Obesity and Sleep Apnea: Evaluating the Bariatric Surgery Option

A review of available literature

This white paper has been prepared by Ethicon US, LLC, and has not been subject to peer review.
Bariatric surgery is used in the treatment of qualifying obese adult patients for significant long-term weight loss. Individual results following bariatric surgery may vary. Bariatric surgery may be appropriate for some patients and not for others, depending on their specific weight, age, and medical history. Patients and doctors should review all available information on non-surgical and surgical options in order to make an informed treatment decision.

ETHICON manufactures and markets general surgical instruments used in bariatric surgery. The potential benefits discussed are associated with the patient’s weight loss and other metabolic effects following bariatric surgery, not with the use of the instruments. ETHICON is offering this information in good faith as an overview to published literature in this area and a starting point for further research. It is not intended to constitute medical advice or recommendations.
Obesity and Sleep Apnea: Evaluating the Bariatric Surgery Option

Introduction
Obesity, a chronic disease of substantial public health concern in the United States, is now being classified as an epidemic. More than one third of the American adult population, 75 million adults, is classified as having obesity, with 15 million people classified as having severe obesity (a body mass index (BMI) of ≥40 kg/m²). Often, individuals living with obesity suffer from obesity-related health conditions such as type 2 diabetes (T2DM), hypertension, hyperlipidemia, sleep apnea and arthritis. There are over 40 known obesity-related conditions. This is particularly problematic because when BMI increases so does the prevalence of obesity-related conditions. As a result, patients with severe obesity often experience diminished quality of life and increased mortality.

The repetitive apneic state and resultant hypoxia throughout the night, occurring 5 to 30 times or more per hour, may have systemic consequences that increase the likelihood of disease (especially cardiovascular disease), including increased sympathetic tone, pulmonary and systemic hypertension, and cardiac arrhythmias.

The Link between Obesity and Sleep Apnea
Sleep quality is an important factor that impacts daily quality of life. Obstructive Sleep Apnea (OSA) is a common disorder in which you have one or more pauses in breathing or shallow breaths while you sleep. Despite sleep apnea being the most impactful respiratory condition associated with obesity, it tends to be underdiagnosed and undertreated for patients with severe obesity. It is estimated that approximately 77% percent of individuals with obesity experience Obstructive Sleep Apnea (OSA) syndrome and that 60-90% of patients with Sleep apnea also have obesity. The prevalence of OSA is higher with increasing BMI. The incidence of OSA is 12 to 30 times greater in patients with severe obesity versus those without severe obesity. Furthermore, OSA may be experienced by over 50% of patients with a BMI higher than 40 kg/m². Changes in anatomic factors due to increased fat mass also play a role in the development of OSA. For men, neck circumferences 17 inches or greater, and for women, neck circumferences 16 inches or greater, are associated with a higher risk for OSA.

An increase by one standard deviation in BMI is thought to be associated with 4-fold increase in risk of developing OSA.

With obesity anatomical changes such as a reduced lung volume limiting the diaphragms descent, increased lateral pharyngeal wall thickness and fat deposits under the mandible and within the tongue, soft palate, or uvula culminate all can contribute to a narrower airway. These factors increase the likelihood of muscle relaxation and throat closure, leading...
to apnea. The repetitive apneic state and resultant hypoxia throughout the night, occurring 5 to 30 times or more per hour, may have systemic consequences that increase the likelihood of disease (especially cardiovascular disease), including increased sympathetic tone, pulmonary and systemic hypertension, and cardiac arrhythmias. Individuals with an upper obese phenotype may present with snoring, excessive daytime somnolence, fatigue, irritability, and erectile dysfunction.

The Bariatric Surgery Treatment Option for Obesity

Traditional approaches to weight loss, including changes in diet and physical activity, are important for a healthy lifestyle. However, a landmark Swedish study found that on average, a 200-pound patient fighting obesity with diet and exercise alone would only be able to achieve a sustained weight loss of 4 pounds over 20 years. Weight loss resulting from behavioral interventions generally leads to a “starvation response.” The body seeks to defend its body weight by increasing appetite while lowering the metabolism. This limits weight loss and promotes weight regain.

Bariatric surgery helps to reset the body’s ability to effectively manage weight by altering the complex relationship the body has with food and its metabolism. New research indicates that with procedures that alter the stomach or intestine, surgery has metabolic and hormonal impacts that enable the body to regulate itself down to a lower set point for body fat. Following bariatric procedures such as sleeve gastrectomy and gastric bypass, the digestive tract is altered in a way that decreases appetite due to modification of gastrointestinal (GI) hormone levels including ghrelin, glucagon-like peptide-1, peptide YY, cholecystokinin, amylin, leptin, insulin, and adiponectin. Many patients experience a decrease in hunger, increased satiety, and even healthier food preferences.

