COMMENTARY

The Endocrine Society's Clinical Practice Guideline on endocrine and nutritional management of the post-bariatric surgery patient: Commentary from a European Perspective

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Abstract

Bariatric and metabolic surgery is experiencing a noteworthy increase worldwide in recent years, but protocols and consensus published in the past decade have not yet established clear evidence-based clinical recommendations. The Endocrine Society, with the participation of the *European Society of Endocrinology*, has promoted the creation of an expert panel to propose a clinical practice guideline for postoperative management of patients, candidates to bariatric surgery, that places a particular emphasis on evidence-based medical aspects. The main arguments reflected in those recommendations are set out in this article and are subject to analysis and discussion from the specific viewpoint of the current European experience.

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Introduction

Obesity is among the greatest public health challenges in the 21st century because it is associated with increased morbidity and mortality risks. The prevalence of obesity in the US continues to be high, exceeding 30% for most age and sex groups (1). In the European region, the World Health Organization, says the prevalence of obesity has tripled in many countries since 1980. The highest prevalence rates (> 25%) are found in regions of Italy and Spain in both sexes, as well as in Portugal, Poland, the Czech Republic, Romania, and Albania in women (2).

Clinical evidence suggests that only bariatric surgery has achieved substantial long-term weight loss in morbid obesity (body mass index ≥ 40 kg/m²) (3). So, it has been estimated that 340 000 procedures were performed worldwide in 2008 (4). The laparoscopic surgical approach, significant reduction in comorbidity associated with obesity, and low rates of complications and perioperative mortality have clearly contributed to the wide acceptance of this treatment for severe obesity by the scientific and civil community.

In this scenario, it would be convenient to evaluate the actual outcome compared with the theoretical results expected. This includes not only results related to weight reduction, but also those referring to the quality of life, medical and nutritional complications derived from these procedures. An expert panel (consisting of a chair, five experts, a methodologist, and a medical

writer) seriously reflected about these issues at the proposal of the Endocrine Society and with the participation of the *European Society of Endocrinology*. Such reflection has resulted in a consensus document, a Clinical Practice Guideline on endocrine and nutritional management of post-bariatric surgery patients published in the November issue of the *Journal of Clinical Endocrinology and Metabolism* (5).

In this Clinical Practice Guideline, the Task Force makes two types of considerations: 'recommendations' based on strong evidence, supported by controlled clinical trials, and providing patients more benefits than risks; and 'remarks', encompassing clinical experiences based on studies with a low grade of evidence, case report series, and unsystematic observations of the panelists which should therefore be considered as technical, therapeutic, regular monitoring suggestions, etc. The Clinical Guideline includes five major headings: prevention and treatment of weight regain, postoperative nutritional management, management of diabetes mellitus and lipids, bone mineral metabolism and hyperuricemia, and gastroenterological and feeding behavior considerations. Readers interested in a detailed analysis of each of these issues may consult the article published in the *Journal of Clinical Endocrinology and Metabolism* (Heber *et al.* (5)). This discussion will analyze and break down some of the recommendations and suggestions provided by the Task Force from the specific European perspective.

Prevention and treatment of weight regain

The guideline recommends that a technically proficient surgical team, preferably accredited by a national certifying organization, provides the necessary guarantees that patients will receive adequate instruction on lifestyle changes after surgery through the collaboration of a multidisciplinary team that allows for a greater assurance of long-term success and helps monitor weight regain once the anatomical integrity of the surgical procedure performed is confirmed and the possibility of revisionary surgery is ruled out.

Since 2004, the American Society of Bariatric and Metabolic Surgery administers the bariatric surgery centers of excellence accredited worldwide. Currently, there are 441 centers and 758 surgeons accredited in the US and Canada. In Europe, accreditation of bariatric surgery centers of excellence is governed by the European Accreditation Council for Bariatric Surgery, a member of the International Federation for the Surgery of Obesity and Metabolic Disorders-European Chapter (IFSO-European Chapter). Currently, 54 European centers are accredited by this institution.

These centers of excellence should meet the requirements set out in the guideline to ensure multidisciplinary evaluation and follow-up of patients undergoing bariatric surgery to ensure the highest long-term success rate with minimal perioperative complications.

