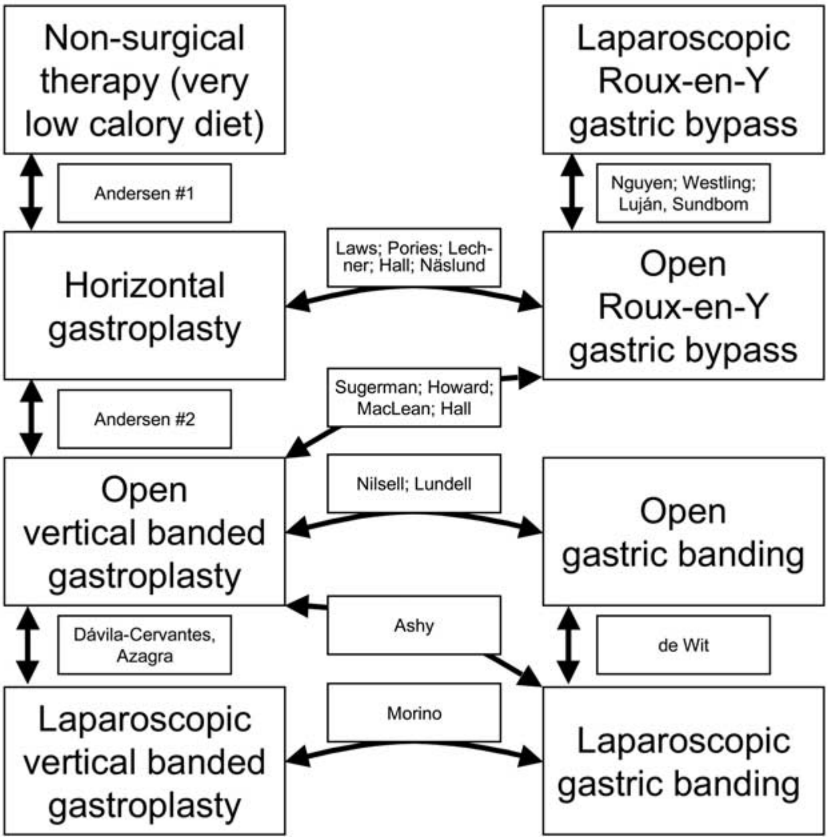

Fig. 1. Randomised controlled trials comparing different obesity surgery procedures among each other or versus medical treatment. Please note that the trial by Hall et al. had three arms and therefore appears twice. The trial by Sundbom evaluated hand-assisted laparoscopic RYGB.

procedures in open access surgery [247], one trial compared open VBG versus LAGB [20], and the third trial compared both procedures in laparoscopic surgery [223]. In the study by Nilsell et al., weight reduction tended to be larger and quicker after VBG, but after five years gastric banding patients reached the same level of weight loss. Reoperations were performed more often in the VBG group (11/30 versus 3/29), a finding which contradicts non-randomized data (EL 2b [29, 333]). In their study of 60 patients, Ashy et al. found greater EWL half a year after VBG as well [20], but failed to report long-term data. Due to shorter hospital stay, less complications, and adjustability Ashy et al. preferred LAGB over open VBG. In comparing LAGB and laparoscopic VBG, Morino et al. described shorter hospital stay after LAGB, but found fewer complications and reoperations after laparoscopic VBG. Weight loss was also better after VBG. Consequently, this group firmly favored the latter technique and commented that the high complication rates after VBG in the Nilsell study might have been due to not dividing the stomach between the staple lines.

It is difficult to draw summary conclusions from these three trials, because they represent a mixture of surgical procedures and approaches. One common result of the three trials is the better weight reduction after VBG. Data on complication rates, however, are conflicting. A very detailed assessment of comparative and non-comparative studies (EL 2a) recently concluded that "laparoscopic gastric banding is safer than VBG and RYGB" [55], because short-term mortality and morbidity were found to be lower after LAGB. Still, the ranges of complication rates were wide, thus suggesting a strong effect of surgical expertise. In a large study on laparoscopic RYGB and gastric banding, Biertho et al. concluded that the balance between weight loss and complications favored LAGB in patients with BMI under 40, whereas RYGB might be preferable in case of a BMI between 40 and 50 (EL 3b, downgraded due to large unadjusted baseline differences [33]).

Of note, no randomized trial so far has compared BPD to other procedures. This is in part a consequence of the 1991 NIH consensus development conference, which simply failed to mention BPD as one of the standard procedures [72]. Two-year follow-up data presented by Rabkin (EL 2b [267]) showed marginally greater EWL after BPD (78%) than after RYGB (74%). In 2004, Deveney et al. confirmed this comparability of EWL after BPD and RYGB (EL 2b [77]). In a small study by Murr et al. (EL 2b [228]), EWL within four years was greater after BPD (71%) than after long-limb RYGB (57%), but some cases of liver failure and metabolic bone disease devloped in the BPD group. Similarly, EWL after two years was 60% following BPD versus 48% following non-adjustable gastric banding (EL 2b [23]), but longer hospital stay and higher major complications rates were also found. In a matched-pair analysis (EL 2b), BPD also resulted in greater EWL (64% versus 48%) when compared to LAGB [86]. In summary, the degree of weight loss caused by BPD is greater, but this is at the expense of other outcomes.

