

the Reporter

Please see page 12 for an important risk alert.

PIAA releases national closed claim data

The following is a compilation of medical malpractice claim data from 1985 to 2003, submitted by more than 40 member companies of the Physician Insurers Association of America (PIAA).

Twenty-four medical specialties are represented in the 185,120 claims and suits reported to the PIAA. This report highlights the three most prevalent medical misadventures per specialty followed by the three most prevalent patient conditions per specialty. These conditions are those presented to the physician at the time of the alleged incident. What follows is not meant to be an in-depth analysis, but a snapshot of claims by specialty.

Anesthesiology

Most prevalent medical misadventures

- No medical misadventure*
- Improper performance
- Intubation problems

Most prevalent patient conditions

- Back disorders, including lumbago, sciatica
- Pregnancy
- Brain damaged infant

Cardiovascular diseases

Most prevalent medical misadventure

- Errors in diagnosis
- No medical misadventure
- Improper performance

Most prevalent patient conditions

- Coronary atherosclerosis
- Myocardial infarction, acute
- Chest pain, not further defined

PIAA comparative claim analysis (1985-2003)

Specialty group	Closed claims	% claims paid	Average indemnity	Total indemnity
Obstetric and gynecologic surgery	25,594	36.06%	\$254,033	\$2,344,474,968
Internal medicine	24,791	26.56%	\$186,945	\$1,231,029,689
General and family practice	21,483	34.57%	\$144,847	\$1,075,631,594
General surgery	20,157	35.47%	\$162,002	\$1,158,151,306
Orthopaedic surgery	18,157	29.62%	\$151,495	\$814,742,158
Radiology	10,473	29.78%	\$165,851	\$517,290,237
Plastic surgery	7,424	27.06%	\$103,938	\$208,812,363
Anesthesiology	7,232	33.67%	\$195,631	\$476,360,297
Ophthalmology	5,556	29.27%	\$164,970	\$268,241,670
Pediatrics	5,504	29.05%	\$246,668	\$394,421,759
Cardiovascular and thoracic surgery	5,297	24.11%	\$201,205	\$256,938,973
Urologic surgery	4,536	30.07%	\$153,205	\$208,971,463
Neurosurgery	4,411	28.61%	\$286,481	\$361,539,128
Otorhinolaryngology	3,047	32.20%	\$184,574	\$181,066,940
Cardiovascular diseases (nonsurgical)	3,014	18.58%	\$236,915	\$132,672,413
Neurology (nonsurgical)	2,983	20.52%	\$289,513	\$177,181,707
Emergency medicine	2,901	28.61%	\$168,567	\$139,910,613
Dermatology	2,191	29.90%	\$118,301	\$77,487,035
Gynecology	2,143	32.10%	\$134,646	\$92,636,174
Psychiatry	1,876	22.17%	\$157,976	\$65,717,852
Radiation therapy	1,757	26.24%	\$231,929	\$106,919,125
Other nonsurgical specialties*	1,676	23.21%	\$158,381	\$61,610,354
Gastroenterology	1,610	19.01%	\$170,115	\$52,055,199
Pathology	1,307	28.69%	\$228,159	\$85,559,763
Totals	185,120	30.68%	\$183,961	\$10,489,422,780

* includes podiatry, physical and rehabilitative medicine and hospitalist.

Cardiovascular and thoracic surgery

Most prevalent medical misadventures

- Improper performance
- No medical misadventure
- Errors in diagnosis

Most prevalent patient conditions

- Coronary atherosclerosis
- Myocardial infarction, acute
- Aortic aneurysm

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* No medical misadventure occurs when there is no allegation of inappropriate medical conduct, but the claim has legal merit because of associated issues, such as problems with medical records, consent issues, communication between physicians, vicarious liability, product liability, etc.

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Dermatology

Most prevalent medical misadventures

Improper performance
No medical misadventure
Errors in diagnosis

Most prevalent patient conditions

Malignant neoplasms of the skin
Acne
Dyschromia

Emergency medicine

Most prevalent medical misadventures

Error in diagnosis
No medical misadventure
Improper performance

Most prevalent patient conditions

Myocardial infarction, acute
Appendicitis
Chest pain, not further defined

Gastroenterology

Most prevalent medical misadventures

Errors in diagnosis
Improper performance
No medical misadventure

Most prevalent patient conditions

Regional enteritis, colitis
Symptoms involving abdomen, pelvis
Malignant neoplasms of the colon, rectum

General surgery

Most prevalent medical misadventures

Improper performance
No medical misadventure
Errors in diagnosis

Most prevalent patient conditions

Calculus of gallbladder with acute cholecystitis, without mention of obstruction
Disorder of the gallbladder, esc. cholecystitis calculus
Inguinal hernia

General and family practice

Most prevalent medical misadventures

Error in diagnosis
No medical misadventure
Improper performance

Most prevalent patient conditions

Obesity
Myocardial infarction, acute
Diabetes

Gynecology

Most prevalent medical misadventure

Improper performance
Errors in diagnosis
No medical misadventure

Most prevalent patient conditions

Pregnancy
Benign neoplasms of uterus
Malignant neoplasms of the female breast

Internal medicine

Most prevalent medical misadventures

Errors in diagnosis
No medical misadventure

Improper performance

Most prevalent patient conditions

Myocardial infarction, acute
Malignant neoplasms of the bronchus, lung
Diabetes

Neurology — nonsurgical

Most prevalent medical misadventure

Errors in diagnosis
No medical misadventure
Improper performance

Most prevalent patient conditions

Back disorders, including lumbago, sciatica
Displacement of intervertebral disc
Cerebrovascular accident

Neurosurgery

Most prevalent medical misadventure

Improper performance
No medical misadventure
Errors in diagnosis

Most prevalent patient conditions

Displacement of intervertebral disc
Back disorders, including lumbago, sciatica
Fracture of vertebral column

Obstetric and gynecologic surgery

Most prevalent medical misadventure

Improper performance
No medical misadventure
Errors in diagnosis

Most prevalent patient conditions

Brain damaged infant
Pregnancy
Admission/office treatment for sterilization

Ophthalmology

Most prevalent medical misadventure

Improper performance
No medical misadventure
Errors in diagnosis

Most prevalent patient conditions

Cataracts
Retinal detachments, defects
Glaucoma

Orthopaedic surgery

Most prevalent medical misadventures

Improper performance
No medical misadventure
Errors in diagnosis

Most prevalent patient conditions

Fracture of the femur
Fracture of the tibia or fibula
Generalized or localized osteoarthritis

