healthcare RISK MANAGER

Volume 10, Number 22, 1st Quarter 2004

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Bariatric Surgery: Do the risks outweigh the benefits?

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Bariatric surgery procedures are performed with increasing frequency each year in the United States. More than 45,000 patients had some type of surgery for obesity in 2001, 65,000 in 2002 and more than 100,000 in 2003. Exponential increase is expected over the next 10 years along with a growing number of facilities offering these services. That growth may have influenced some physicians to proceed into this area without adequate training and safeguards in place.

To date, MAG Mutual Insurance Company has incurred $3,838,071 for 24 bariatric surgery claims. Most of these claims have been filed in the last two years. Frequent postoperative complications included gastric leakage, blood clots, respiratory compromise and wound infection. Although most of these claims resulted from recognized complications, the allegations which brought the physicians into the cases were usually failure to timely recognize complications and intervene.

From an actuarial standpoint, we expect that increased numbers of bariatric procedures will produce an increase in associated complications. Consequently, we are likely to see a rise in the number of bariatric surgical claims.

Morbid obesity is a potentially deadly condition on its own and can cause significant

Closed Claim Abstract

CASE #1

In 1997 a 35-year-old, 325-lb woman flew to a distant city to have an open Roux-en-Y procedure because there were no local surgeons who performed bariatric procedures. The procedure and hospitalization went well, and the patient was released after five days to be followed by her local surgeon. She experienced nausea and vomiting after returning to her home. The local general surgeon treated her with phenergan which relieved the nausea. She presented to the Emergency Department the next day with low-grade fever and nausea. Again she was treated and sent home. That night she was transported to the Emergency Department in shock. The shock resulted from sepsis and peritonitis caused by a leaking suture line. The patient died. A case was brought against the local surgeon, and the Emergency Department physician who allegedly did not recognize the known complication. This case points out the danger of taking over postoperative care when not familiar with the procedure or its complications.

CASE #2

A 30-year-old man had a laparoscopic Roux-en-Y procedure at a hospital's newly opened bariatric surgery clinic. The night after surgery he developed leg pain which was documented in the medical record, but not reported to the attending surgeon. About 6:00 AM he arrested. Resuscitation was successful, but the patient suffered moderate brain damage and is permanently disabled. Physicians and patients are at risk when support staff is inadequately trained.

CASE #3

A 47-year-old hypertensive diabetic woman, weighing 400 lbs underwent laparoscopic adjustable gastric banding. She did well initially, but soon became noncompliant with her dietary restrictions. She developed erosion of the stomach and had to have corrective surgery and subsequent removal of the device. She sued her bariatric surgeon alleging that she was not properly informed and in fact was not a good candidate for surgery. This case illustrates the need for informed consent, extensive informed preoperative screening and psychological evaluation before surgery.

comorbidities.[1] Patients who are morbidly obese (BMI>40) have a significantly increased risk of dying prematurely than their normal weight contemporaries. Since nonsurgical programs have very poor success in treating patients in the higher BMI classes, patients with a BMI>40 are potential candidates for weight loss surgery. Patients with BMIs between 35 and 40 may be considered candidates for surgery if they have a comorbidity caused by obesity. A BMI of 35-40 roughly corresponds to 100 pounds more than a patient's ideal body weight.

Despite development of safer procedures there are still serious risks. Gastric bypass, particularly the Roux-en-Y, is the most frequently performed bariatric surgery procedure in the United States. However, the laparoscopic adjustable gastric band (lap-band) is gaining prevalence. The band was FDA approved in 2001[2] and complication rates and long-term problems at this early stage seem to be lower with the lap-band procedures.

Health benefits are most often sited as the deciding factor for the surgery, however, post-bypass interviews have documented that many patients are highly influenced by the cosmetic benefits of the surgery.

The preoperative period should be a time for a comprehensive evaluation of every patient contemplating surgery. The patient should be evaluated not only by surgical specialists, but by psychologists, dietitians, physical therapists and the postoperative care team.

The decision process must be made methodically. During this process, displaying photographs of now slim and beautiful patients may overshadow or minimize very serious considerations. It is imperative that the patient understands the procedure, the life-altering changes that will occur and the potential for risks both known and unknown. The patient must further understand the lifelong commitment to health maintenance, special nutritional needs, the possibility of restrictions on child bearing and the potential to regain weight. Additional long-term complications, including malnutrition, vitamin/nutritional deficiencies and stenosis of the stomach opening can occur. Patients should understand that bariatric surgery is still in the developmental stages.[3] **The bariatric surgery informed consent process must be extremely thorough.** Some practices even require their patients to read extensive literature about the procedure and successfully complete a competency exam as part of the informed consent process before proceeding with the surgery.