When making a choice between gastric banding, VBG, RYGB and BPD, it is well documented (EL 1b as outlined above, except for BPD) and generally accepted that weight loss is more pronounced after the latter procedures. In fact, weight loss decreased according to the procedures performed in following decreasing order: BPD, RYGB, VBG, and gastric banding. Therefore, in patients with milder degrees of obesity, procedures that produce greater absolute weight loss may not be advantageous, although this can only regarded as a recommendation by rule of thumb. However, the reverse conclusion, that gastric banding and VBG should not be used in massive obesity, does not seem to fully apply, because recent reports showed that LAGB is associated with sufficient EWL also in patients with a BMI of 60 to 100 (EL 2b [86]; EL 4 [96]).

A remarkable proposal for operative selection among the various procedures was published in 2002 by Buchwald [42], who first reviewed a large number of case series (EL 4) and then constructed a clinical algorithm based on BMI, age, gender, race, body habitus, and comorbidity. For example, according to the algorithm a patient with a BMI of 48 should not receive gastric banding irrespective of other factors. Likewise, a patient with a BMI greater than 55 should receive either BPD or long-limb RYGB. This panel agrees to the relative importance of these parameters for choosing a procedure, but is reluctant to propose any strict criteria. BMI, comorbidity, and age should play a key role in selecting the procedure. Data on other criteria are largely missing, except for psychological parameters as described above.

The concept of selecting the procedure according to eating habits was initially proposed by Sugerman et al. [326]. Although this was a RCT, the study's comparison between sweet eaters and non-sweat eaters was non-randomized and possibly data-driven (EL 2b). More recent studies have failed to confirm this finding (EL 2b [144]). Notwithstanding, eating habits should influence the choice of the procedure to some degree. Most surgeons require LAGB and VBG patients to accept restrictive dietetic rules, and perform RYGB or BPD if this criterion is not fulfilled. Comorbidity also plays some role in decision-making. As some, but not all, studies showed that esophageal reflux may get worse after gastric banding (EL 4 [16, 80, 352]), RYGB might be preferable in such cases (EL 4 [24, 36, 110, 164]). The only RCT on this issue, however, failed to find a difference between LAGB and VBG with regard to reflux symptoms (EL 1b [192]).

The intragastric balloon was introduced in 1982 as an as adjunct to non-operative treatment of obesity [116, 246]. A series of small studies compared intragastric balloons against sham control (EL 1b [141, 172, 187, 210, 270, 278]) or no additional intervention (EL 1b [119]). Both, experimental and control groups lost weight due to low-calorie diet, but no additional effect of the balloon was found in five of the seven trials. With newer smooth-surface balloon, mean EWL after six months of intragastric balloon treatment was between 20% and 50% (EL 4 [87, 90, 140]) depending on patient compliance and balloon volume (EL 2b [281]). Since the balloon carries a non-negligible risk of prolonged vomiting, pain, gastric ulcers, and spontaneous deflation with intestinal obstruction, the device has not yet become standard (EL 4 [41]; EL 5 [100, 185]). Especially in comparison to obesity surgery, the balloon was found to produce insufficient and non-durable weight loss (EL 2b [166]). Nowadays, however, some centers still use the gastric balloon in selected patients with a BMI between 30 and 35 (EL 4 [281, 335]). It also is being used as a weight-reducing adjuvant therapy before bariatric surgery (EL 4 [87, 209, 345]). Loffredo et al. proposed that the amount of weight reduction obtained with the balloon could serve as a guidance in selecting the type of bariatric procedure (EL 2b [189]) and has started a RCT testing this hypothesis.

Although sleeve (or longitudinal) gastrectomy is a specific step within the BPD operation, some surgeons have used it also as a first-stage procedure in patients with BMI > 60 to reduce surgical risks, followed about a year later either by RYGB or BPD. EWL within the first year after sleeve gastrectomy as the sole procedure has been reported to range between 33% and 45% (EL 4 [7, 272]), but the limited experience with sleeve gastrectomy prohibits any statement about its clinical value. Still, sleeve gastrectomy may be used as an interim procedure in high-risk morbidly obese patients, especially in case of intraoperative hemodynamic instability (EL 4 [7, 272]).