Otorhinolaryngology

Most prevalent medical misadventure

Improper performance
No medical misadventure
Errors in diagnosis

Most prevalent patient conditions

Sinusitis
Deviated nasal septum
Diseases of the upper respiratory tract

Pathology

Most prevalent medical misadventure

Errors in diagnosis

No medical misadventure

Improper performance

Most prevalent patient conditions

Malignant neoplasms of the cervix
Malignant neoplasms of the female breast
Malignant neoplasm

Pediatrics

Most prevalent medical misadventure

Errors in diagnosis
No medical misadventure
Improper performance

Most prevalent patient conditions

Brain damaged infant
Meningitis
Routine infant or child health check

Plastic surgery

Most prevalent medical misadventures

Improper performance
No medical misadventure
Failure to communicate/instruct patient

Most prevalent patient conditions

Desire for plastic surgery
Congenital anomaly of the skin, integument
Dyschromia

Psychiatry

Most prevalent medical misadventure

No medical misadventure
Failure to supervise/monitor case
Medication errors

Most prevalent patient conditions

Depressive disorder, not further defined
Neurotic disorder, not further defined
Schizophrenia

Radiation therapy

Most prevalent medical misadventure

Errors in diagnosis
No medical misadventure
Improper performance

Most prevalent patient conditions

Symptoms involving abdomen, pelvis
Chest pain, not further defined
Malignant neoplasms of the female breast

Radiology

Most prevalent medical misadventures

Errors in diagnosis
No medical misadventure
Improper performance

Most prevalent patient conditions

Malignant neoplasms of the female breast
Malignant neoplasms of the bronchus, lung
Neoplasm of the breast, unknown if malignant or benign

Urologic surgery

Most prevalent medical misadventure

Improper performance
No medical misadventure
Errors in diagnosis

Most prevalent patient conditions

Calculus of kidney, ureter
Malignant neoplasms of the prostate
Disorder of the penis

risk management consult

Q. My practice is small, but I have patients who do not speak English. Am I required to provide interpreters and to pay their fees?

Answer: According to the Office for Civil Rights (OCR), any entity receiving federal reimbursement from Medicare or Medicaid is responsible for ensuring effective oral and written communication with program beneficiaries who have Limited English Proficiency (LEP).

You can take several steps to meet this obligation to LEP patients, and providing interpreters at no cost to the patient is one option. Visit OCR's website for more information — www.hhs.gov/ocr/lep/guide.html.

Q. I have heard that the TSBME will implement regulations on the use of lasers. Is this true? If so, where do I find the regulations?

Answer: Effective December 1, 2004, physicians must comply with the TSBME regulations regarding the use of lasers for ablative and non-ablative treatments. Review section 193.11 on the TSBME website at www.tsbme.state.tx.us/rules/rules/193.htm#19311.

Q. I am a family practice physician and see many patients with decreased vision and cognitive changes that may affect their ability to drive. Do I have a responsibility to report these patients to the Department of Public Safety?

Answer: The Texas Statutes Health & Safety Code, Chapter 12: Powers & Duties of Texas Department of Health, section 12.096 states:

(a) A physician licensed to practice medicine in this state **may** [emphasis added] inform the Department of Public Safety of the State of Texas or the medical advisory board, orally or in writing, of the name, date of birth, and address of a patient older than 15 years of age whom the physician has diagnosed as having a disorder or disability specified in a rule of the Department of Public Safety of the State of Texas.

(b) The release of information under this section is an exception to the patient-physician privilege requirements imposed under Section 159.002, Occupations Code.

Added by Acts 1995, 74th Legislature, chapter 165, section 9, effective Sept. 1, 1995. Amended by Acts 2001, 77th Legislature, chapter 1420, section 14.768, eff. Sept. 1, 2001.

Q. What are the requirements for retention of medical records for physicians in Texas?

Answer: The records of adults (those 18 years of age and older) must be retained for a minimum of seven years from the date of the last encounter. The records of minors (those under age 18) must be kept for at least seven years from the date of last encounter or until the patient is 21, whichever is longer. The records of deceased patients should be kept for a minimum of two years. Hospitals are required to keep records for 10 years and physicians may choose to retain their records for 10 years as well.

Q. When I order labs or other tests for my patients, I inform them they need to call in two weeks for the results. I document this directive in the encounter note. Since I put the responsibility on the patient to call, do I have any liability?

Answer: Informing the patient to contact the practice and documenting that action is good in most circumstances. However, should the patient fail to follow through and experience an adverse outcome as a result of failure to diagnose and treat in a timely manner, the liability would most likely be shared. A consistent tracking process for follow up on all labs and tests ordered, verification of receipt of reports, and documentation of patient notification is advisable and may serve to diminish the risks inherently involved.

Q. In the age of HIPAA, what is the best way to thank patients for recommending the practice to a family member, friend, or colleague?

Answer: Send a note of thanks if you wish, but do not identify the referred patient. To avoid a breach of confidentiality, sample wording may include: "It is always a compliment when a patient refers someone to us for care. Please accept my sincere thanks."

Q. I may be the only physician without a computer and internet access, but a colleague told me the TSBME adopted a definition of a medical record. Will you share it with me?

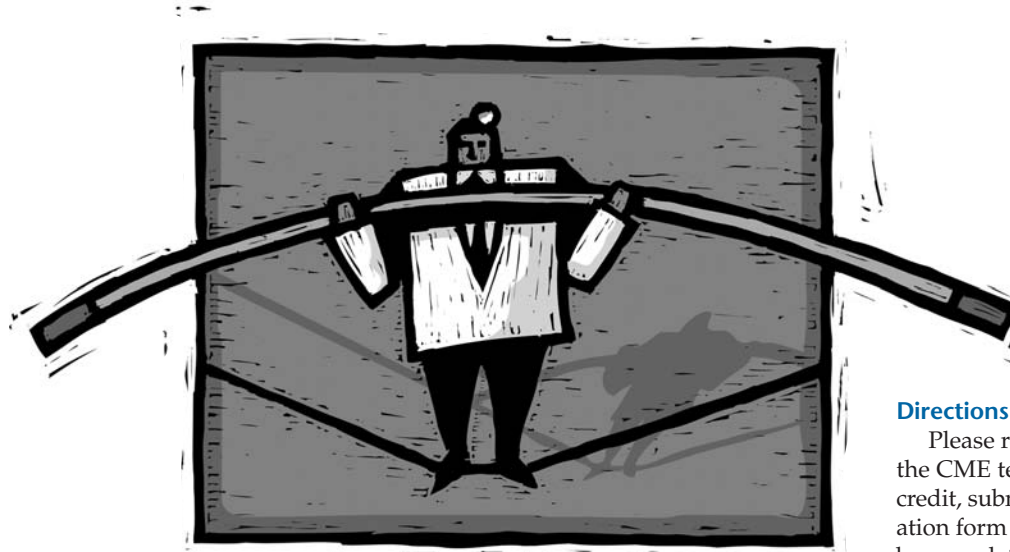
Answer: In the September 5, 2003, issue of the *Texas Register*, the TSBME adopted a definition of medical records that establishes standards for the content of medical records. Under the regulation, an "adequate medical record" should contain 1) documentation of each patient encounter (including reason for the encounter, history and physical, test results, diagnosis, plan of care, and date and legible identity of provider); 2) past and present diagnoses so as to be accessible to the treating or consulting physician; 3) rationale for and results of diagnostic tests and ancillary services; 4) patient's response to treatment; and 5) relevant risk factors.

