

Evidence-based German guidelines for surgery for obesity

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Abstract

Background The young field of obesity surgery (bariatric surgery) in Germany expands as a consequence of the rapid increase of overweight and obesity. New surgical methods, minimal access techniques, and the enormous increase of scientific studies and evidence, all contribute to the success of bariatric surgery, which is the only realistic chance of permanent weight loss and regression of secondary diseases in many cases.

Methods A systematic literature review, classification of evidence, graded recommendations, and interdisciplinary consensus.

Results Obesity surgery is an integral component of the multimodal treatment of obesity, which consists of multidisciplinary evaluation and preparation, conservative and surgical treatment elements, and a life-long follow-up. The guideline confirms the body mass index (BMI)-based spectrum of indications (BMI > 40 kg/m² or > 35 kg/m²

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with secondary diseases) and extends it through elimination of all age restrictions (>18 years and <60 years) and most of the contraindications. Precondition for surgery is the failure of a structured conservative program of 6–12 months or the expected futility of it. Type II diabetes mellitus becomes an independent indication criterion for $\text{BMI} < 35 \text{ kg/m}^2$ (metabolic surgery). The standard techniques are gastric balloon, gastric banding, gastric bypass, gastric sleeve, and biliopancreatic diversion. The choice of procedure is based on profound knowledge of results, long-term effects, complications, and patient-specific circumstances. The after-care should be structured and organized long term.

Conclusion The S3-guidelines contain evidence-based recommendations for the indication, selection of procedure, technique, and follow-up. Patient care should improve after implementation of these guidelines in clinical practice. Compliance by decision makers and health insurers is warranted.

Keywords Obesity · Obesity surgery · Bariatric surgery

Introduction

The body weight of Germans is rising steadily. One out of two Germans is overweight and one out of five is obese. The classification of obesity is based on body mass index (BMI), which is calculated by division of body weight by height squared (kg/m^2). For Europeans, obesity is classified as grade I ($\text{BMI} 30\text{--}34.9 \text{ kg/m}^2$), grade II ($\text{BMI} 35\text{--}39.9 \text{ kg/m}^2$), and grade III ($\text{BMI} \geq 40 \text{ kg/m}^2$). Obesity is a sequence of positive energy balance with excessive deposits of surplus energy in fat tissue. It may be called morbid for a $\text{BMI} \geq 40 \text{ kg/m}^2$ or $\text{BMI} \geq 35 \text{ kg/m}^2$ with comorbidities. Super- or mega obesity is often referred to when the BMI exceeds 50 kg/m^2 .

Obesity is associated with a number of severe diseases, such as insulin resistance, type II diabetes mellitus, lipid disorders, hypertension referred to as metabolic syndrome when occurring simultaneously, gallstones, certain cancers, GERD, hepatic steatosis, degenerative joint disease, obstructive sleep apnea syndrome, hypoventilation syndrome, and psychiatric disorders. Morbid obesity reduces life expectancy by up to 20 years [1].

The effectiveness of obesity surgery (bariatric surgery) has been confirmed beyond doubt in extensive meta-analyses EL1a, [2–4]. In the large, prospective, matched-pair Swedish Obesity Subjects (SOS) study, a conservative standard treatment ($n=627$) was compared with bariatric surgery ($n=641$) of various types (vertical gastropasty ($n=451$), gastric banding ($n=156$), gastric bypass ($n=34$) EL 2b, [5]. The mean body weight of the conservative group was 0.1% lower than the initial weight after 2 years and 1.6% above the initial weight after 10 years. The mean

body weight loss in patients operated on was 23% after 2 years and 16% after 10 years, respectively (gastric banding 14%, vertical gastropasty 16%, gastric bypass 25%). Long-term results were stable for 15 years EL 2b, [6]. The remission rates of the associated diseases is very high, and the long-term mortality is reduced by a lower incidence of myocardial infarction, diabetes mellitus, and cancer by up to 40% EL 2b, [6, 7].