Bariatric surgery is the most effective long-term treatment option for qualifying patients with obesity. It has been shown to improve associated conditions through weight loss, or in some cases such as T2DM, through metabolic processes that can complement or replace the need for other treatments. According to the American Heart Association Scientific Statement from 2011, “It is clear that obesity surgery today offers the only effective long-term treatment option for the severely obese patient.” Bariatric surgery has been shown to provide the greatest amount of excess weight loss with greater than 45% one year post surgery compared to 10% or less for lifestyle and pharmacological treatments. Obesity-related health conditions have been resolved in up to 80% of patients. Approximately 179,000 bariatric procedures were performed in 2014 in the US.

Sleep Apnea Improvements with Weight Loss Post Bariatric Surgery

Bariatric surgery has been identified by medical societies such as the Academy of Nutrition and Dietetics and the American Heart Association as the most successful therapy for severe obesity. Although full remission of OSA through weight loss procedures is not entirely typical, the severity of the condition often improves. Decreases in the degree of OSA (50% reduction) have been shown following weight loss of as little as 10% using both medical and surgical interventions. In a systemic review of post-surgery patients, almost 90% of patients experience resolution or improvement of their sleep apnea. In another study conducted four years after gastric banding, sleep apnea was resolved in 75% of patients. Pulmonary disorders, such as chronic obstructive pulmonary disease and OSA, have been shown to decrease significantly after bariatric surgery, from 57.7% to 16.2% at 3 years after bariatric surgery.

A weight reduction of 31% to 72.5% has been shown in studies of severely obese patients who have undergone weight loss surgical procedures. This weight reduction was associated with a decrease in respiratory disturb index of 89% to 98%, improved nocturnal oxyhemoglobin saturation, improved subjective daytime somnolence, improved sleep continuity and architecture (including increased total sleep time, percentage of slow wave sleep, and percentage of rapid eye movement sleep), and decreased cardiac dysrhythmias.

A significant reduction in apnea-hypopnea index in patients (n=342) following bariatric surgery was shown in a meta-analysis by Greenburg and colleagues. In a separate meta-analysis by Sarkhosh and colleagues, 11% of patients (n=3,586) undergoing bariatric surgeries (including laparoscopic sleeve gastrectomy, laparoscopic adjustable gastric banding, Roux-en-Y gastric bypass, and studies with mixed procedures) experienced sleep apnea before surgery. After surgery sleep apnea was resolved in 63% of patients and improved in 31%. On average, 88.5% of

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patients experience improvement or resolution in their sleep apnea, which further elucidates the profound efficacy of bariatric surgery in improving obesity-related conditions.26

### Presence of sleep apnea in patients with obesity (n=3,586)24

<table>
<thead>
<tr>
<th>Presence of sleep apnea</th>
<th>Pre surgery</th>
<th>Presence</th>
<th>11%</th>
<th>394</th>
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<tbody>
<tr>
<td>Presence of sleep apnea in the 11% of patients with obesity post bariatric surgery</td>
<td>Resolved</td>
<td>63%</td>
<td>284</td>
<td></td>
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<tr>
<td>Improved</td>
<td>31%</td>
<td>122</td>
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Failure to recognize and treat sleep apnea may make weight-loss interventions much less successful and predispose patients to increased cardiovascular risk.27 Untreated sleep apnea is associated with an increased risk of stroke, hypertension, diabetes, arrhythmias, cardiomyopathy (enlargement of the muscle tissue of the heart), congestive heart failure, and heart attacks. It also affects concentration ability and energy levels that can affect school, work, and family life.

### Differentiating Bariatric Surgery from Other Weight Loss Treatment Options

Traditional approaches to weight loss, including changes in diet and physical activity, are important for a healthy lifestyle; however, these interventions generally fail to reset a patient's appetite and metabolism in a manner that would allow the maintenance of a lower body weight. Weight loss resulting from behavioral interventions generally leads to a “starvation response”, whereby the body seeks to defend its body weight by increasing appetite while reducing metabolism and spontaneous physical activity.14 This limits weight loss and promotes weight regain.14 Therefore, an ideal weight loss intervention not only promotes initial weight loss but induces a physiological change that allows for a long-term weight-loss maintenance.