TSBME's rule also requires that any amendments to the medical records be clearly marked, and that there be adequate documentation in the medical record to support the billing codes used by the physician. The latter requirement highlights TSBME's authority to perform audits of physician billing if there is a complaint of improper billing practices.

Please email your risk management consult questions to barbara-rose@tmlt.org.

A balancing act

evaluating the liability risks of bariatric surgery



Objectives

At the conclusion of this activity, the physician will be able to:

1. Discuss the eligibility criteria for the surgical treatment of obesity.
2. List current bariatric surgical procedures and their reported morbidity and mortality rates.
3. Identify risk management issues for surgeons and other physicians involved in the care of post-bariatric surgery patients.

Course author

Laura Brockway is a senior communications and advertising representative at TMLT.

Disclosure

Laura Brockway has no commercial affiliations/interests to disclose related to this activity.

Target audience

This one-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

CME credit statement

TMLT is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

TMLT designates this educational activity for a maximum of 1 category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Ethics statement

This course has been designated by TMLT for 1 hour of education in medical ethics and/or professional responsibility.

Directions

Please read the entire article and answer the CME test questions. In order to receive credit, submit the completed test and evaluation form to TMLT. All test questions must be completed. Please print your name and address clearly. Allow four to six weeks from receipt of test and evaluation form for delivery of certificate.

Estimated time to complete activity

It should take approximately one hour to read this article and complete the questions.

Release/review date

This activity is released on December 1, 2004, and expires on December 1, 2006. Please note this CME activity does not meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.

Are the following statements true or false?

Annually, the number of deaths attributed to obesity-related health problems is quickly approaching that of deaths related to tobacco use.¹

More than 6 million Americans meet the strict definition of morbid obesity — that is having a BMI (body mass index) of 40 kg/m² or more.²

Obesity costs the United States about \$100 billion annually in direct health care expenses or in lost productivity.³

All of these statements are true. Despite increased public awareness and aggressive

education, obesity has achieved epidemic proportions in the United States. To combat this public health crisis, physicians and patients are turning to the only intervention associated with long-term success — bariatric surgery. The number of bariatric surgical procedures performed in the U.S. has increased dramatically from 45,000 in 2001 to an estimated 140,000 by the end of 2004.⁴ This growth is expected to increase exponentially over the next 10 years.⁵

As is often the case in medical malpractice litigation, with the growth of bariatric surgery has come a rise in the number of claims involving bariatric surgical procedures. Given the pervasiveness of these operations, it seems that few physician specialties will be untouched by this complex area of litigation. At TMLT, claims have been filed not only against surgeons, but also anesthesiologists and radiologists. The specialists called in to consult when complications arise — pulmonologists, cardiologists, gastroenterologists — have also been named in these suits. The physicians who refer patients for surgery or who provide long-term care after surgery — internists, family physicians and ob-gyns — can also find themselves named in bariatric claims.

This article will provide a brief description of current bariatric surgical procedures, discuss the literature that compares these procedures and follows outcomes, address complications, and discuss risk management issues for surgeons and other physicians who care for bariatric patients. Please note that this article will focus solely on bariatric surgery, and will not discuss other methods of weight loss or the controversies surrounding the overall health benefits of weight loss.

Introduction

Morbid obesity correlates with a BMI greater than 40 kg/m² or with being at least 100 pounds overweight. It is a potentially deadly condition on its own, as obese individuals have a significantly higher risk of dying prematurely than others of normal weight. Most morbidity and mortality is associated with comorbid conditions, including hypertension, hypertrophic cardiomyopathy, hyperlipidemia, diabetes, cholelithiasis, obstructive sleep apnea, hypoventilation, degenerative arthritis and psychosocial impairments.⁶

While it has been shown that intentional weight loss can improve many of these conditions, obesity remains a chronic problem. “Unfortunately, conservative medical treatment programs (dietary regimen, behavioral modification, and exercise) have been largely unsuccessful in achieving and maintaining long-term results in morbidly

obese patients. Although initially promising, medical therapy has been limited by the side effects of the drugs and by their inability to maintain significant weight loss over long follow-up periods. Therefore, more aggressive treatment is typically required for obese subjects at risk for medical complications of obesity. Given these limitations, surgery has become an attractive alternative because it represents a long-term solution.”⁷

Recognizing that surgical treatment could provide long-term weight control for the morbidly obese, the National Institutes of Health convened a consensus panel in 1991. The panel concluded that bariatric surgery was appropriate for adult patients who met specified criteria. “Since publication of their recommendations, antiobesity operations have gained acceptance and are more frequently performed.”⁸

Presently, any general surgeon can perform bariatric surgery, and no specific surgical training is mandated. However, the American Society for Bariatric Surgery (ASBS) offers guidelines for granting privileges in bariatric surgery, and recommends that all surgeons receive training and gain competence by assisting experienced bariatric surgeons.⁹ According to the American College of Surgeons (ACS), bariatric surgery is the fastest growing subspecialty in American surgery. The ASBS, with more than 1,200 member surgeons, has a representative on the ACS Board of Governors and is a specialty surgical society in the Specialty and Service Society section of the American Medical Association.