The number of bariatric interventions has increased rapidly in Germany in recent years. This success was pioneered by the development of new techniques that minimize surgical trauma, an enormous increase in scientific studies and the recognition that a lasting weight reduction plus regression of associated morbidity can be achieved only through bariatric surgery in many cases. The aim of the guidelines is a systematic evaluation of the evidence in the published scientific literature on the effectiveness of bariatric surgery in order to provide decision aids for all bariatric surgeons, physicians, other health care professionals, patients and health care providers, and insurers. The guidelines are intended for quality improvement in the treatment of obesity. Primary objective of the guideline is the medical effectiveness in terms of reducing mortality and morbidity, but also an increase in the quality of life. Any guidance of the scientific medical societies is not legally binding. The short version presented here includes a brief description of the consensus process, all recommendations and an accompanying commentary. The original version with detailed information on methodology, the evidence of the literature, and all citations is available on the website of the AWMF (<http://www.awmf.de>) or of the medical societies involved.

Methods

The S3-guidelines meet the requirements of the systematic development and interdisciplinary consensus (“guideline-assessment instrument” of the AWMF and AZQ, 2005; www.delbi.de). Thus, this is an evidence-based guideline as defined in § 137e (Federal Ministry of Health (2000) Social Security Code V (SGB V), 135-7).

The guidelines of the European Society for Endoscopic Surgery (EAES) under the primary authorship of S. Sauerland served as the scientific basis for our paper. The 2005 EAES guideline met all requirements of evidence-based and consented guidelines [8]. Therefore, the literature search and classification of evidence was adopted from the EAES paper. In addition, all subsequent publications in English or German language were screened in Medline (PubMed) for the period 5/2004-4/2009. The classification of evidence was according to the proposals of the Oxford Centre for Evidence-based Medicine. When randomized controlled trials (Ib evidence) were missing or were of poor quality,

non-randomized controlled clinical trials (IIb evidence) were used. If there was a lack of evidence, levels I and II case series were used to compare the preoperative and postoperative status (IV evidence).

The recommendations were graded as A, B, or C and termed correspondingly as “must”, “should”, or “may”. In addition, the graded recommendations were marked by two vertical arrows (grade A, ↑↑), one vertical arrow (grade B, ↑), or one horizontal arrow (grade C, ↔), respectively. The grades of recommendation were strongly determined by the level of evidence.

The formal consensus conferences were held on November 11, 2008 and April, 3, 2009 in Frankfurt am Main, Germany. The structured consensus process was carried out at specified steps. All recommendations were of strong consensus (agreement of >95% of participants) or by consensus (agreement of >75% of participants). The manuscript was then submitted to the presidents of the scientific societies involved for comments. The comments were incorporated into the script, after a second consultation and appropriate modification. The final version was adopted as the original version in agreement with the entire expert panel.

This article includes all evidence-based recommendations for preoperative evaluation, indication, choice of procedure, technique, and follow-up, but it is a version shortened on methodology and the literature review. Each chapter of recommendations is followed by a text commenting them for better understanding and practical use.

Results/recommendations

Evaluation and diagnostics

A surgical measure for weight loss requires a prior multidisciplinary work-up. ↑↑

In this context, the patient should be seen by a specialist for conservative management of obesity. ↑

All patients have to be managed by a nutritionist/dietician preoperatively. ↑↑

Other disciplines and experts are involved depending on the comorbidities of the obese patient. ↑↑

In particular, one should consider consulting a psychologist, psychiatrist, or psychosomatic specialist with experience in treating obese patients. ↑

Large upper abdominal surgery, such as bariatric surgery, require an extensive preparation and thorough medical history with recording and documenting all concomitant diseases, current medication, signs and symptoms. ↑↑

An upper GI-endoscopy must be performed prior to bariatric surgery. ↑↑

Secondary causes of obesity, such as hypothyroidism, are to be excluded before a bariatric operation. ↑↑

Comment

In general, the preoperative evaluation of bariatric patients follows the same standards of major upper GI surgery. These include the differential diagnosis and also an upper GI-endoscopy. The guidelines recommend a team of specialists for the management of obese patients. Bariatric surgery is not recognized as an official subspecialty/fellowship program of general or visceral surgery; however, the German surgical society has recently defined quality standards for bariatric surgeons. As yet, there are no bariatric specialists in internal medicine (“obesitologist”), nutritional/dietary medicine, or psychology. Lacking official terms for such specialists, the guideline refers to these potential specialists as being experienced in the management of obese patients.