Bariatric surgery remains the most effective long-term treatment for severe obesity and has been shown to improve associated conditions through metabolic processes that can complement or replace the need for other treatments.17 In 2014 179,000+ surgeries were completed in the U.S.17 Evidence suggests that the attenuation of counter-regulatory effects (i.e., increased appetite, reduced metabolic rate) observed following diversionary bariatric procedures and sleeve gastrectomy may be caused by a physiological change generally not seen with dietary caloric restriction alone.28 Following bariatric surgery, decreased appetite may also be influenced by modification of gastrointestinal (GI) hormone levels including ghrelin, glucagon-like peptide-1, peptide YY, cholecystokinin, amylin, leptin, insulin, and adiponectin.28 Altered GI signals may also counteract the environmental effects of the continuously changing chemical compositions of foods, including non-natural additives in processed foods and absence of important nutrients (e.g., fiber, phytochemicals, and other trace compounds).29 In tandem with regulatory central nervous system changes, overall food intake is decreased, the physiological set point for fat mass is reset to a level closer to normal, and glucose homeostasis is maintained.29

### Cost Effectiveness of Bariatric Surgery

Following bariatric surgery, patients may have substantially lower costs associated with reduced medications and a reduced interaction with all levels of the healthcare system as their obesity-related conditions improve.31 According to the American Journal of Managed Care (AJMC), a peer-reviewed journal on health outcomes research, health insurers recover their costs for bariatric surgery in about two years for laparoscopic surgery and in about four years for open surgery.32 The analysis covered six months of pre-surgical evaluation and care, the surgery itself, and up to five years of post-surgical care. Bariatric surgery appears to be a clinically effective and cost-effective intervention for moderately to severely obese people compared with non-surgical interventions.
**Bariatric Surgery Risks**

All surgeries have risks, such as adverse reactions to medications, problems with anesthesia, problems breathing, bleeding, blood clots, inadvertent injury to nearby organs and blood vessels, even death. According to outcomes data from Bariatric Surgery Centers of Excellence, bariatric surgery has an overall mortality of about 0.1%, which is less than cholecystectomy (0.7%) and hip replacement (0.93%) surgeries. The success of bariatric surgery is highly correlated with the experience of both the surgeon and the health center.

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<th>Mortality Rate for Surgical Procedures</th>
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<tr>
<td>Bariatric Surgery</td>
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<td>0.1%33</td>
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The overall likelihood of bariatric surgery major complications is 4.3%. The risk for serious complications depends on the type of bariatric surgery, the patient’s medical condition, and age, as well as the surgeon’s and anesthesiologist’s experience. General risks associated with bariatric surgery include a failure to lose weight, nutritional or vitamin deficiencies, inflammation of the gallbladder, gallstones, dilated pouch, dysphagia, GERD, incisional hernia, malnutrition, and weight regain. Bariatric surgery may also cause changes to the autonomic nervous system, specifically to the processes that regulate energy balance and metabolic function. While these changes may help to sustain a lower weight set point, they also could induce changes to circulating bile acids, distribution of bacteria in the gut microbiota, and altered vagal and sympathetic neural activity.

Each type of bariatric surgery is associated with its own risks. Risks related to gastric bypass may include nutrient deficiency, anastomotic stenosis, leak or fistula, marginal ulcer/gastritis and stenosis, bowel injury or obstruction, nausea/vomiting, internal/incisional hernia, and pouch dilation. Sleeve gastrectomy may be associated with gastric leak, intra-abdominal abscess, pulmonary embolism, delayed gastric emptying, splenic injury, stricture, and late cholelithiasis. Gastric banding risks can include gastric perforation, port rotation or leak, band or port-site infection, band obstruction, malposition, nausea/vomiting, and band erosion.

**Identifying Candidates for Bariatric Surgery**

Bariatric Surgery can be considered for weight reduction in patient that are 18 years of older with a BMI of 40 or ≥35 with an obesity related condition such as Sleep Apnea. Bariatric surgery is a viable alternative when diet exercise and other behavioral interventions are not effective. Bariatric surgery has been show to produce +25% weight loss at 5 years.

Since bariatric surgery is a life changing event it is important to ensure patients are well informed, motivated and cognizant of the operative risk. It is also important to advise patents on the need for long term follow up. Clinical evidence suggests that the overall risks of severe obesity often outweigh the risks for bariatric surgery. Bariatric surgery results may vary and surgery may or may not be appropriate for particular patients depending on their specific age, weight and medical history. Patients and doctors should review all available medical information on surgical and non-surgical options in order to make an informed decision.

**How to Refer Patients**

After discussing a patient’s candidacy for surgery, it is important to emphasize behavioral and psychological readiness for the procedure, discuss benefits and possible complications, manage post-operative expectations, as well as emphasize the long-term responsibilities associated with bariatric surgery. Additionally, encourage them to check with their current health insurance plan to determine specific requirements for surgery and proactively provide them with the necessary documentation that will be required for their surgical consultation. These documents may include weight loss attempts, medical records, and a pre-surgery health evaluation.

**Additional Resources**

Online resources are available at ethicon.com/obesity, or ASMBS.com for those healthcare professionals interested in learning more about bariatric surgery or realize.com for patients who are interested in finding a surgeon for a consultation.

Patients can receive more information and answers to common questions about obesity and bariatric surgery by calling Ethicon’s Obesity Patient Hotline at 1 (855) 273-2549.
References

8. What is Sleep Apnea? NIH. http://www.nhlbi.nih.gov/health/health-topics/topics/sleepapnea/