Beyond the traditional surgical concepts of gastrorestriction and malabsorption is the gastric pacemaker, a completely new device, which is currently being evaluated in a randomized, placebo-controlled trial [362]. Preliminary data showed an EWL of about 30% after 15 months (EL 4 [69, 217, 219]). Although the technique is minimally invasive with apparently little surgical complications, longer term results are awaited before this device should be used outside trials.

Surgical access: open vs laparoscopic

All procedures have been proven to be technically feasible via laparoscopy. There is evidence that the laparoscopic approach is advantageous for gastric banding, VBG, and gastric bypass (GoR B). Preliminary data suggest that the laparoscopic approach may be also preferable for BPD, if surgical expertise is available (GoR C), but further studies are needed.

In 1994, laparoscopic Roux-en-Y gastric bypass (RYGB) was described by Wittgrove et al. (EL 4 [357–359]), who found it to give superior results as compared to open surgery. Later, laparoscopic Roux-en-Y gastric bypass (RYGB) was compared to open RYGB in three similarly designed RCTs. In the first study by Nguyen et al. (EL 1b [241–243]) EWL was similar after both procedures, whereas reductions in postoperative complications and hospital stay favored the laparoscopic approach. Late anastomotic strictures, however, were seen more frequently after laparoscopic RYGB. Westling and Gustavsson found that weight loss was unaffected by the surgical approach, but postoperative hospital stay was two days shorter after laparoscopic surgery (EL 1b [355]). Most recently, laparoscopic and open gastric bypass were compared by Lujan et al. in a well-performed study (EL 1b [191]). The duration of surgery and hospital stay were shorter in the laparoscopic group. Both groups experienced similar degrees of EWL, but the high rate of incisional hernia in the open group (10/51) led to a significant long-term advantage for the laparoscopic technique (0/53). In addition to these three RCTs, a small, but rigidly designed trial by Sundbom and Gustavsson compared hand-assisted laparoscopic versus open RYGB (EL 1b [329]). Weight loss was similar in both groups, as were postoperative complications. DeMaria et al. confirmed these results in a nonrandomised study (EL 2b [74]).

Until now, two RCTs have compared laparoscopic versus open vertical banded gastroplasty. The quality of one trial was good because of properly concealed allocation and blinded outcome assessment (EL 1b [70]), but the second trial should certainly not be classified as level 1 evidence, since all four converted cases were shifted from the laparoscopic into the open group for analysis (EL 2b [22]). Both trials clearly documented a longer duration of surgery in the laparoscopic group. Hospital stay was 4 days in both groups in both trials. Respiratory and physical function was restored quicker after laparoscopic surgery [70]. As EWL was similar, laparoscopic surgery seems to be favorable, although more data are needed.

In adjustable gastric banding, one RCT dealt with the comparative effectiveness of laparoscopic versus open approach in 50 patients (EL 1b [71]). LAGB was found to be advantageous due to a one day reduction in hospital stay and fewer readmissions, while reduction of BMI was similar. However, the laparoscopic operation took twice as long as its open counterpart. For non-adjustable gastric banding, level II evidence indicates that laparoscopic surgery produces similar weight loss but quicker reconvalescence as compared to open surgery [112].

As the first laparoscopic biliopancreatic diversion (BPD) was performed only in 1999 (EL 4 [25, 275]), scientific evaluation of this technique has not advanced as for the other procedures. Early results were published by a few centers (EL 4 [25, 256, 275, 297, 346]) and showed promising results in terms of technical feasibility and postoperative morbidity, but long-term data are lacking so far. The only comparative study (performed in superobese patients) found similar weight loss and reconvalescence after laparoscopic and open BPD, but better improvement of comorbidities in the laparoscopic group [165]. This finding, however, should be attributed to different durations of follow-up in the two groups (EL 3b, downgraded accordingly).

In summary, laparoscopic surgery has had a major impact on obesity surgery [55, 287]. According to surveys of American Society of Bariatric Surgery members, the percentage of laparoscopic procedures in relation to all bariatric procedures has increased from about 10% in 1999 to nearly 90% in 2004 [32]. These dramatic changes have been fuelled by affirmative trial data but also commercial interests. A second and equally important effect is the lowered threshold in considering patients for surgery [289].

Training and qualification

All surgeons performing obesity surgery should have an adequate technical expertise (GoR A). He or she should be a qualified and certified general or gastrointestinal surgeon with additional training in obesity surgery (GoR B). Technical expertise in laparoscopic surgery alone is insufficient to start a bariatric surgery program (GoR B).

According to the Cancun statement of the IFSO (EL 5 [126]), every obesity surgeon should be a "fully-trained, qualified, certified general or gastrointestinal surgeon, who has completed a recognized general/gastrointestinal surgery program" with additional training in "bariatric surgery including patient education, support groups, operative techniques, and postoperative follow-up". In addition, the IFSO recommends certain written approvals of expertise, course attendance, membership in an obesity surgery society, continuing medical education, and other criteria. Similar guidelines have been issued for U.S. hospitals (EL 5 [314]), where board-certified training of surgeons and standard hospital infrastructure are formally required. Surgical experience should be documented by "an appropriate volume of cases (open and/or laparoscopic)".