All patients must be seen by the surgeon and also by a specialist for the conservative management of obesity, and in addition, by a trained nutritionist/dietician. It is important to diagnose an obstructive pulmonary disorder early as its frequency increases with higher BMI EL 2b, [9]. Some centers routinely perform a polysomnography before surgery because the rate of sleep apnea syndrome may reach 40–91% of patients EL 4, [10, 11].

A psychologist or psychiatrist is included into the preoperative work-up only selectively, although the prevalence of mental disorders rises with increasing BMI EL 2b, [12, 13]. These are mainly affective disorders, anxiety disorders, eating disorders, and personality disorders. DeZwaan and coworkers made suggestions on the content of such an evaluation of mental status [14], but the value of a psychological screening by non-specialists through self-designed questionnaires remains unclear.

Mental disorders cannot serve as a suitable parameter for the indications for surgery with the exception of few diseases, such as the bulimia nervosa EL 2a, [15]. Neither binge-eating nor sweet-eating are predictors of weight loss after surgery EL 4, [16]. Consequently, preoperative evaluation of mental status does not have a gatekeeper function, but it aims to discover patients with need for psychological treatment of relevant mental problems including eating disorders. Furthermore, patients should be prepared and set for the postoperative course. The central goals of preoperative evaluation of mental status are, therefore, to obtain a detailed psychological and biographical history, the clarification of motivation and knowledge of the planned intervention, and the expectations (e.g., problem solver, “quick fix”) EL 4, [14, 17].

A special preoperative weight loss program may reduce the liver volume and may thus improve intraoperative visibility EL 2b, [18]. Moreover, the postoperative weight loss is faster, but the remission of the obesity-associated morbidity is unaltered. EL 1b, [19].

Indication

Bariatric surgery is indicated in patients with a BMI \geq 40 kg/m² without contraindications after failure of conservative treatment or when efforts appear futile. The patient must fully understand the extent and consequences of bariatric surgery. \uparrow \uparrow

In patients with a BMI of 35–40 kg/m² and with one or more obesity-associated disorders (e.g., type 2 diabetes mellitus, coronary heart disease, etc.) is also a candidate for surgical treatment if conservative treatment has failed or appears futile. \uparrow \uparrow

Surgery may also be considered in patients with type 2 diabetes mellitus and a BMI of 30–35 kg/m². These well-selected cases should be enrolled into trials. \Leftrightarrow

Higher age (>65 years) constitutes no contraindication per se in the presence of good general condition. \uparrow

For patients in advanced age, the indication for bariatric surgery should be individually justified. The aim of the operation is often the prevention of immobility and long-term care. \uparrow

Fertility is not a contraindication to bariatric surgery. \uparrow

Surgical procedures can be considered after repeated failure of conservative multimodal therapies in extremely obese adolescents with significant comorbidity as the last alternative. \Leftrightarrow

Some diseases and socio-psychological conditions were considered contraindications in the past. However, if they can be treated successfully or converted into a stable state, patients should be re-evaluated for surgery. \uparrow

Comment

Traditionally, obesity surgery is considered appropriate for adult patients with either a BMI of 40 kg/m² or more, or a BMI between 35 and 40 kg/m² with obesity-related comorbidity. These selection criteria have been laid down in March 1991 by the National Institutes of Health Consensus Development Panel and have subsequently been adopted by all major surgical and non-surgical societies. These recommendations were then formulated with the aim to prepare the way for obesity surgery within a well-defined spectrum of indications. As a consequence, the great majority of surgical experience and scientific evidence relates to patients who were selected by such arbitrarily chosen criteria.

As the short-term risks of obesity surgery clearly exceed that of conservative treatment, it is advisable that all patients should have tried other ways of weight loss prior to surgery. The failure of conservative treatment is a prerequisite for surgery. The conservative multimodal treatment options have failed when the treatment goal has not been achieved within 6–12 months. The goals are defined (“best clinical practice”) as a loss of 10–20% of

initial weight with a BMI of 35–39.9 kg/m² and 10–30% with a BMI 40 kg/m², respectively. The following assessment criteria are available:

Nutrition: Energy-reduced diet in addition to another nutritional intervention (such as formula diet, other energy-reduced form of a mixed diet).