One of the main conclusions of the expert panel in the document is that bariatric surgery does not guarantee successful weight loss and long-term maintenance of weight reduction. More than half the patients may regain 20–50% of weight lost in 10 years. On the other hand, loss of patients to follow-up at late stages may underestimate the true prevalence of weight regain. Although the main causes of weight regain are related to non-compliance with recommendations for lifestyle changes, apart from other socio-economic and psychological considerations, adherence to scheduled visits and so on, the surgical procedure selected may significantly condition patient behavior and expected results.

The Swedish Obese Study (SOS), a prospective, non-randomized study with a matched control group including 4047 subjects, showed a greater weight loss with the Roux-en-Y gastric bypass (RYGB) procedure compared with the adjustable gastric band (AGB) (27 vs 13%) at 15 years of follow-up, with a 99.9% patient retention. During follow-up, maximum weight loss was achieved 1–2 years after surgery for all three subtypes of surgery (vertical banded gastroplasty (VBG) 25%, AGB 20%, and RYGB 32%). Weight regain was observed in all surgical subgroups up to the 10th year, with subsequent stabilization until 15 years of follow-up (VBG 18%, AGB 13%, and RYGB 27%) (6, 7). In other words, ~65 and 72% of patients undergoing VBG and AGB respectively, did not achieve

a weight loss >20% of initial weight at 10 years of follow-up, compared with 26% of subjects who underwent RYGB.

In contrast to the above data, in the experience with biliopancreatic diversion (BPD) reported by Scopinaro *et al.* (8), including more than 2500 patients with long-term follow-up, weight loss, expressed as initial excess weight percent loss, hardly changed over more than one decade (72% at 2 years, 74% at 10 years, and 76% at 15 years). Similar data have been reported for duodenal switch–BPD (DS/BPD) at 10 and 15 years (9).

Although AGB and RYGB achieve poorer long-term results compared with malabsorptive procedures, they continue to be the most popular bariatric techniques because they involve a short hospital stay, less surgical complications, and much lower costs. In addition, nutritional deficiencies are uncommon. These are attractive characteristics for both patients and insurance companies paying for the procedures, because weight reduction and control of comorbidities are much higher than achieved with other medical procedures. Thus, restrictive (AGB, sleeve gastrectomy (SG), and VBG), restrictive/malabsorptive (RYGB), and pure malabsorptive (BPD, DS) techniques are performed in the US in 48.6, 49.0, and 2.0% of patients respectively (10). However, very different trends have been observed in the US and Europe as regards use of the most common procedures. Thus, from 2003 to 2008, use of AGB increased in the US/Canada from 9 to 44%, while use of RYGB decreased from 85 to 51%. In Europe, use of AGB decreased over that same period from 63.7 to 43.2% and RYGB increased from 11 to 39%. There are also in Europe procedures with a greater weight such as SG, done in 7% of patients (4% in the US/Canada) and BPD/DS in 4.5% (1.0% in the US/Canada) (4). These data are supported by recent registries in, Germany, Sweden, or the United Kingdom (11–13).

These trends in the most common surgical procedures are particularly relevant for long-term results because restrictive techniques are more often associated with weight regain. Therefore, patients should be warned of this possibility if they do not strictly follow the recommendations given. Because of the known attrition rates during patient follow-up and percent weight regain more than 5 years after surgery, candidates for bariatric surgery should be selected among patients who best comply with recommended lifestyle changes and scheduled visits. In addition, multidisciplinary teams must reinforce their strategies to ensure patient retention and control in measurements related to lifestyle changes. Patient participation in intensive educational programs including incentives and using the currently available communication tools (telephone contact, electronic mail, messages, blogs, and so on) would help minimize the impact of long-term weight regain (14–16).

Postoperative nutritional management

The guideline reminds us of the important fact that subjects undergoing bariatric surgery should take 60–120 g protein daily to maintain lean body mass during weight loss and long-term maintenance, particularly after malabsorptive procedures. These nutritional measures should be associated with vitamin and mineral supplementation as considered appropriate for each surgery and adjusted based on regular clinical and biochemical monitoring.

