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. Alternative weight reduction approaches, such as diets 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. Indeed, a recent article noted that complications from bariatric surgery occur in four out of ten procedures. Its use as a weight loss approach for children and adolescents has spurred a widespread medical, legal and ethical debate.

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. 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 sur-
gery, and many surgeons who are otherwise very
experienced are not well versed in techniques involv-
ing the various approaches to bariatric surgery.8
Further, credentialing requirements will often vary
considerably from institution to institution.

Similarly, facilities do not necessarily possess dedi-
cated 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 cer-
tain minimal levels of experience and proficiency for
both practitioners and facilities.9 COE designation,
however, is only contingent on having done >100
cases per year in the presence of two bariatric sur-
geons. As a similar response, the American College of
Surgeons is establishing a Bariatric Surgical Center
designation with minimal requirements for participat-
ing 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 com-
plexions 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, liti-
gators 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,10 transport,11 and treat12 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 defi-
cient in its knowledge of the medical risks of the co-
morbidities 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 con-
sults.13 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.6,14 Some
have even advocated prior litigation history as a rele-
vant issue for these patients.15

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 edu-
cational tools, and quizzes or examinations have been
proposed to ensure that knowledge is actually and
appropriately conveyed.16 Moreover, many centers
now require that the patient execute an aftercare com-

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