Physical exercise: Implementation of a cardiovascular and/or strength endurance sport with at least 2 h per week, if no barriers exist (such as osteoarthritis of the knee for walking or shame when swimming).

Psychotherapy: Implementation of an inpatient or outpatient psychotherapy (behavioral therapy or depth psychology) in cases of an eating disorder (binge-eating, night-eating) or psychopathology (e.g., depression, anxiety).

Group therapy: Modification of life style should be conducted and supervised within a group, if possible.

The guideline has introduced another new criterion besides failure of conservative multimodal therapy, namely futility of efforts. Primary surgery may be indicated when chances of success of conservative therapy appear remote due to the nature and/or severity of the disease or due to psychosocial factors. Primary surgery may also be indicated if radical weight loss may not be postponed for medical reasons. These exceptional cases have to be worked up by an experienced multidisciplinary team.

Some reports have shown that surgical treatment is similarly effective in patients with a BMI between 25 and 35 kg/m². Given the strength of the existing evidence, it seems too early to strongly recommend obesity surgery in cases with a BMI < 35 kg/m² who suffer from substantial obesity-related comorbidities. Only type II diabetes mellitus has become an indication criterion for patients with a BMI < 35 kg/m² in the context of clinical trials. Thereby, the guideline carefully introduces metabolic surgery into German clinical routine.

The expansion of bariatric surgery beyond traditional BMI-based boundaries is based on the impressive response rates postoperatively. In a recent prospective randomized trial by Dixon et al. 2008 EL 1b, [20], an operative method (gastric banding) was compared with a conservative therapy (encouragement to lifestyle changes plus, if accepted, hypocaloric diet) in diabetic patients with a BMI 30–40 kg/m². The excessive weight loss was 62.5% after 2 years after gastric banding compared to 4.3% in the conservative control, and the remission rate of diabetes was 73% after gastric banding compared with 13% with conservative therapy. The 2004 meta-analysis by Buchwald et al. EL1a, [2] shows an average remission rate of 77% for type 2 diabetes mellitus: 38% after gastric banding, 84% after gastric bypass, and 98% after BPD with or without duodenal switch. The metabolic improve-

ment is remarkable because it appears independent from weight loss after restrictive/malabsorptive combination procedures EL [4, 21]. Patients with insulin-treated type 2 diabetes mellitus experience a rapid decline in anti-diabetic drug dose, with a large proportion of insulin injection, or without insulin after 6 weeks postoperatively. This effect remains stable for many years EL 2b, [5]. In addition, bariatric surgery may prevent the development of type 2 diabetes mellitus in a longitudinal comparative analysis EL 1b, [22]. The guidelines abolish traditional age limits up at 65 years and down at 18 years. In adolescents, the decision for surgery will have to be an extremely selective one, and only after an intensified multidisciplinary protocol in experienced centers.

Choice of procedure

A single procedure of choice that fits all situations does not exist. † †

Effective surgical procedures for the treatment of obesity are gastric banding, gastric sleeve, Roux-Y gastric bypass, or biliopancreatic diversion with duodenal switch (BPD-DS). † †

Gastric minibypass, biliopancreatic diversion or vertical-banded gastroplasty have also proven their effectiveness and may be used selectively. ⇔

The choice of procedure must consider BMI, age, gender, comorbidities, adherence, and occupation. † †

The patient should be informed in detail about all standard procedures. These are gastric banding, gastric bypass, gastric sleeve, biliopancreatic diversion with duodenal switch, as well as staged procedures (e.g., intragastric balloon or gastric sleeve resection as a first step).

The patient must be fully informed about his surgical procedure and alternative treatment options, late effects, morbidity, mortality, and long-term care, elucidating the lifelong supplementation and postbariatric plastic surgery. † †

The preference of the informed patient should be considered in the selection process and in absence of contraindications. † †

Two-stage approaches are able to reduce the perioperative risk and should be particularly considered in patients with extreme forms of obesity (BMI > 50 kg/m²) and/or significant comorbidity. †

The use of a gastric balloon can be considered in the case for short-term weight loss. ⇔

The operations are to be performed by surgeons with expertise in obesity surgery and in hospitals with institutional experience. † †

Comment

In Germany, gastric banding, gastric bypass, gastric sleeve resection, and BPD-DS are by far the most common

operations for obesity. They are referred to as standard procedure, because they have proven their long-lasting effectiveness with the exception of lack of long-term data beyond 5 years for gastric sleeve.