Criteria

The 1991 NIH criteria for eligibility for surgical treatment of morbid obesity include:

- a BMI of 40 kg/m² or higher
- a BMI of 35 kg/m² or higher with certain comorbidities (such as severe sleep apnea, hypertension, obesity-related cardiomyopathy, severe diabetes mellitus, serious musculoskeletal or neurologic concerns)
- long-standing history of obesity
- multiple unsuccessful attempts to lose weight using nonsurgical methods
- ability to comply with dietary and behavioral changes as recommended by the weight management team.¹⁰

“The option for surgical treatment should be offered to patients who are morbidly obese, well informed, motivated, and acceptable operative risks. The patient should be able to participate in treatment and long-term follow-up. Some patients with manifest psychopathology that jeopardizes an informed consent and cooperation with

long-term follow-up may need to be excluded. A decision to elect surgical treatment requires an assessment of the risk and benefit in each case.”⁶

Procedures

Bariatric surgical procedures are classified as restrictive or malabsorptive, or a combination of both. “Restrictive procedures restrict the amount of food the stomach can hold, producing a sense of fullness with little food intake. Malabsorption procedures interfere with normal digestion and absorption of nutrients, limiting the amounts of calories available for digestion.”¹¹

Vertical banded gastroplasty (VBG)

Vertical banded gastroplasty involves creating a vertical pouch by stapling the front and back walls of the stomach together below the esophagogastric junction. The end of the newly created pouch is constricted with either a band or ring. As a purely restrictive procedure, all food the patient eats is digested normally.¹²

The early morbidity rate (within the first 30 days) for VBG is less than 10% and the perioperative mortality rate is less than 1%. Studies have shown that gastroplasty is not as effective as other procedures in achieving long-term weight reduction. While early excess weight loss (defined as the difference between preoperative and ideal weight) has been reported in the range of 60%, only about 25% to 45% of patients maintain their weight loss.¹³

Associated complications include stomal stenosis, staple line disruption, pouch dilation, erosion of the band and GERD.⁷

Gastric banding (GB) and laparoscopic gastric banding (LAGB)

In gastric banding, the surgeon places a band around the stomach just below the esophagogastric junction to restrict the amount of food ingested. The FDA approved a laparoscopic banding system in 2001. In LAGB, an adjustable band is placed around the upper stomach. A balloon in the band is connected to a port that is placed subcutaneously. The port can be accessed to inflate or deflate the balloon, changing the size of the band circumference.¹²

Reported complications include band stenosis, band erosion, band slippage, gastric pouch dilation and esophageal dilation. “Weight loss results and complication rates with the inflatable bands are better than those observed after the earlier banding techniques. Although erosion of the inflatable bands is relatively uncommon, usability of the subcutaneous reservoir deteriorates over time.”¹³

While the Lap-Band is currently the most popular bariatric surgery performed outside the U.S., long-term results have not been favorable here.⁷ It has been criticized for a high failure rate and poor results in African Americans. “The Lap-Band is a restrictive procedure and can be defeated by eating high-calorie sweets, and there are surgical learning curve issues regarding band placement and management. The current recommendation is that the Lap-Band needs more study before universal use in the United States.”¹⁴

Roux-en-Y Gastric Bypass (RYGB)

Roux-en-Y gastric bypass is the most commonly performed bariatric procedure in the U.S., and is considered the most effective.¹⁴ It is a combination restriction-malabsorption procedure in which the surgeon creates a small pouch by either stapling or transecting the stomach. The pouch is then connected to and empties into the Roux limb of the jejunum.⁷

“The incidence of perioperative complications observed with current modifications of the Roux-en-Y technique has improved substantially during the past decade with morbidity and mortality rates reported in the range of 10% and 1% or less, respectively.”¹³ Complications can include anastomotic ulceration and stenosis, hemorrhage, and anastomotic leak leading to peritonitis, internal hernias, staple line disruption, acute gastric distention, and possible nutritional deficiencies.⁷

Biliopancreatic diversion (BPD)

Another combination procedure is biliopancreatic diversion. The surgeon creates a limited gastrectomy, and the small intestine is transected approximately 250 cm from the ileocecal valve and attached to the gastric pouch. While the literature reports this procedure results in significant, long-term weight loss, concern exists that it may induce serious nutritional complications.⁷

An alternative to BPD is BPD with duodenal switch (BPDDS) in which a sleeve gastrectomy is created to maintain the pylorus and avoid anastomotic complications. The transected, distal small bowel is then connected to the stomach via a small part of the duodenum. Initial data on BPDDS suggests that it can achieve weight loss similar to BPD with fewer side effects.⁷

In BPD and BPDDS, the incidence of early complications has been reported in the range of 10% to 15% with a 1% mortality rate. Complications include protein malnutrition, anemia, bone demineralization, incisional hernia, gastric leak and fistula, intestinal obstruction and stomal ulcer.¹³ “BPD

and its variants are the most major procedures performed for obesity and it follows that prospective patients who wish to consider BPD should seek out experienced surgeons with life-long follow-up programs.”¹²

Over the past ten years, effective laparoscopic approaches to RYGB, VBG and gastric banding have emerged. “These procedures, it should be noted, are technically complex, require advanced surgical skills, have a steep learning curve, and should be performed only by an experienced bariatric surgeon.”¹⁵

Comparing the procedures

According to several studies comparing the outcomes of bariatric procedures, RYGB is considered the superior approach. “Weight loss results with the Roux-en-Y technique have been superior to those observed after other gastric restrictive operations in multiple clinical comparisons. Mean excess weight loss in gastric bypass patients typically ranges from 65% to 75%, which corresponds to loss of approximately 35% of initial weight.”¹³ A study following 608 gastric bypass patients (with 97% follow-up) reported up to a 68% reduction in excess weight, with weight loss being maintained for up to 14 years.¹⁶

When compared to LAGB, patients who underwent RYGB had an excess weight loss of 74.6% versus 40.4% weight loss after gastric banding. This difference was maintained for up to four years. In a study from Sweden, 58% of 90 patients who underwent LAGB were eventually converted to RYGB because of complications.⁷

Studies have also shown greater weight loss with RYGB compared to VBG. One study found average weight loss one year after surgery was 42% after VBG and 68% after RYGB. The differences in weight loss remained significant at the three-year follow-up period. “In addition, long-term evaluations confirmed that weight loss was maintained for up to 14 years after gastric bypass surgery, whereas patients who underwent VBG have poor sustained weight loss at 10 or more years post procedure.”⁷

BPD procedures have achieved greater excess weight loss than those reported with RYGB. In a comparison of 138 patients who underwent RYGB and 105 patients who underwent BPDDS, excess weight loss reported at two years was 74% for RYGB and 78% for BPDDS. “These results coupled with the possibility of lower rates of protein deficiency and anastomotic complications make distal gastric bypass/duodenal switch an attractive surgical option. However, more long-term data are required before it is universally accepted.”⁷

Bariatric surgery has also been shown to

improve several comorbid conditions, including obesity-associated diabetes and glucose intolerance, sleep apnea and obesity-associated hypoventilation, total cholesterol and triglyceride levels. In women, sex hormone balance, menstrual irregularity, fertility, and urinary stress incontinence have also improved following weight loss surgery. “Weight loss resulting from bariatric surgery has been associated with significant improvement of the left ventricular ejection fraction and lesser but measurable improvements in mean blood pressure, cardiac chamber size, and ventricular wall thickness.” The results from studies specifically addressing hypertension and surgical weight loss are conflicting.¹³

