

## Current Status

# Bariatric Surgery Claims – A Medico-Legal Perspective

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The increase in frequency of bariatric surgery has been accompanied by an increase in litigation involving patients and practitioners in this emerging field. With much being written about the medical aspects of bariatric surgery, the legal and risk management perspective of these procedures is now getting increased attention. This article examines from a legal and risk management perspective the issue of patient selection, informed consent, postoperative management, the use of promotional materials and other issues that can result in a doctor or facility being sued.

*Key words:* Medico-legal, bariatric surgery, morbid obesity, gastric bypass, risk management

## Introduction

Bariatric surgery was first described in 1953, but after several false starts marked by complications and litigation, bariatric surgery has achieved a rebirth, especially in the laparoscopic era.<sup>1,2</sup> Alternative weight reduction approaches, such as diets<sup>3</sup> and plastic surgery techniques, typically pose small but potentially significant medical risks. Bariatric surgery poses significant medical risks including a 10-15% risk of major complications and a 0.5-2% risk of mortality.<sup>4</sup> Indeed, a recent article noted that complications from bariatric surgery occur in four out of ten procedures.<sup>5</sup> Its use as a weight loss approach for children and adolescents has spurred a widespread medical, legal and ethical debate.<sup>6</sup>

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The increase in frequency of bariatric operations has been accompanied by a concomitant increase in litigation involving patients and practitioners in this area, such that it behooves the legal analyst to examine the basis for such claims, as well as the risk management, medical and legal strategies to minimize and defend them.

## Claims, Defenses and Risk Management

The two most common themes in the prosecution of bariatric surgery cases involve screening and education on the one hand, and delay in the recognition of postoperative complications on the other.<sup>7</sup>

Surprisingly, few claims focus on the technical performance of these procedures. During the discovery portion of litigation, plaintiffs typically seek to develop and establish the lack of training of the physician and, more frequently, target the lack of appropriate screening and education of the patient. In addition, deficiencies in staffing, training and equipment of the facility, as well as deficiencies in the postoperative management and follow-up are frequently cited as vulnerabilities. Because the field of bariatric surgery is relatively new and quickly developing, fellowships and surgical residency programs in which techniques are taught are still in the nascent stage. Typically, younger bariatric surgeons are exposed to bariatric surgery during residency and then hone their skills in a post-residency minimally-invasive or laparoscopic fellowship. Unfortunately, the degree of training varies, with some surgeons learning through

observerships or week-end courses. As a result, the techniques used by seasoned practitioners in other contexts are not necessarily adaptable to bariatric surgery, and many surgeons who are otherwise very experienced are not well versed in techniques involving the various approaches to bariatric surgery.<sup>8</sup> Further, credentialing requirements will often vary considerably from institution to institution.

Similarly, facilities do not necessarily possess dedicated staffing and equipment for such procedures. In response to these issues, the American Society for Bariatric Surgery has fostered both a certification for practitioners and a Certificate of Excellence (COE) for facilities offering these procedures that require certain minimal levels of experience and proficiency for both practitioners and facilities.<sup>9</sup> COE designation, however, is only contingent on having done >100 cases per year in the presence of two bariatric surgeons. As a similar response, the American College of Surgeons is establishing a Bariatric Surgical Center designation with minimal requirements for participating surgeons, but where the Center is approved.

Postoperative bariatric complications can be either those related to the surgery (e.g. anastomotic leaks, ischemic bowel, and wound complications) or systemic (e.g. pulmonary, cardiac and metabolic). Systemic complications can be the first manifestation of a surgical complication. For instance, a persistent tachycardia on the 5th postoperative day may be the first manifestation of an anastomotic leak. Other often trivial complaints such as bloating, distention and hiccoughs can be early harbingers of a serious problem. It is critical that hospital staff, be they medical, nursing or ancillary, be taught to recognize these subtle and early signs of problems. Early diagnosis and correction of a surgical problem may avert a disastrous outcome for patient and surgeon alike.

An institutional commitment is required for these centers as well, especially extending to ancillary services. The Emergency Department personnel at these institutions must be educated, because patients may return for emergency evaluation and assistance because of sequelae from these procedures. In the early days of litigation concerning these claims, litigators defending these cases could allege that the facility could not be expected to have equipment capable of evaluating obese patients. A facility might contend that they could not be expected to have a CAT-scan machine capable of accommodating a patient that weighed 181.8 kg (400 lb). As the field

evolved medically and facilities performing these procedures have started to hold themselves out to the public as possessing special staffing and equipment needed to examine,<sup>10</sup> transport,<sup>11</sup> and treat<sup>12</sup> such patients, what was once a defense to these claims has become a theory of prosecution. Indeed, the failure to obtain the proper supportive equipment can often make a situation impossible to manage.