Many published series on different bariatric operations have reported learning curve effects, but there is no clear threshold for the distinction between an unexperienced and an experienced surgeon. Consequently, the American guidelines recommended that "priviliges should not be granted or denied based on the number of procedures performed". The IFSO statement, however, declared that obesity surgery should be learned from an experienced surgeon, defined as "one who has performed at least 200 bariatric surgical procedures and has 5 or more years experience".

So far, only two clinical studies have explored the volume-outcome relationship in bariatric surgery. Courcoulas et al. found that surgeons with fewer than ten procedures per year had significantly higher morbidity (28% vs. 14%) and mortality (5% vs. 0.3%) than high-volume surgeons (EL 2b [64]), but this result was partly attributable to better patient selection and overall hospital volume. As medium volume surgeons (with 10 to 50 cases per year) had also worse results when compared to high-volume surgeons, the authors were unable to recommend a minimum caseload for obesity surgery, although there was a significant trend toward higher mortality among patients in the lower activity group. The second, larger, study looked at hospital volumes and noted a nearly three-fold increase in comorbidity-adjusted complication rates in hospitals with less than 100 cases per year. Given the large proportion of low-volume hospitals and surgeons in Europe, this panel warns against starting a bariatric surgery program without having the necessary prerequisites in terms of staff, infrastructure, and volume requirements.

General perioperative aspects

Antibiotic (GoR A) and antithromboembolic (GoR B) prophylaxis should be administered to all obesity surgery patients.

Antibiotic administration was first studied by Pories et al., who gave cefazolin or placebo over 2 postoperative days to gastric bypass patients (EL 1b [266]). Wound infections were significantly reduced, thus making infection prophylaxis a standard. Antibiotics should always be given in an appropriate dose (EL 1b [105]), but there are no data available to specifically recommend certain groups or dosage regimens of drugs.

Prophylaxis of thromboembolic complications has also been an essential part of bariatric procedures. The incidence of fatal pulmonary embolism has been described to be 0.2% (EL 4 [285, 354]). More recent series, however, have shown that anticoagulation may not be necessary in patients with short operative times, use of postoperative pneumatic compression stockings, and quick mobilisation (EL 4 [123]). The current standard consists of low-dose heparin in combination with intermittent pneumatic compression stockings (EL 5 [363]). Most data in this field have to be extrapolated from other types of surgery, as until today only one small RCT has been performed in obesity surgery (EL 1b [157]). In this study, no difference between daily doses of 5700 lU versus 9500 lU nadroparin was detected.

Specific technical aspects of the procedures

Key aspects of surgical technique in LAGB are the pars flaccida approach (GoR B), correct positioning (GoR A) and fixation (GoR A) of the band. In VBG, pouch volume should be less than 30 ml (GoR C) and the staple line should be completely transsected (GoR B). There is variability in many technical aspects of RYGB without clear data to justify clear-cut recommendations. The standard GB includes a pouch volume of about 20 or 30 ml (GoR C), an alimentary limb length of at least 75 cm (GoR C), and a biliary limb of at least 50 cm (GoR C). Long limb distal GB seems to be preferable in superobese patients, as this induces greater weight loss (GoR B). In BPD, the length of common canal should always be greater than 50 cm (GoR C). In BPD with duodenal switch and sleeve gastrectomy, the length should be between 50 and 100 cm (GoR C). There are preliminary data suggesting that closing mesenteric defects may prevent internal hernia (GoR C).

LAGB

Nowadays, adjustable bands are generally preferred to non-adjustable ones, as this avoids postoperative food intolerance, vomiting, and other complications (EL 2b [112]). The selection of banding devices is influenced by clinical but also cost-related data. Most commonly used are the Lap-Band and the Swedish Adjustable Gastric Band [106], which have yielded similar results (EL 2a [111]). All new bands should be compared against these standard devices (EL 4 [366]). One randomized trial showed that the Lap-Band resulted in less complications as compared to the Heliogast band (EL 1b [35]).

The pars flaccida technique is generally preferred in the preparation of the path for the band (EL 2b [68]; EL 4 [274]). In respect to band position, gastric banding was found to be superior over esophagogastric banding (EL 1b [351]). A further study described more dysphagia after esophagogastric banding (EL 2b [177]). Weiner et al., (however, favored esophagogastric over retrogastric placement due to a lower risk of band slippage (EL 1b [343]). In a Czech language article, Kasalicky et al. described that cuff fixation is a worthwhile option to prevent band slippage (EL 1b [160]). It is common practice to secure the band by a few non-resorbable gastro-gastric sutures on the anterior gastric wall. Furthermore, fixation of the port to the surface of the anterior rectus sheath is necessary to avoid turning and inaccessibility of the port (EL 2b [348]). The routine use of early postoperative barium swallows to detect gastroin testinal perforations is usually unnecessary (EL 4 [239]). Most authors refrain from inflating the band during the first postoperative weeks (EL 2b [46]).