Early complications

The reported, overall complication rate for bariatric surgery is between 10% and 15% depending on the procedure.¹⁷ The perioperative mortality rate of bariatric surgery is less than 1%, and is usually associated with anastomotic leaks with peritonitis or pulmonary embolism.⁷ Other early complications include deep venous thrombosis, wound infections, dehiscence, staple-line leaks, stomal stenosis, and marginal ulcers.¹⁴

It should be noted that most studies on the complication rates are based on results from academic centers, and may not truly reflect the experience of nonspecialized centers. To determine if complication rates were higher in actual practice, a study published in the *American Journal of Surgery* reviewed data from the National Hospital Discharge Survey (NHDS). “Because the NHDS is obtained from discharge coding information obtained from a nationally representative sample of hospitals, it provides a cross-sectional estimation for treatment outcomes for medical care as actually practiced in the community. We found that the overall in-house complication rate was 9.6%, which compares favorably with reports from other tertiary referral centers.”⁸

The ASBS also tracks procedure and complication rates in the International Bariatric Surgery Registry. In a report that included data from 17,676 patients whose primary operation occurred between 1986 and 2002, it was found that 89.1% of patients had no 30-day complication; 3.1% had a major 30-day complication; and 7.8% had a minor 30-day complication. The most frequently reported major complication was GI leak (0.7%). The most frequently reported minor complication was wound infection (1.6%). The 30-day mortality rate was 0.25%, and pulmonary embolism was the most frequently reported cause of death.⁶

Late complications and side effects

After malabsorptive procedures, patients are vulnerable to anemia, metabolic bone disease, malabsorption of iron, the B vitamins, fat-soluble vitamins, calcium, potassium, magnesium, thiamin, and folic acid.¹⁵ “Fortunately, the majority of post-gastric bypass vitamin and mineral deficiencies are mild and easily corrected by taking oral supplements.”¹⁸ Purely restrictive procedures carry a low risk for nutritional complications.¹¹

“In addition to nutritional deficiencies, common late complications of RYGB and BPD include marginal ulcers (in as many as 10% of patients) and bowel obstruction (as many as 3%). After open bariatric procedures, hernias are a common late complication.” Cholelithiasis frequently occurs after rapid weight loss, and the reported incidence after bariatric surgery ranges from 3 to 30%. Late breakdown of the stapled gastric partition is responsible for patients regaining lost weight after gastric bypass. “The incidence of staple-line leaks and gastro-gastric fistulae after transection are reported in the range of 1% to 2%.”¹⁸

Vomiting is the most common complaint after antiobesity surgery and has been reported in 30% of patients. Typically, vomiting is associated with noncompliance with the recommended diet. Eating too much food, eating too fast, inadequate chewing, and consuming liquids and solids at the same time can all result in recurrent vomiting. “If these symptoms are associated with epigastric pain, significant dehydration, or not explained by dietary indiscretions, an alternative diagnosis must be explored. One of the most common complications causing nausea and vomiting in gastric bypass patients is anastomotic ulcers, with and without stomal stenosis.”⁷

Patients may also develop “dumping syndrome,” which results from the rapid emptying of food and liquids into the small bowel. Symptoms include weakness, nausea, dizziness, sweating, vomiting, abdominal pain, and palpitation, and are related to the consumption of foods high in sugar. “Dumping syndrome is common in early postoperative periods and subsides within 12 to 18 months after surgery. Prevention includes consumption of small, infrequent meals, avoidance of foods with high sugar content, eating and drinking slowly, chewing food thoroughly, and drinking liquids between meals.”¹¹

Risk management issues for surgeons

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

quate 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 risk (and the surgeon increased liability).”⁵

TMLT claims staff have identified a number of issues that consistently emerge in claims against surgeons who perform bariatric procedures. These include patient selection, informed consent and postoperative follow-up. (*Two closed claim studies addressing these issues can be found on page 10.*)

Patient selection

At TMLT, patient selection has become one of the main issues in bariatric malpractice claims. “Some surgeons may not be following the national recommendations and may not have established their own guidelines for who they will accept for surgery,” says Jill McLain, vice president of claim operations at TMLT.

“Another potential risk involves choosing patients who are poor surgical candidates. This could include anything from patients with severe sleep apnea, to patients with a history of drug abuse, to patients with serious emotional issues related to their obesity,” McLain says. Other patients who may not be “acceptable operative risks” include those who are unable to follow the dietary guidelines or those who may not have the necessary social support to help them cope with the dramatic changes that occur after the surgery.

“If you take the wrong kind of patient, subject them to major surgery with a long recovery period and this still does not solve their problem, they may file a lawsuit. If it’s the wrong patient to begin with, the rest does not matter,” McLain says.

The ACS also urges vigilance when it comes to patient selection. “Not all persons who are obese or who consider themselves overweight are candidates for bariatric surgery. These procedures are not for cosmesis but for prevention of the pathologic consequences of morbid obesity. Screening of patients to ensure appropriate selection is a critical responsibility of the surgeon and the supporting health care team.”³

A number of studies have been conducted to identify which patient characteristics are associated with postsurgical weight loss, but no reliable psychological predictors of success have been found. “Accordingly, routine preoperative psychological evaluation should be required in patients who have a history of severe psychiatric disturbance or who are currently under the care of a psychologist/psychiatrist. Such patients, and those under

the age of 18 years, should be required either to have psychiatric clearance in writing from their counselor or to undergo psychiatric evaluation before surgery.”⁶

Informed consent

In Texas, obtaining informed consent is the nondelegable duty of the physician, and the informed consent process for bariatric surgery must be extremely thorough. In bariatric malpractice claims, patients often allege they were not fully informed of the risks or that the surgeon minimized the risks.

Health benefits are most often cited as the deciding factor for surgery; however, post-surgery interviews reveal that many patients are highly influenced by the cosmetic benefits of the surgery. “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.”⁵

“The patient must further understand the lifelong commitment to health maintenance, special nutritional needs, the possibility of restriction 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 also understand that bariatric surgery is still in the developmental stages.”⁵

Patients may also need help establishing realistic weight-loss expectations. “Practitioners should explain that, even after bariatric surgery, patients are not likely to become what society considers ‘thin’ — in fact, it is unlikely they will achieve their ideal body weight. Actual postsurgical weight loss, expressed as a percentage of excess weight loss, will depend on the patient’s age, baseline weight, overall health status, motivation and commitment.”¹⁵

To help with the informed consent process, TMLT risk management staff recommend the surgeon use a consent form that explains the risks and complications of the procedure, alternative methods of treatment and the risks of the alternatives. The form should be completed and signed by the patient and surgeon well in advance of the procedure. To further document the patient’s understanding, have the patient initial each complication or risk on the form.