"It is imperative that the patient understands the procedure, the life-altering changes that will occur and the potential for risks both known and unknown."

A *Macon Telegraph* article, "Gastric-bypass surgery offers life-changing weight loss, but at what risk?" brought attention to the growing number of bariatric procedures performed in Georgia each year and highlighted the number of deaths following these procedures. It goes on to say that eight patients, as of the publication date, died in Georgia hospitals following gastric bypass surgery in recent years, seven of them since June 2002 in four different hospitals.[4]

Bariatric surgical procedures are defined by two types, restrictive and malabsorptive. Both types require extensive follow-up to monitor potential serious complications and operative failure.[5] Obesity surgery attempts to promote weight loss by limiting the amount that the stomach can hold, thus reducing food intake and/or causing food to be poorly digested and absorbed. Restrictive surgeries create a small pouch at the top of the stomach where food enters. Malabsorptive surgeries cause food to bypass much of the absorptive area of the intestinal track.[6]

In an effort to improve quality, the American Society of Bariatric Surgeons (ASBS) began tracking procedure and complication rates. They estimate that mortality rate for gastric-bypass (most often open Roux-en-Y) is about 1 in 200 (includes only deaths occurring within 30 days of surgery) as compared with 1 in 42 for heart bypass surgery. The mortality rate for adjustable gastric banding is estimated to be 1 in 2000.[7] Improved techniques have increased the overall short-term survival rate, however, morbidly obese patients are additionally at a greater risk than others of postoperative complications. (See 2nd Quarter Risk Management Newsletter, 2002)

In 2003 JAMA Archives of Surgery published an assessment of complication rates after open and laparoscopic gastric bypass. The study reviewed 3,464 cases and showed that the type and frequency of complications after open and laparoscopic Roux-en-Y gastric bypass are different.[8] Laparoscopic Roux-en-Y gastric bypass was associated with a decrease in the frequency of iatrogenic splenectomy, wound infection, incisional hernia and mortality. However, with lap Roux-en-Y there was an increase in the frequency of early and late bowel obstruction, gastrointestinal tract hemorrhage and narrowing of the stomach opening. No significant differences in the frequency of anastomotic leak, pulmonary embolism or pneumonia were seen. International studies with as long as 10 years of follow-up have shown serious complications to be less likely after the lap-band, but as yet have not reached definitive conclusions. The safety, efficacy and long-term consequences of bariatric surgery for children and teenagers is as yet unknown and is considered experimental.

Surgeons who consider performing bariatric surgery procedures should look carefully at their ability to provide

adequate screening, surgical skills, counseling, nutritional support and long-term surveillance by the bariatric team. If any one of these criteria is in doubt, the surgeon should acknowledge that the patient may experience increased risks (and the surgeon increased liability).

Clinical management companies have emerged to provide training, preoperative screening, dietary management, preparation, postoperative support and long-term surveillance of patients. Companies such as Inamed® provide these services and train surgeons. They also offer data compilation and analysis as well as presentations, congresses and professional "roundtables".[9] Others such as LivLite (http://www.livlite.com/programs/index.cfm) and U.S. Bariatric Management Institute (http://www.usbmi.com/) can be accessed through their websites.

Presently no specific surgical training is mandated and any general surgeon can legally perform bariatric surgery. The American Board of Bariatric Medicine recommends that all surgeons receive training and gain competence by assisting an experienced bariatric surgeon, and they offer a certification examination. Specialized laparoscopic training is recommended even if the surgeon is experienced with open bypass procedures. Bariatric surgery education ranges from two-day classroom lectures to a 3-14 day proctorship; some at experienced bariatric surgery centers, others at a dry lab and with cadavers. Inamed, the manufacturer of the lap-band, provides training on the lap-band procedure as a prerequisite to purchasing the device.

Teamwork between patient and medical providers is imperative. All members of the bariatric team must be prepared to meet the special needs of these patients. Lifelong medical surveillance is a must because all procedures carry some risks.

In summary, it is important to develop a program that will improve patient outcomes and reduce your exposure to liability. Remember these procedures should be considered permanent and require a serious long-term commitment from you, the bariatric surgeon, and your patients.