One interesting study examined whether complete resection of the greater omentum performed together with adjustable gastric banding offers metabolic advantages (EL 1b [334]). Two years after surgery, glucose metabolism (i.e. oral glucose tolerance, fasting plasma glucose, insulin, and insulin sensitivity) was significantly more improved in omentectomized patients, although weight loss was similar in both groups.

VBG

There are no randomized trials available to define the technical aspects of the procedure. Nevertheless, the following points are standard in laparoscopic surgery. Dissection at the lesser curvature should preserve vagal nerve branches. A circular stapler (usually 21 mm) should be used to create the transgastric window. The pouch volume should be less than 30 ml, which generally requires calibration with a 34 Fr nasogastric tube.

The pouch outlet should be banded with a polypropylene or polytetrafluoroethylene mesh collar, so that outer circumference and inner lumen are about 5 cm and 1 cm respectively in diameter. In one study, less complications were encountered with polypropylene than with Gore-Tex bands (EL 2b [340]). This panel also discourages the use of silastic rings. According to MacLean et al. (EL 4 [195]), the gastric pouch needs to be separated at the vertical staple line and sutured in order to avoid staple line disruption. A small trial by Fobi et al. confirmed a lower complication rate after transsection of the staple line (EL 1b [102]). This holds true also for laparoscopic VBG (EL 4[137]).

RYGB

Similar to other procedures, pouch volume is believed to be a key aspect in RYGB. Usually, a tube with a balloon is passed into the stomach and inflated with 15 to 30 ml saline before the gastric pouch is stapled. However, it should be noted that no clinical data so far back up a specific pouch volume. Small staples (3.5 mm) are recommended for creating the pouch, and the dissection at the lesser curvature requires careful management to prevent postoperative distension of the gastric remnant. Measuring pouch size is not the standard (EL 5 [332]).

The Roux limb should be created so that it measures 75 to 100 cm in patients with BMI under 50, but between 100 and 250 cm in case of a higher BMI. These lengths can be derived from several comparative studies (EL 1b [39, 60]; EL 2b [40, 197]). Brolin et al. compared Roux limb lengths of 75 cm versus 150 cm in superobese patients and found a difference in BMI of 10 kg/m^2 after two years follow-up (EL 1b [39]). Ten years later, Choban and Flancbaum went even further in their trial when they found greater EWL in those superobese patients, who received a 250 cm as opposed to a 150 cm Roux limb [60]. The length of the biliopancreatic limb was kept similar in all patients. In the second part of this trial, 67 patients with a BMI between 40 and 50 were randomized to Roux limb lengths of either 75 or 150 cm, but here no apparent advantages were noted with one or the other technique [60]. Roux limb length therefore should be adapted to match initial BMI, in patients with BMI over 50. In 2004, a similar recommendation was given by SAGES (Society of American Gastrointestinal Endoscopic Surgeons; EL 4 [152]). The retrocolic-retrogastric, retrocolic-antegastric, and antecolic-antegastric routes all seem acceptable for the Roux limb (EL 4 [4]). Papasavas et al. found slightly less stenoses after retrocolic-retrogastric positioning (EL 2b [257, 258]), while others reported less hernias for the antecolic route (EL 2b [163]).

The creation of the gastrojejunostomy is a further critical aspect of RYGB, because 3% to 5% of patients may develop stenosis [292]. When reviewing the case series on stenoses (EL 4 [292]), stapled anastomoses appear to give better results than the hand-sewn type. This corresponds well to RCT data in gastric cancer patients (EL 1b [142, 300, 307, 353]). In obese patients there is only a trial with pseudorandomization by alternation (EL 2b [1]), where stenosis occurred in 10 of 30 handsewn anastomoses and 8 of 60 mechanical anastomoses ($p = 0.047$ by Fisher's exact test). Laterolateral anastomoses are currently standard and can be created by circular or linear stapling, although the latter seems perferable. A preliminary comparison between 21 and 25 mm stapled end-to-end anastomoses found no differences (EL 1b [331]). Different devices with similar effectiveness are currently in use (EL 1b [54]). The mesentery defect should be closed in order to avoid internal hernia (EL 4 [97, 154, 258]). A surgical drain should be place at the gastrojejunostomy site (EL 4 [298]), but the nasogastric tube may be removed at the end of the procedure (EL 2b [145]).

BPD

As described above, when speaking of BPD our article refers to biliopancreatic diversion with duodenal switch and sleeve gastrectomy. The vertical subtotal gastrectomy (sleeve gastrectomy) should be performed on a 34 to 60 Fr bougie along the lesser curvature so that the gastric tube consists of about 10% to 30% of the original stomach (100 to 200 ml).