Perhaps the most contentious area of litigation involves that of informed consent. Patients either do not know, or do not wish to know the risks that these procedures pose. Society at large seems to be deficient in its knowledge of the medical risks of the comorbidities of morbid obesity and the medical value of bariatric surgery. This view is reinforced by several high profile celebrity patients, with dramatic weight loss after surgery. Education of patients concerning risks begins with a sophisticated screening process designed to identify those patients who are realistic, highly motivated and with appropriate social support to enable them to succeed in this endeavor. This requires a high level of patient cooperation and a good deal of family support and assistance. Screening of medical risks is an integral part of this process and includes endocrine, cardiac and respiratory consults.<sup>13</sup> While some eschew psychiatric consultation because it reinforces the stereotype of obesity as a mental disorder, a psychological screening protocol, including evaluation of prior failed attempts at weight reduction, activity level, substance abuse, including diet pills, evaluation of coping mechanisms, current stressors, and social and family support systems, are just as critical as the medical evaluation.<sup>6,14</sup> Some have even advocated prior litigation history as a relevant issue for these patients.<sup>15</sup>

If the first prong of the algorithm is to rigorously screen out inappropriate candidates, the second is to optimize the chances of success of those candidates that survive the screening process. Because of the intensity of denial of the medical risks in patients seeking cosmetic benefits and the exaggeration of these cosmetic benefits, some very aggressive informed consent techniques are required, rather than the typical physician-patient dialogue. Booklets, videos, and questionnaires should be utilized as educational tools, and quizzes or examinations have been proposed to ensure that knowledge is actually and appropriately conveyed.<sup>16</sup> Moreover, many centers now require that the patient execute an aftercare com-

pliance contract, the signing of which brings home the importance of continued compliance, because all patients undergoing the procedures are advised to maintain routine visits for at least 5 years.<sup>17</sup>

Studies on informed consent have uniformly revealed that 6 months after an operation, when asked about their recollection of the risks and benefits of procedures which had been provided prior to the operation, patients have fairly good recall regarding the benefits that were explained, but have forgotten much of the information provided on the risks of the procedure.<sup>18</sup> Human nature may explain this phenomenon, but does not necessarily provide a rationale for not addressing it. Printed literature would stand as testament to an adequate risk/benefit discussion.

The intensified and enhanced educational process for these procedures has three objectives. The first is to increase patient recollection of risks in an effort to make them more realistic concerning the outcome and more important, more compliant with aftercare. The second objective is to provide the patient with appropriate and sufficient information with which to actually make the decision to proceed. Thus, the fact that some of this information may later be forgotten does not negate the salutary effect of the patient having this information at the time that the decision is made. The third objective is, from a practical and legal perspective, the need to demonstrate and document that the patient was a true partner in the decision-making process. It is for this last objective that the quiz and the execution of the aftercare compliance contract play a critical role. Family involvement should be an integral part of the consent process as well as the medical success of the procedure. Without family recognition of the importance of follow-up, success is unlikely. Moreover, depending on the family dynamic, an ill-educated family member is frequently the instigating force behind a lawsuit. This is certainly the case in instances of mortality in which the surgeon has not previously met the family members. From a legal and risk management perspective, it is critical that the family be educated concerning misconceptions regarding the risks and benefits of this procedure as well.

A secondary aspect of altering the legal climate concerning these claims is educating the public of the medical benefits and risks of these procedures. After all, it is the public that comprises our jury pools. The media, to a great extent, has and no doubt will con-

tinue to sensationalize these cases in a polarized way, heralding each celebrity success as an amazing breakthrough, and bemoaning each failure as a tragedy of epic proportions crying out for blame. Little can be done to alter their perspective. As a practical matter, certain steps can be taken in terms of the presentation of their program by the facility and physician to the public that can help to create a legal climate that minimizes the risk of suits and provides little fodder for suits that are commenced. Promotional materials should be reviewed and tailored so as not to suggest unrealistic outcomes. They should refrain from suggesting a frequency or percentage of success, because this is often secondary to patient selection, rather than the proficiency of the staff or facility and it can be misleading. Indeed, the very definition of success is open to interpretation, because in some centers it is defined as weight loss >25% of preoperative weight. The potential benefits of the operation may be detailed, but also should not be exaggerated and should not be presented in a categorical manner.<sup>19</sup>

Certainly there should not be any mention of the anticipated weight loss; there should not be any minimization of the medical risks and indeed mortality. Facilities should refrain from making references to specific physicians, because this could potentially create vicarious liability for these physicians based on the theory of ostensible agency.<sup>20</sup>

## Conclusion

Bariatric Surgery is a relative newcomer to the field of surgery that can be of great benefit to selected patients. With proper education of the patients and the public, perhaps the legal environment will not limit its access and make it unavailable to those who need it most.