The postoperative period

The following recommendations may help to reduce risk during the postoperative period:

• Surgeons are encouraged to act quickly to rule out pulmonary embolism and staple line leak and infection, the leading causes of perioperative mortality.⁷

• Consider prophylaxis to prevent deep vein thrombosis and pulmonary emboli. Some patients may benefit from prophylaxis even after discharge.

• Ensure the facility you are operating in has the appropriate specialists on call.

• Surgeons who bring in other specialists to handle the patient's surgically-related complications are advised to communicate very clearly about who is responsible for monitoring the various aspects of the patient's condition. It is also important to ensure that the patient understands the specialists' roles.

• Document your communication with the specialists and with the patient in the medical record. Be specific.

• While patient management will vary, follow-up after discharge is extremely important. In an article from *Surgical Clinics of North America*, one surgeon describes his process. "All patients should have easy access to the operating surgeon and to a clinical nutritionist. During the first year, visits are scheduled at three-month intervals after reintroduction of solid food. Weight and blood pressure are recorded at each visit. Two follow-up visits are scheduled at six-month intervals during the second year. After the second year, all patients should be followed annually in a physician's office."¹⁸

Risk management issues for primary care and consultant physicians

"Comprehensive follow-up care is critical to optimal patient outcomes following bariatric surgery, and the primary care physician is in a unique position to render excellent procedure-specific, patient-customized care. In addition to lifelong monitoring of the patient's weight, signs and symptoms of comorbid conditions, and metabolic and nutritional concerns, the health care provider must help motivate the patient to comply with postoperative dietary restrictions, embrace new eating behaviors, and strive for new activity levels."¹⁵

Long-term complications

While the surgeon generally manages the early complications of bariatric surgery, the primary care physician may be called on to manage any long-term complications. As stated above, these can include nutritional deficiencies, marginal ulcers, bowel obstruction, hernias, cholelithiasis, vomiting, and dumping syndrome.

"Periodic assessment of patients' post-surgical metabolic and nutritional status

should include fasting plasma glucose, a lipid profile, liver function tests, and thyroid function tests, as well as levels of hemoglobin, iron, serum albumin (to detect protein calorie malnutrition), vitamins B12 and D, folate, magnesium, zinc, glycosylated hemoglobin, homocysteine, and parathyroid hormone."¹⁵ It is also prudent to monitor comorbidities closely as the patient's body weight declines. Medications used to treat these conditions may need to be adjusted or discontinued.⁴

Primary care physicians are also urged to pay attention to patients' mental health status during the postoperative weight loss period. Depression can be common as many patients are conflicted about weight loss and the dramatic lifestyle changes that occur. "These unresolved mental health issues can lead patients to attempt to figure out ways around the surgery, either by frequently eating small amounts of calorie-dense foods or downing high-calorie liquids."⁴

Lifelong dietary guidelines

Patients may also rely on their primary care physician for guidance on healthful eating behaviors. The lifelong dietary guidelines for the bariatric surgery patient include:

- eat three meals per day (containing protein and fiber) and two protein snacks per day;
- restrict total meal size to less than 1 cup;
- eat slowly and chew thoroughly;
- eat only nutrient-dense foods;
- do not eat and drink at the same time;
- drink plenty of water, from 90 minutes after each meal to 15 minutes before the next meal;
- avoid liquid calories; and
- walk at least 30 minutes per day.¹⁵

Primary care physicians must also ensure that post-bariatric surgery patients understand the importance of taking vitamin and mineral supplements. "Patients have to remain on nutritional supplements over their lifetime because of absorption issues. But many patients feel so much better after losing so much weight that they are less interested in continuing to take pills."⁴

Referrals

Another area of potential litigation for primary care physicians involves patient referrals. It is not uncommon for plaintiffs to name the original, referring physician in claims involving bariatric surgical procedures. TMLT claims and risk management staff offer these recommendations to help minimize the risk to primary care physicians:

• Know who you are referring to — their surgical experience, their commitment to long-term patient follow-up, the availability

of multi-specialty support, etc.

• If you are not comfortable sending the patient to a specific surgeon or program, provide the patient with a list of bariatric surgeons in your area. The ASBS (www.asbs.org) website lists members by geographic region.

• If you do not believe the patient meets the criteria for bariatric surgery, explain this to the patient. Be specific about why the patient does not meet the criteria. Point out the likelihood that the surgeon will come to the same conclusion and choose not to operate. Document this discussion in the medical record.

• If the patient insists on a referral and you choose to honor the patient's request, document your objections in the medical record.

Special considerations

Adolescents

In considering the surgical weight loss options for the pediatric population, physicians who treat adolescents generally advocate more conservative patient selection criteria than the 1991 NIH recommendations. "Simple adoption of these guidelines for use in younger age groups would overlook the unique metabolic, developmental, and psychological needs of adolescents and could result in the inappropriate use and/or overuse of weight loss surgery in adolescents."¹⁹

In an article published in *Pediatrics*, members of the ASBS outlined special considerations for surgery in this population:

- Bariatric surgery in these patients must occur in an appropriately equipped facility.
- A multidisciplinary team should be involved in patient selection, preparation, surgery and immediate and long-term follow-up care.
- The preoperative patient assessment, both medical and psychological, must be thorough.
- The adolescent must be able to participate in the decision-making process and have parental support.
- The need for life-long care must be emphasized to the patient and parents.²⁰

"The long-term effects of bariatric surgery in younger, reproductively active populations have not been well characterized. Ideally, adolescents who undergo bariatric surgery should be treated consistently, at regional centers of excellence, with ongoing clinical data collection and targeted research."¹⁹

Women of childbearing age

The ASBS recommends that women who have undergone bariatric surgery defer pregnancy until postoperative weight

loss stabilizes, usually 12 to 18 months. "All female patients of childbearing age, regardless of their preoperative fertility status, should be advised to use contraception for a minimum of one year following surgery; women who have undergone a malabsorptive procedure should be advised to choose an option other than oral contraceptives."¹⁵

While the safety of pregnancy after bariatric surgery has been documented in a number of studies, the potential for nutritional deficiencies does exist. "Once pregnancy occurs, the primary care provider and the obstetrician must conduct vigilant surveillance of the patient's weight gain (25 lb is optimal), her nutritional status, and fetal development."¹⁵

Other risk management issues

- Pay special attention to your advertising. Surgeons are advised to avoid any language that "guarantees" results and to stay away from words such as thin or slim.

- To ensure that patients understand the risks involved and to document this understanding, some surgeons include a testing mechanism in the informed consent process (such as having the patient complete a true/false test covering the informed consent materials).

- Claims arising from bariatric surgery performed outside a hospital (such as at a stand-alone surgery center) or at a hospital that is poorly equipped to handle morbidly obese patients are difficult to defend. Necessary equipment can include large-size tourniquets, special lifting and moving equipment, tables and testing equipment that can accommodate patients weighing up to 750 pounds.