Little data have been published on limb length, but the common limb should measure over 50 cm, but less than 100 cm. Correspondingly, the alimentary canal should be between 200 cm and 300 cm long. Duodeno-ileostorny can be created by circular stapling, linear stapling with hand sutures, or a completely hand-sewn technique (EL 2b [346]). The integrity of all staple lines needs to be confirmed by methylene blue testing. To shorten the duration of surgery in high-risk patients, some authors have proposed to perform BPD either as a two-stage procedure with gastrectomy first (EL 4 [7, 272]) or without gastrectomy (EL 4 [276]).

General aspect

Other simultaneous procedures may be carried out in obesity surgery patients. First, ventral hernia should be repaired by mesh implantation under the same anaesthesia, as this reduces the risk of bowel ischemia (EL 2b [89, 286]). Second, cholecystectomy has been proposed for all patients (with or without gallstones) at the time of surgery (EL 4 [3, 8, 50, 99, 290]), because obesity surgery furthers postoperative gallstone formation and necessitates cholecystectomy in about 10% of patients following RYGB (EL 4 [3, 8, 73, 305, 306]). Other, more recent studies, however, have shown that simultaneous cholecystectomy can be safely restricted to those patients with asymptomatic gallstones detected on intraoperative ultrasound (EL 4 [134, 155, 338]) or with symptomatic cholecystolithiasis (EL 4 [151]). The post-operative use of ursodeoxycholic acid was shown to reduce the risk of subsequent cholecystolithiasis (EL 1b [218, 321, 364]). A daily dose of 500 to 600 mg of urso-deoxycholic acid for 6 months was shown to be an effective prophylaxis for gallstone formation.

Long-term after-care

A multidisciplinary approach to aftercare is needed in all patients regardless of the operation (GoR B). Patients should be seen 3 to 8 times during the first postoperative year, 1 to 4 times during the second year and once or twice a year thereafter (GoR B). Specific procedures may require specific follow-up schedules (GoR B). Further visits and specialist consultation by surgeon, dietician, psychiatrist, psychologist or other specialists should be done whenever required (GoR C). Outcome assessment after surgery should include weight loss and maintainance, nutritional status, comorbidities, and quality-of-life (GoR C).

Obesity is a "chronic disorder that requires a continuous care model of treatment" [125]. Although there are only a few comparative studies on the frequency, intensity or mode of follow-up, close regular follow-up visits have become routine in most centres (EL 4 [217]). Baltasar et al. highlighted several cases of serious complications and even death which were due to metabolic derangement caused by inadequate follow-up (EL 4 [26]). This is why patients who do not understand or comply with strict follow-up schedules should be denied surgery, as recommended above.

Postop. Months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	thereafter
LAGB (minimal)	X		X			X						X												X	once a year
LAGB (intensive)	X	X	X	X		X		X		X		X			X			X			X			X	twice a year
VBG (minimal)	X					X						X												X	once a year
VBG (intensive)	X		X			X			X			X						X						X	once a year
RYGB (minimal)	X					X						X												X	once a year
RYGB (intensive)	X	X	X			X			X			X						X						X	once a year
BPD (minimal)	X		X			X						X												X	once a year
BPD (intensive)	X	X	X			X			X			X						X						X	once a year

Fig. 2. Suggested timing of postoperative follow-up visits.

The frequency of the visits should be adapted to the procedure, the patient's weight loss over time and the overall probability of complications. Therefore, closer follow-up visits are generally required during the first postoperative year. Shen et al. (EL 3b) examined the association between the number of postoperative visits during the first year and EWL. A significant difference favoring more than 6 visits per year was found for gastric banding but not for gastric bypass patients [304]. In consequence, many obesity surgeons favor closer follow-up visits after LAGB than after VBG or BPD (EL 4 [46, 217]). Based on current practice patterns (EL 4 [92, 217]), this panel unanimously recommended a follow-up protocol as shown in Figure 2. No data are available to indicate that follow-up should be different after open and laparoscopic surgery. It has been recommended to sonographically exclude gallstones at the 6 and 12 months visit. Follow-up should always be continued lifelong, as long as the surgical procedure or device has not been reverted or removed.

For optimal continuity of care, it seems recommendable to have one physician as the primarily responsible person for follow-up. It is therefore usually the surgeon or the nutritionist, who oversees the patient's course, circulates information to other colleagues and coordinates multidisciplinary consultations. Postoperatively, all patients should be seen several times by the dietician and the psychologist (EL 4 [217, 268]). In addition, it may be necessary to consult the gastroenterologist (for upper gastrointestinal endoscopy), the pneumologist (for sleep apnea), the radiologist or other disciplines. Again, communication and collaboration is essential, since many different comorbidities may be affected by weight reduction.