The differences in the effectiveness have been clearly demonstrated in three large meta-analyses by Buchwald et al. EL 1a, [2–4]. Mean weight loss was 47.5% (95% CI 40.7–54.2) after gastric banding, 61.6% (95% CI 56.7–66.5) after gastric bypass, and 70.1% (95% CI 66.3–73.9) after biliopancreatic diversion with or without duodenal switch (136 papers on 22,094 patients [2]). The postoperative 30-day mortality for all laparoscopic restrictive procedures was 0.07% (95% CI 0.02–0.12), 0.16% (95% CI 0.09–0.23) for the laparoscopic gastric bypass, and 1.11% (95% CI 0.00–2.70) for the laparoscopic malabsorptive procedures, respectively (61 papers with 478 study arms and 85,048 patients) [3]. The most recent meta-analysis [4] including 621 papers, 888 study arms, and 135,246 patients found an improvement in diabetic metabolic status in 87% after bariatric surgery and a complete remission in 78%. The analysis suggests that the more invasive procedures have a better effect.

Gastric sleeve resection is not depicted in the meta-analysis as it is a fairly new surgical technique, but a recent review suggests that weight loss and remission of comorbidities are comparable to gastric bypass EL 4, [23]. In a randomized study from Belgium, sleeve gastrectomy achieved a higher weight loss than gastric banding EL 1b, [24]. Purely restrictive procedures are very effective and superior to conservative therapy EL 1b, (20) particularly in patients with lower BMI (30–40 kg/m²). The long-term follow-up was reported in only 26 patients EL 4, [25] and 41 patients EL 4, [26], respectively. Eleven of the latter 41 patients underwent an additional duodenal switch or “resleeve” between the third and sixth year. The overall long-term mean excess weight loss exceeded 50%.

It is recognized by the guideline panel that a surgical “gold standard” does not exist despite rapidly increasing scientific evidence, and that the choice of procedure cannot be based on objective parameters only. The operative procedures differ in effectiveness and morbidity, and thereby, they compete with each other at first stage and complement each other in a staged concept and in revision surgery. The choice of treatment is an individual decision based on surgeons' experience and individual patient criteria, including psychosocial factors.

Technical aspects and complications

Gastric balloon: In liquid-filled balloons, methylene blue is added to indicate a spontaneous balloon collapse early. † †

Balloons should be avoided in cases of prior gastric surgery because of an increased risk of perforation after implantation. † †

Gastric banding: The gastric band must be positioned via the pars flaccida of the lesser omentum, in order to limit the rates of dislocation to a minimum. † †

The implantation must be carried out laparoscopically. † †

Roux-Y gastric bypass: the construction of a gastric bypass is done laparoscopically. † †

The stomach pouch should be small. †

The length of the alimentary limb should be about 150 cm to achieve an adequate weight loss with little metabolic complications. †

The antecolic–antegastric position of the alimentary limb should be preferred. †

Biliopancreatic diversion: the biliopancreatic diversion with duodenal switch should be performed laparoscopically. † †

The length of the common channel should roughly measure 100 cm. †

Gastric sleeve: Gastric sleeve must generally be done laparoscopically. † †

The creation of a gastric sleeve requires calibration. †

Simultaneous cholecystectomy is recommended in patients with preoperative symptomatic cholelithiasis only. †

In asymptomatic cholecystolithiasis, prophylactic cholecystectomy may be considered on individual grounds. ⇔

The elective surgical treatment of incisional hernias should be deferred until a stable weight and improved nutritional status are achieved. †

Severe alteration of patient's appearance following massive weight loss may result in medical and psychosocial stress and disorders. These consequences have to be explained to the patient prior to his bariatric operation. Similarly, the potential necessity for postoperative plastic surgery must be part of the initial informed consent. † †

The plastic surgical corrections after successful weight reduction should be an integral part of the overall treatment concept. †

Comment

The evidence of the various operations and technical variations is presented and discussed in detail in the original version of the guideline. The evidence-based standards have become well established in surgical training and need not be repeated here. The key message is that bariatric surgery is purely laparoscopic—no other area of visceral surgery has become so exclusively minimal invasive. In this regard, the new subspeciality of bariatric surgery may serve as a pacemaker for the entire field of visceral surgery.