## References

1. Buchwald H. Mainstreaming bariatric surgery. *Obes Surg* 1999; 9:462-70.  
Indeed in the eyes of many practitioners, insurance carriers and the population at large, obesity and more specifically obesity surgery is still subject to many prejudices not tolerated in other areas of society. While med-

ical evidence is that morbid obesity in many instances is the result of inborn factors in metabolism, prejudice against the obese is one of the few tolerated prejudices in our society. Discriminatory actions that would never be condoned in the context of religion, ethnicity, racial, gender or sexual orientation are tolerated in the context of obesity. Indeed, intolerance of the obese violates no laws, regulations or even social mores. This prejudice finds its way into the legal system in several ways. First party insurance carriers have litigated this issue under the rubric of elective surgery vs medical necessity.

2. Hall MA. State regulation of medical necessity: The case of weight-reduction surgery. *Duke Law J* 2003; 53: 653-72.  
Liability carriers in many states have restricted or refused to write malpractice coverage or have placed substantial surcharges on practitioners that perform these operations. Furthermore, the media has sensationalized both the remarkable successes of this surgery in certain celebrities, as well as some of the catastrophic complications that may occur, creating a number of basic misconceptions and inappropriate expectations in the population.
3. With the exception of fen-phen, most diet pills have not been controversial in terms of their side-effects.
4. Eagan CM. Bariatric surgery: malpractice risks and risk management guidelines. *Am Surg* 2005; 71: 369-75.
5. Agency for Healthcare Research and Quality Obesity Surgery Complication Rates Higher Over Time. Press Release, July 24, 2006.  
[www.ahrq.gov/news/press/pr2006/obessurgpr.htm](http://www.ahrq.gov/news/press/pr2006/obessurgpr.htm)
6. Inge TH, Krebs NF, Garcia VF et al. Bariatric surgery of severely overweight adolescents: concerns and recommendations. *Pediatrics* 2004; 114: 217-23.
7. Based on a review of legal suits filed in the United States from 2000-2005.
8. Bariatric surgery is a generic term encompassing several procedures. The first procedure, the now abandoned jejuno-ileal bypass, achieved widespread popularity in the 1970s but some patients began to experience long-term metabolic and physiologic derangements. The gastric bypass, described by Mason in the 1960s, became the operation of choice. Currently the Roux-en-Y gastric bypass is the most commonly performed weight loss operation in USA, with approximately 150,000 performed in 2005. Either performed laparoscopic or open, the operation entails connection of a loop of small intestine to a proximal gastric pouch of 15-30 cc. The other operations include laparoscopic gastric banding, which restricts intake, and the malabsorptive biliopancreatic diversion with or without duodenal switch.
9. Champion JK, Williams M. Economic impact of

bariatrics on a general surgery practice. *Obes Surg* 2006; 16: 113-18.

These requirements include performance of 100 cases. Week-end training at a mini-seminar is not sufficient. While all agree that emphasis on screening and informed consent is important, no formal protocol has been established concerning these issues as yet.

10. Beds, tables, blood-pressure cuffs.
11. Elevators, wheelchairs, and gurneys.
12. Longer instruments including retractors and staples.
13. Laville M, Romon M, Chavier G et al. Recommendations regarding obesity surgery. *Obes Surg* 2005; 15: 1476-80.  
Medical contraindications include the absence of prior identifiable medical management, potential problems with medical follow-up, psychotic disorders and severe depression, alcoholism or drug dependence, serious disorders in feeding particularly of a bulimic type, impaired masticatory function, contraindications to general anesthesia, and diseases threatening life in the short-term.
14. Garcia VF, DeMaria EJ. Adolescent bariatric surgery: treatment delayed, treatment denied, a crisis invited. *Obes Surg* 2006; 16: 1-4.
15. There is no ethical controversy about whether this should be permitted, but if prior litigation history is linked to success of the procedure, it is potentially relevant although not politically correct.
16. One aspect of this may include demonstrating photographically some failures and less than optimal or sub-optimal outcomes.
17. Scheier L. Bariatric surgery: life-threatening risk or life-saving procedure, *J Am Dietetic Assoc* 2004; 7: 1338-40.  
The act of signing such a contract brings home the significance of the patient's participation in the program, including issues such as postoperative cessation of smoking, compliance with diet, compliance with medications and also demonstrates the patient's and perhaps family's willingness to continue with the program after the surgery and recognition that the surgery is not the end-point of the program.
18. Madan AK, Tichansky DS. Patients postoperatively forget aspects of preoperative patient education. *Obes Surg* 2005; 15: 1066-9.
19. Seven areas of benefit have been identified in the literature including activity/mobility, symptoms, personal hygiene/clothing, emotional stability, social interaction, sexual function, and eating behavior.
20. Hill v. St. Claire, 67 N.Y.2d 72, 499 N.Y.S 2d 904 (1986).

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