The importance of psychological counseling is difficult to quantify. Comparisons of patients who attended or quitted postoperative group meeting or psychotherapy (EL 3b, downgraded due to noncomparability of groups) found that attenders had slightly more weight loss and better quality-of-life when compared to non-attenders [139, 245, 269]. Although this panels supports the idea of an intensified postoperative counseling, current data does not justify a firm recommendation.

Nutritional treatment aims to ensure that patients consume a diet that meets normally accepted nutritional recommendations for macro-, micro-nutrients and vitamins in-take, but at a reduced energy intake commensurate with maintaining a reduced body weight. Many patients have pre-existing nutritionally inadequate diets [EL 4 [44, 98, (6) 133]), and deficiencies are commoner in the older and more overweight EL2A (EL 2b [183, 184]) and may be exacerbated by drugs commonly used to treat obesity comorbidities (EL 4 [180, 280]). Such deficiencies are more likely to be exacerbated rather than improved by bariatric surgery, especially malabsorptive procedures (EL 4 [27, 91, 130, 194, 268]). For this reason individual nutritional (diet) assessment and advice is necessary both pre- and post-operatively in order to ensure that nutritional status is optimised. It is likely that most patients will require nutritional supplements of vitamins and minerals (EL 2b [37, 51, 131, 308, 310]).

Clinical and scientific documentation of patients' postoperative course should not only focus on weight. Additionally, the clinical course of comorbidities should be closely monitored, and all patients should be questioned about their quality-of-life (QoL), as it recommended by the 1991 NIH conference (EL 5 [238]). For the assessment of QoL, validated instruments are freely available and should be used [221, 254, 361]. In 1997, the ASBS issued guidelines on scientific reporting, which ideally should include the course of BMI and EWL over at least two postoperative years (EL 5 [10]).

Band adjustments are a specific part in the follow-up of LAGB patients. First band filling should be performed between 2 and 8 weeks after band implantation-usually after 4 weeks (EL 2b [46]). For this first filling, 1 to 1.5 ml saline are injected. Band adjustments thereafter should be carried out as required in an individualised manner according to weight loss, satiety and eating behaviour, and gastric problems (e.g. vomiting). Four, six or eight week intervals between adjustments are widely accepted. A much simpler approach for band filling was recently found to produce similar EWL, while reducing workload immensely. Twenty patients treated by Kirchmayr et al. received a bolus-filling 4 weeks after surgery thus obviating the need for subsequent stepwise re-calibration (EL 1b [167]). This panel awaits further studies confirming the safety of this or similar concept. The volume of the pouch should be examined radiographically after 12 months and (as an option) also after 6 months.

Dealing with complications

Surgeons should be aware that postoperative complications may have an atypical presentation in the obese, and early detection and timely management are necessary to prevent deleterious outcomes (GoR C).

Common to all procedures which employ gastrointestinal suture or anastomoses is the possibility of anastomotic leakage and bleeding [48]. Clinical signs, such as fever, tachycardia, and tachypnea, were found to be highly predictive of anastomotic leaks after RYGB (EL 4 [168]). Generally, anastomotic leakage can be treated by drainage with or without oversewing (EL 4 [298]). Revisional surgery for suspected anastomotic leakage can be done via open or laparoscopic approach (EL 5 [346]). Staple line bleeding with minor or major blood loss can often be treated conservatively (EL 4 [212, 244]; EL 5 [275]). Splenectomy is seldomly required.

LAGB

Complications after LAGB include gastric erosion, band slippage, pouch dilation, occlusion of the stoma, and port-related complications. Gastric erosion usually causes mild pain, various types of infections and prevents further weight loss (EL 4 [2]). When gastric erosion is confirmed on gastroscopy, the band needs to be removed urgently, but not immediately. Patients may be converted to RYGB (EL 4 [156, 341]), VBG, or BPD (EL 4 [84]), or rebanding (EL 4 [118]). However, rebanding should be avoided if further weight reduction is the principal aim (EL 2b [341]).

The incidence of band slippage essentially depends on band positioning (EL 2 [68]). Patients usually complain of burning sensations and discontinuation of weight loss. Initial management consists of band deflation. If the pars flaccida technique was not used in the primary operation, therapy consists of laparoscopic revision (EL 4 [59]). Other alternatives are band repositioning, rebanding, or conversion to other procedures (EL 4 [349]).

Pouch dilatation can occur in the early or late follow-up. Early dilatation is mostly caused by a wrong position of the band (EL 4 [58]). Patients do not get a feeling of satiety, stop to loose weight, and suffer from vomiting. A contrast meal verifies the diagnosis, but minor degrees of dilatation can be considered not clinically relevant (EL 4 [174]). Therapy consists of immediate gastric tube placement and band deflation followed by reinflation after a few months. In case pouch dilatation persists, band repositioning or conversion to other procedures should be tried (EL 4 [248]).