The last point in the clinical practice guideline also recommends gradual progression of food consistency from a completely fluid diet in the early stages to a well tolerated solid diet to prevent vomiting, damage to anastomotic sutures, or symptoms related to the dumping syndrome.

Protein intake in the ranges recommended by the panelists is difficult to achieve in procedures with a restrictive component. The setback is that many patients are intolerant to animal proteins, and 30–50% of patients do not take the desirable amounts of protein during the first year after surgery (17, 18). A change in dietary orientation by selecting different protein sources (meat, fish, eggs, legumes with cereals, cheese, tofu...) combined with powder protein supplements may allow for achieving the expected protein intake. Surprisingly, in restrictive procedures (such as SG or RYBG), a low protein intake is not always associated with lean mass loss or with low plasma protein levels during the first year (19). Impact would be different if bypass limbs are longer than 150 cm or if a malabsorptive technique, associated with a more evident risk of protein malnutrition, has been performed.

Vitamin and mineral supplementation after bariatric surgery is well established and, as widely discussed in the consensus document, the potential deficiencies attributable to each type of surgery are well known. In malabsorptive techniques, for example, deficiencies in lipid soluble vitamins are relevant and not always easy to compensate because the patients do not always follow the postoperative recommendations. Thus, it would appear obvious that malabsorptive procedures would not be convenient at centers who cannot monitor the levels of lipid soluble vitamins (A, D, E, and K) or minerals such as zinc, selenium, copper, or other vitamins; thiamine, pyridoxine, or carotenoids, which are so frequently impaired after this type of surgery and require close postoperative monitoring in these patients (20–22). It should also be noted that adequate definition of a deficiency in lipid soluble vitamins requires joint assessment of these with their binding proteins (vitamin A and retinol binding globulin or prealbumin) to estimate the corresponding ratio, as occurs with the vitamin E/cholesterol ratio. Each laboratory should establish its normal ratios in order to more precisely define deficiencies in these lipid soluble vitamins.

Management of diabetes mellitus

Panelists recommend that postoperative glycemic control should consist of achievement of preprandial blood glucose levels <110 mg/dl and postprandial blood glucose levels no >180 mg/dl, to achieve HbA1c values of 7% or less.

Recommendations for moderate glycemic control (140–180 mg/dl) in diabetic inpatients are within those stipulated by the American Diabetes Association (23) and the American College of Physicians (24), and are safer than those based on intensive insulin therapy (with a blood glucose goal of 80–110 mg/dl) because of the high risk of hypoglycemia. These suggested control values should closely be monitored because up to 30% of diabetics undergoing RYGB and BPD may be discharged from the hospital requiring no insulin and be controlled on diet alone or low doses of oral antidiabetics (25). New bariatric procedures intended to achieve higher diabetes resolution rates are currently being tested. While no universal agreement exists about what should be considered as diabetes remission, an expert group recently defined the criteria for partial, complete, and prolonged remission so that all metabolic surgery groups may make comparisons using the same criteria (Table 1) (26).

Bone health

The guidelines recommend that patients undergoing bariatric surgery are monitored every 6 months for calcium, phosphorus, vitamin D, PTH, and alkaline phosphatase levels, and have a bone densitometry (dual-energy X-ray absorptiometry (DEXA)) yearly until adequate control is ensured.

Vitamin D insufficiency and deficiency affects more than 90% of patients with morbid obesity before bariatric surgery, according to studies conducted in Europe, and is usually associated with increased PTH levels above the normal range in more than 40% of subjects (27, 28). Bone mineral metabolism is an essential target before bariatric surgery, but particularly after surgery when calcium and vitamin D absorption mechanisms are more compromised, as occurs in RYGB and BPD. Panelists recommend supplements of calcium

Table 1 Definitions of partial, complete, and prolonged remission in patients with type 2 diabetes undergoing bariatric surgery.

Partial remission
Blood glucose 100–125 mg/dl (5.6–6.9 mmol/l)
HbA1c <6.5%
At least 1 year without drug treatment
Complete remission
Blood glucose <100 mg/dl (<5.6 mmol/l)
HbA1c within normal range
At least 1 year without drug treatment
Prolonged remission
5 years of complete remission

Adapted from Buse *et al.* (26).