- Surgeons are advised to follow the national criteria for patient selection or to establish and document their own selection criteria. Some facilities have determined that an independent team of physicians and the patient, not just the patient and the operating surgeon, should make the decision.

- A thorough preoperative anesthesia assessment and an anesthesia care plan will help anesthesiologists predict and respond to the common airway and ventilation complications. The informed consent for anesthesia should also be very thorough and documented in the record.

- It is difficult to defend surgical claims when the documentation from the procedure is incomplete. Dictation and documentation should be very thorough.

- Be aware that "a small number of morbidly obese patients will outeat any bariatric operation. Whenever a patient has failed a second technically sound and intact operation, surgeons should approach the

prospect of a further revision with considerable caution and skepticism. Rejection of such patients for another operation is frequently a prudent decision."¹⁸

- The ACS and ASBS have created guidelines for credentialing and privileging. Hospitals may also consider recredentialing criteria, including establishing a minimum number of procedures to maintain competency. Several leaders from the ASBS have founded a "centers of excellence" program, to be implemented by a non-profit organization called Surgical Review Corporation. (Information is available at www.surgical-review.org/Home.aspx.)

- Physicians can stay informed about the latest developments in bariatric surgery through the ASBS and the ACS. The NIH has also established the Longitudinal Assessment of Bariatric Surgery (originally known as the Bariatric Surgery Clinical Research Consortium) to conduct clinical, epidemiological, and behavioral research in bariatric surgery. LABS research will help determine the risks and benefits of surgery and will provide guidance on appropriate patient selection.²¹

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closed claim study

Bariatric closed claims: improper performance and failure to monitor

by Barbara Rose and Laura Brockway

The following closed claim studies are based on actual malpractice claims from Texas Medical Liability Trust. These cases illustrate how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. The ultimate goal in presenting these cases is to help physicians practice safe medicine. An attempt has been made to make the material less easy to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.

Closed claim study 1

Presentation

A 45-year-old woman with a 20-year history of morbid obesity was referred to a general surgeon, the defendant in this case. She weighed 296 pounds and was 5'4" in height. Her symptoms included severe low-back pain and arthralgia in her knees, ankles, and feet. Over a three-month period, the physician and patient discussed gastric bypass surgery. The physician obtained informed consent and performed a Roux-en-Y gastric bypass procedure.

Physician action

Postoperatively, the patient developed a low-grade pyrexia, sinus tachycardia, and leukocytosis. She was returned to surgery four days later and the surgeon found leakage from the staple line. The gastric pouch spontaneously perforated near the staple line. Part of the stomach appeared unhealthy with vascular deficiency. Following the second surgery, the patient became septic and developed acute respiratory distress syndrome. She remained in the surgical ICU for several weeks, under the treatment of a team of specialists.

The patient was taken back to surgery a few weeks later for drainage of a left subphrenic abscess and tracheostomy. She continued to show signs of persistent fistula. Again, the staple line leaked, requiring another

surgery two months later. During this surgery, two fistulas were repaired and the colostomy was closed. The patient's condition slowly improved, and she was discharged from the hospital four weeks after the fourth surgery. She was instructed to follow up with the general surgeon.

Ten days after leaving the hospital, the patient returned to the surgeon. The tracheostomy and gastrostomy tubes were removed without difficulty. The patient reported that she was able to eat small meals, but continued to have diarrhea. The surgeon instructed the patient to return for follow-up care in three weeks. She did not show up for the appointment and never returned to the surgeon.

Over the next 13 months, the patient was hospitalized several times for chronic liver disease, sepsis, and persistent gastrointestinal fistulas. She eventually underwent a takedown of the gastric bypass procedure performed by another surgeon. Her post-operative course was complicated by multi-system failure. She died shortly after the surgery.

Allegations

A lawsuit was filed against the general surgeon. The allegations included:

- failure to test the anastomosis for leaks intraoperatively;
- failure to obtain a timely upper GI series;
- failure to properly monitor the patient; and
- failure to perform a timely surgical revision of the leakage.

Legal implications

The plaintiff's attorney was able to retain an expert in general surgery who was highly critical of the surgeon, and who related the development of the patient's severe complications and eventual death to the first gastric bypass surgery. Specifically, the expert stated that the surgeon fell below the standard of care in failing to test for leakage from the staple line at the time of

the surgery. He was also critical of the delay in recognizing the complication and returning the patient to surgery.

Defense consultants offered differing opinions about this case. One surgeon stated that it was his practice to test for staple line leaks before closing when performing gastric bypass procedures. Another consultant surgeon said that testing for leakage intraoperatively would not necessarily have shown a leak and would not have prevented the subsequent complications. Two other surgeon consultants believed the patient suffered from Crohn's disease, and it was this underlying condition that caused the staple line to leak and contributed to her final outcome.

Disposition

Due to the grave complications from a difficult surgical procedure and high medical expenses, this case was settled for an amount in the low six figures.

Closed claim study 2

Presentation

A primary care physician referred his patient, a 36-year old woman, to a general surgeon for consultation about vertical banded gastroplasty. The patient was 5'9" in height and weighed 290 pounds. The surgeon discussed the procedure — its risks and benefits — with the patient, and provided her with a three-page handout.

Physician action

Six months later, the surgeon performed the vertical banded gastroplasty on the patient. The procedure was carried out without complication, and the patient did well postoperatively. Four days after the surgery, a barium swallow study was performed, and it showed no evidence of extravasation of contrast. The patient was discharged. The surgeon next saw the patient eight days later for removal of her

skin clips. The patient's weight was 268 pounds and she did not report any problems. She was told to return in one month.

Seven days after this office visit, the patient came to the emergency department with fever and left-sided pleuritic chest pain. An x-ray showed a left lower lobe infiltrate and the patient was diagnosed with community-acquired pneumonia. She was given Erythromycin and discharged.

Three days later, she again came to the ED with complaints of left-sided chest pain, fever, chills, nausea, vomiting, weakness and headache. The patient was admitted, and her care was turned over to a hospitalist who consulted the surgeon to rule out any complications from the gastroplasty. On her second day in the hospital, the surgeon ordered a CT scan, which revealed a left upper quadrant abdominal abscess. The surgeon performed an exploratory laparotomy and drained the abscess. No areas of perforation were noted.

One day after the laparotomy, the patient continued to have fever and infection. The surgeon started the patient on prophylactic Heparin for the prevention of deep venous thrombosis. Throughout the patient's hospital stay, the surgeon ordered early and frequent ambulation and TED hose as a prophylactic measure. The surgeon ordered a barium swallow study, which showed a small leak from the stomach. An NG tube was placed, and the surgeon opted to use suction and TPN to avoid further surgery.