1) MAG Mutual Risk Management Newsletter. Volume Eight #16 2002
2) FDA Letter to Ellen Duke, CEO BioEnterics June 5, 2001
3) American Board Of Bariatric Medicine @ Http://Abbmceertification.Org
4) Macon Telegraph on Sun, Feb. 09, 2003, "Gastric-bypass surgery offers life-changing weight loss, but at what risk?" by Wayne Crenshaw
5) Http://www.Lapsurgery.Com/Sages.Htm
6) Http://www.Lapsurgery.Com/Asbs.Htm
7) LifeShape.net
8) Gastric Banding Arch Surg. 2003;138:957-961.
Complications after Laparoscopic Gastric Bypass A Review Of 3464 Cases
Yale D. Podnos, MD, MPH; Juan C. Jimenez, MD; Samuel E. Wilson, MD; C. Melinda Stevens, BS; Ninh T. Nguyen, MD
9) http://www.inamed.com/products/obesity/us/clinician/bps/index.html

"Don't Get Stuck: Avoid Needlestick Injuries in Your Office"

By Reid A. Pearlman, JD, Risk Management Consultant

The Centers for Disease Control estimate that 600,000 to 800,000 needlestick/sharp injuries (NSIs) occur nationwide each year.[1] Of those injuries, half occur in outpatient settings and about 50,000 involve doctors.[2] MAG Mutual's own data reveals that NSIs are our leading cause of workers' compensation claims among health-care workers. While usually minor, needlestick incidents can be disastrous. In fact, national studies demonstrate that nearly 20 cases of HIV, 1,000 cases of Hepatitis C and 400 cases of Hepatitis B are contracted by outpatient staff each year.[3] Excessive NSIs can also disrupt office morale and efficiency, and even prompt an Occupational Health and Safety Administration (OSHA) investigation.

Thankfully, some 75 percent of all NSIs are preventable. We know a great deal about how and when injuries occur. About 30 percent occur during use, when a needle or sharp is inserted, manipulated or withdrawn from a patient. Half occur after a device has been used, but before disposal. The remaining 20 percent happen during disposal. [4]

We have also learned about **why** injuries occur. For instance, it is nearly impossible to prevent an accident during administration, even with a 'safe' device, because incidents are usually caused by an unanticipated, sudden patient movement. Fortunately, the remaining injuries are largely avoidable through use of innovative safety devices. With more than 1,000 safety systems in the market-place, many good options abound.

Practices should consider several factors when evaluating safety devices and features, including user safety, patient safety and comfort, ease of use, training and compatibility with existing equipment.[5] Indeed, the best devices include safety features that do not require user activation. They also clearly indicate whether the safety feature is activated and do not allow deactivation so that protection

continues through disposal. Devices must be reliable and support effective patient care.

OSHA's Bloodborne Pathogens Standards require every practice to have an "exposure control plan". This formal, written plan mandates the use of "universal precautions" to limit exposure to contagious diseases, "engineering and work practice controls" to promptly incorporate beneficial techniques and advanced devices into the workplace, and "personal protective equipment" to prevent bodily fluids from reaching healthcare workers.[6]

Technological innovation is an important part of the revised 2001 OSHA Standards. The updated guidelines broadened the definition of engineering controls to include "injury protection and needleless systems". These high-tech administration systems include "jet injectors", transdermal methods (like microneedles and patches) and transmucosal media (such as oral, nasal and aerosol products). OSHA standards require annual employer review of appropriate commercially available and effective safer devices and require solicited input of non-managerial employees to identify, evaluate and select effective engineering and work practice controls. This final mandate recognizes the valuable insight of those who are directly responsible for patient care and therefore, bear the greatest risk of infection.

Whatever approach you decide to take, everyone wins by improving sharps safety. With solutions readily available and considering the dire consequences of seroconversion, prevention of needlestick injuries demands our utmost attention.

1) "Health & Safety Management for Medical Practices", Linda Chaff, 2002, American Medical Association, publisher, pg. 37

2) "AMA Aims to Cut Needlestick-Spread Disease", Victoria Stagg Elliott, American Medical News, Jul. 3, 2000

3) "Sharps Injury Information", International Sharps Injury Prevention Society, found at www.isips.org

4) "Occupational Safety: Selected Cost and Benefit Implications of Needlestick Prevention Devices", GAO Study No. 01-60R, Nov. 17, 2000

5) "Sharps Safety and Needlestick-Prevention Device Assessment Form", Healthcare Risk Control, ECRI, Vol. 4, No. 9.1, Nov. 2002.

6) 29 CFR 1910.1030.

MAG Mutual does not presume to establish any standard of care or establish rules for the practice of medicine. The particular patient-care strategies or range of patient-care strategies mentioned in this newsletter should be tempered by the physician's judgment. This publication is produced to inform you of issues relating to medical professional liability insurance and other matters of importance to physicians. Material given in this newsletter does not constitute legal advice or opinion. If you have questions in any of the areas discussed in this publication, you should seek a qualified legal opinion.

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