Other practical recommendations are those of the simultaneous cholecystectomy only in symptomatic patients, and the postponement of elective repair of incisional hernia after the end of the weight loss. For the first time, a bariatric guideline acknowledges post-bariatric plastic body contouring as an integral part of a holistic approach towards obesity.

Long-term after-care

A systematic approach to aftercare is needed in all patients regardless of the operation. Patients require regular follow-ups by specialists in the management of obesity and a nutritionist/dietician. † †

Bariatric surgical patients should be monitored closely in the first postoperative year. †

The supplementation of vitamins and minerals should be routine after malabsorptive and combined procedures and during a period of severe weight loss and repeated vomiting after pure restriction. † †

Deficiencies should be detected by means of laboratory control. † †

The postoperative treatment by a psychologist or psychiatrist may be recommended in patients with preexisting psychiatric disorder and or postoperative development of binge-eating (“loss of control eating”) or other mental disorders. ⇔

Participation in patient support groups can be recommended. ⇔

Patients of childbearing age should implement birth control during the period of rapid weight loss. †

Dose adjustments of drugs may have to be carried out. † †

Comment

Obesity is considered a chronic illness that does not cease after bariatric surgery. All panel members recommend a long-term care, although no evidence-based, generally accepted after-care scheme exists. The frequency of follow-up appointments will depend on the surgery performed, the dynamic of weight loss and for any problems or complications. Latter occur predominantly in the first year following surgery. Regarding nutrition, a change in diet is recommended based on general standards for a balanced diet with supplementation of trace elements (iron) and vitamins (vitamin D).

The follow-up serves primarily for the necessary adjustments of the gastric band and the prevention of late complications and deficiencies that may occur despite supplementation. Weight loss is greater in patients with regular postoperative supervision EL [4, 27, 28]. Follow-up of obesity patients requires a competent physicians and an experienced nutritionist/dietician. Patient support groups can have a positive effect in the postoperative course and for a sustained weight loss EL [4, 29, 30].

The working group for the treatment of obesity of the German Surgical Society has implemented a nationwide registry. Documentation of all clinical cases/data is required as a quality assurance instrument in the certification process of the society. The registry supports field research and benchmarking.

Discussion

Bariatric surgery develops somewhat sluggishly in Germany due to restrictions from health insurers and prevailing misconceptions amongst physicians, decision makers, and the public. This is in sharp contrast to convincing data, that bariatric surgery is the most effective treatment for sustained weight loss in many patients. Still, the number of procedures has increased in recent years but runs far behind other western countries. This led to the decision of the German Surgical Society to summarize the state-of-the-art in the field of obesity surgery. The aim of these guidelines is to update previous guidelines and to improve the quality of care of obese patients in Germany by presenting evidence-based rather than best clinical practice guidelines. The society wants to establish and foster bariatric surgery as a serious subspeciality in German visceral surgery. At the same time, the society is strongly interested to implement a quality control system. Evidence-based guidelines may serve as an important instrument of quality control.

Since the results of this consensus conference have been derived directly from the relevant literature by an interdisciplinary panel of official delegates from the surgical, medical, nutritional, and psychological societies, it can be hoped that they find widespread acceptance. The strength of these guidelines is a strong consensus with the non-surgical panel members. However, the recommendations are no cookbook and not legally binding. This German consensus represents a common ground, which can be transferred to all bariatric centers in the country, respecting local circumstances that will often necessitate modifications. 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.

The guidelines also highlight the need for future studies regarding the relative effectiveness of the different laparoscopic procedures and long-term follow-up after gastric sleeve resection. It is of utmost importance to prove the effectiveness of surgery beyond the traditional borders. Since evidence is mounting rapidly, the present recommendations need to be updated after about 3 years.

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