On her 7th day in the hospital, the patient developed shortness of breath and hypoxia for the first time. The hospitalist consulted a pulmonologist, and ordered a ventilation/perfusion lung scan. The radiologist read the scan and orally reported to the hospitalist that it was negative for pulmonary embolism. However, the radiologist's written report indicated "low to indeterminate for possible pulmonary embolism." This report was not read by the hospitalist until ten days later. In retrospect, the hospitalist indicated that if he had known about this finding, he would have started the patient on Heparin or recommended a Greenfield filter.

The patient's condition worsened, and she was returned to the OR. The surgeon repositioned the chest tube and repaired the leak in the stomach. The patient did well postoperatively and continued to improve until two days later when she began to complain of chest pain. The hospitalist and pulmonologist ordered another lung scan and again, the radiologist read the scan as having a low probability for pulmonary embolism. The next day, the hospitalist received a call from the radiologist who was now changing the report to indicate an "intermediate to high probability of pulmonary embolism." The hospitalist and

pulmonologist ordered a change from prophylactic anticoagulation to full Heparin anticoagulation.

The next day, the surgeon placed a Greenfield filter in the patient's inferior vena cava, and performed a total gastrectomy, cholecystectomy and appendectomy. The patient remained in critical condition for the next two days. She began to have seizures, suffered an acute brain stem stroke, and became neurologically unresponsive. The patient's family signed a DNR order, and the patient died.

An autopsy was performed and the pathologist determined the cause of death to be submassive pulmonary emboli with prolonged heart failure and shock leading to acute respiratory distress syndrome. The findings also revealed the presence of chronic gastritis suggesting the possibility of pre-existing *heliobacter*-induced gastritis and peptic perforation following the gastroplasty.

Allegations

A lawsuit was filed against the surgeon and the allegations included:

- failure to provide prophylactic anticoagulation at the time of the original surgery;
- failure to perform a barium swallow study before the gastroplasty; and
- employing an improper technique to repair the leak in the stomach.

Legal implications

The plaintiff's case did not focus on the initial surgery, but the postoperative care. The plaintiff's expert was critical of the surgeon for not performing a barium swallow before the second surgery. This would have revealed the leak and would have allowed it to be repaired earlier. Though the cause of death was pulmonary emboli, it was the opinion of the plaintiff's expert that the patient's infection led to the pulmonary emboli. He could not offer any explanation as to how this occurred. Further, as the physician "in charge" of this patient, the surgeon should have done more to prevent the development of pulmonary emboli. The expert stated that it was not reasonable to rely on a pulmonologist who was saying the patient had a low probability of pulmonary emboli.

Defense consultants were supportive of the surgeon's care in this case. Though a leak did occur, the barium swallow performed four days after the gastroplasty negated the possibility that a tear occurred during the surgery. The experts believe the leak occurred because of the patient's pre-existing gastritis.

The cause of death was pulmonary embolism, not infection. Regarding the plaintiff's expert's claim that the infection led to the pulmonary emboli, defense experts

indicated this was a "ridiculous statement," and that there is a "mountain of literature" to dispute this. The consultant surgeons also stated that it was reasonable for the surgeon to rely on the hospitalist and pulmonologist who were following the patient's pulmonary status.

Disposition

This case was taken to trial and the jury returned a verdict in favor of the defense.

Risk management considerations

As indicated in the CME article, the TMLT claim department has identified patient selection, informed consent, and post-operative follow up as relevant issues in lawsuits alleging malpractice before, during, or after surgical weight reduction procedures.

The first closed claim indicated the patient did not keep her second postoperative appointment and never returned to the surgeon for care. Did the surgeon's practice have a system to follow up with a patient who does not keep an appointment and does not call to reschedule? Prudent practice and risk management suggests the need to contact patients requiring timely continuity of care when they fail to show. Design a system for staff to document the missed appointment in the record, contact the patient to determine why it was missed, reschedule, and document all of these actions in the record.

No one disputes the fact that patients should be compliant with their physicians' directives and accountable for their choices and actions. Each scenario will merit review of its uniqueness and the degree of follow up required. A patient who has post-operative complications, three additional surgeries, and an extended hospital stay warrants timely, uninterrupted follow up care. Develop a system, implement and use it consistently and the medical record will reflect a conscientious practice committed to quality patient care.

Barbara Rose can be reached at barbara-rose@tmlt.org. Laura Brockway can be reached at laura-brockway@tmlt.org.

TEXAS MEDICAL LIABILITY TRUST

P.O. Box 160140
Austin, TX 78716-0140
800-580-8658 or 512-425-5800
Fax: 512-425-5998
E-mail: laura-brockway@tmlt.org
www.tmlt.org

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TMLT risk alert — important information regarding COX-2 inhibitors

The recall of Vioxx on September 30, 2004, was reported by Merck to have been based on the APPROVe trial involving 2,600 patients where it was discovered that 3.5% of the patients assigned to Vioxx had myocardial infarction or stroke as compared to 1.9% of the patients assigned to placebo.¹

A subsequent meta-analysis of 29 clinical trials demonstrated a greater than two-fold increase in risk of myocardial infarction in patients taking Vioxx.² Pfizer has also reported that it will add a “black box” warning that Bextra causes Stevens-Johnson syndrome more often than other COX-2 inhibitors.³

These findings have resulted in increasing concern about the safety profile of the two currently available remaining COX-2 inhibitors, Celebrex and Bextra, possibly due to a “class effect” which may not be limited to Vioxx. Evidence for a mechanism of increased cardiovascular risk involves the suppression of prostaglandin I₂ by COX-2

inhibitors which might predispose patients to myocardial infarction or thrombotic stroke.¹ Preliminary clinical evidence for a possible class effect includes a retrospective study reported on November 9, 2004, at the American Heart Association meeting which demonstrated a 2.19 increase risk of heart attack or stroke in very high risk patients undergoing coronary bypass surgery who were taking Bextra.³

Historically, it has been communicated to physicians that COX-2 inhibitors significantly reduce the incidence of gastric ulcers and GI hemorrhage, which has led to their widespread use. However, it is now apparent that the “risk benefit” ratio of this class of drugs has changed.

The TMLT Risk Management Department wants to make you aware of the following guideline contained in the *New England Journal of Medicine*. “Selective inhibitors of COX-2 remain a rational choice for patients

at a low cardiovascular risk who have had serious gastrointestinal events, especially while taking traditional NSAIDs. It would also seem prudent to avoid coxibs [COX-2 inhibitors] in patients who have cardiovascular disease or who are at risk for it.”⁴

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