(calcium citrate 1200–2000 mg) and vitamin D as ergocalciferol 50 000 IU one to three times per week, which may be increased to 50 000 IU one to three times a day if needed.

In Europe, cholecalciferol is usually preferred to ergocalciferol, as stated in the clinical guideline. Although a similar bioequivalence ($1\text{ }\mu\text{g}=40\text{ IU}$ of vitamin D) has been reported in practice, cholecalciferol is two to three times more potent than ergocalciferol when administered by both the oral and i.m. routes (29, 30). The longer effect of cholecalciferol allows for an improved control of PTH secretion compared with ergocalciferol (31). The higher efficacy and potency of cholecalciferol appears to be related to a greater affinity for the vitamin D binding protein and receptor, and to the fact that cholecalciferol is a preferred substrate for 25-hydroxylation (29). In practice, 1000–2000 IU/day are required to maintain $25(\text{OH})\text{D}_3$ levels higher than 75 nmol/l (30 ng/ml), but post-bariatric surgery patients usually need higher doses to achieve those levels. Since the dose to be administered is related to body weight, a more precise approximation to the total amount to be given may be obtained by the following formula: $\text{dose (IU)}=40\times(75-\text{serum }25\text{-OHD}_3)\times\text{body weight}$ (32), provided weight is $<125\text{ kg}$. With adequate supplementation and monitoring vitamin D and PTH levels and other bone remodeling parameters, a significant negative change in bone mineral density cannot be expected in the midterm (33).

Recent publication by the Institute of Medicine (IOM) of calcium and vitamin D recommendations for the general population raised controversy, because the report concludes that vitamin D levels of 50 nmol/l (20 ng/ml) are sufficient for maintaining adequate bone health, as there is no adequate evidence supporting a role of vitamin D in non-skeletal actions to recommend higher dose (34, 35). Other authors, however, propose a higher cut off point because there is evidence that a vitamin D level of 75 nmol/l (30 ng/ml) improves bone quality and is also associated with lower PTH concentrations (36). The American Association of Clinical Endocrinologists (AACE) also continues to recommend vitamin D levels ranging from 75 to 125 nmol/l (30 to 50 ng/ml) to ensure levels that may have potential non-skeletal benefits (37). In the setting of bariatric surgery, the challenge often is to achieve the control of secondary hyperparathyroidism and compliance with the prescribed treatment, because patients usually show a fair or poor compliance with calcium and vitamin D supplementation. Furthermore, in some patients submitted to more malabsorptive procedures, adequate vitamin D levels ($>50\text{ nmol/l}$ (20 ng/ml)) or significant reductions in PTH levels ($<100\text{ pg/ml}$) are not achieved despite high daily doses of calcium and cholecalciferol.

As expected, other consensus statements published about bariatric surgery include many of the aspects listed in this clinical practice guideline (38), but

guidelines issued in Europe have been more focused on recommendations for indicating bariatric surgery in risk groups than on postoperative follow-up (39, 40).

Unlike in the US, where obesity and bariatric surgery rates are leveling off (41), the expected increase in severe obesity rates in Europe will most likely overwhelm the current capacity of surgical teams unless other non-surgical therapeutic measures are available. As regards prevention, the European Obesity Day was created only 1 year ago to promote awareness of the need to take joint actions at European level with the participation of patients, healthcare professionals, and politicians (42). Increasing use of bariatric surgery is a reality that demands more answers every day and is not free from complications. Therefore, future efforts include preparation of a map of centers of excellence in bariatric surgery in Europe, the need for supporting controlled clinical trials to better assess the aspects discussed in this practice guideline for which a clear response is lacking, such as predictors of long-term weight changes and actions to prevent weight regain, and management of nutritional deficiencies and their impact on quality of life. However, the greatest demand for research revolves around diabetes surgery (aimed at resolution of the disease). The pathophysiological mechanisms involved in the effect of surgery and long-term clinical response should be investigated. National or European registries are needed in the near future to know what is being done in each country according to its healthcare system, to assess the results and complications of each surgical procedure, and to promote research to achieve a deeper understanding of pathophysiological aspects (hormones, cytokines, genes, etc.) to clarify unresolved hypotheses.

Declaration of interest

The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

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