Access ports can twist or become infected. While port rotation can be corrected by revisional surgical fixation (EL 4 [170, 225, 349]), infection requires port removal. First, the tube is placed in the abdominal cavity. When infection has settled down, the tube is reconnected, and a new port is place at a different position. A spontaneous disconnection between tube and port should be suspected in patients who report an acute abdominal pain (EL 4 [365]). Laparoscopic grasping of the tube with reattachment is a feasible treatment option (EL 4 [365]).

VBG

After VBG, the range of complications includes stoma stenosis, pouch dilatation, band erosion and staple line disruption. Erosion or infection of the band at the pouch outlet should be treated by band removal (EL 4 [340]). In severe cases, conversion to LAGB or other procedures may be necessary (EL 4 [66, 176]). As described above, staple line disruption should be prevented intraoperatively by the use of MacLean's technique with complete transsection of the vertical staple line with oversewing (EL 1b [102]; EL 2b [195]). The advantage of not transsecting the staple line, however, is that small disruptions can be accepted without major effects on weight loss (EL 4 [213]). Severe cases of esophageal reflux after VBG may require conversion RYGB (EL 4 [24]).

RYGB

Stoma stenosis, gastric distension, anastomotic leakage, gastrojejunal ulcers and nutritional deficiencies may occur after RYGB. Stoma stenosis due to anastomotic strictures usually occurs during the first postoperative months (EL 4 [284, 292]). Most cases of stoma stenosis are amenable to endoscopic dilatation, but some require conversion for persistence of stenosis or perforation caused by dilatation (EL 4 [28, 288, 292]). On the opposite site, an unwanted dilatation of the gastrojejunostomy may respond to sclerotherapy (EL 4 [316]). Stomal ulceration can usually be treated conservatively with an H_2 blocker and sucralfacte (EL 4 [284]).

BPD

The spectrum of complications after BPD is similar to RYGB. Complications have been found to be more likely in patients converted from other procedures to BPD (EL 3b [26]). According to the report by Anthone et al., a lengthening of the common canal can be necessary to treat hypalbuminaemia or persistent diarrhea (EL 4 [18]). In that study, the initial length of the common canal was 100 cm.

Discussion

During the last years, the rapidly growing and often lucrative field of obesity surgery has attracted many laparoscopic surgeons. As also the prevalence of obesity has increased steadily, the number of bariatric operations has increased dramatically. Although obesity surgery represents the only therapeutic opportunity for strong and long-term weight loss, balancing between treatment benefits and side effects is often difficult, because many morbidly obese patients present with severe comorbidity. Furthermore, also the less than morbidly obese population is seeking help of bariatric surgeons. This led to the decision to summarize the state of the art in the field of obesity surgery. The EAES guidelines developed here were also necessary to update previous guidelines of other societies.

Since the results of this consensus conference have been derived directly from the relevant literature by an interdisciplinary panel, it can be hoped that they find widespread acceptance [132]. However, the recommendations are no ‘‘cookbook’’, because national and local circumstances will often necessitate modifications. This European consensus represents a common ground, which can be transferred to all obesity surgery centres. Still, any scientific recommendation represents a compromise between practically orientated firmness of language and its underlying scientific basis. Often, the scarceness of reliable evidence precluded the panel from formulating important decisions. On the other hand, it would have been of no practical value to come up with only bland generalities. Therefore, some recommendations were agreed upon, although only weak evidence had been found to support them, whereas other crucial points, like the choice of surgical procedure, were left unresolved, although some medium-quality, but not convincing evidence was available.

Among the possible shortcomings of these guidelines is the absence of an anesthesiologist, an internist, and a patient in the panel, since the paragraphs on preoperative and postoperative care cover also important aspects of general medicine. As most of the panel members are working in multidisciplinary teams, it can be expected that the most common non-surgical aspects of obesity surgery have been adequately addressed. The input of the nutritionist and the psychiatrist was very valuable. A patient representative often acts as a safeguard against recommending a procedure with unpleasant non-medical side effects and related problems with compliance. However, due to the difficulties in finding a competent person, patients are usually not participating in clinical guideline development. Furthermore, the inclusion of additional persons would have led to a panel size that makes group discussions difficult to moderate [211, 227, 240].

Owing to the lack of published data on various aspects of obesity surgery these recommendations also highlight the need for future studies. Especially the relative effectiveness of the different laparoscopic procedures is worth a number of controlled trials. Some technical modifications and newer devices also require scientific evaluation. Future studies should pay closer attention to the different subgroups of obese and morbidly obese patients, because different risk-benefit ratios are likely in these heterogeneous groups of patients. Since some ongoing studies were already identified during the guideline development process, it should be noted that the present recommendations need to be updated after about five years in order to take advantage of this new knowledge [303].

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