BARIATRIC SURGERY:
A MEDICO LEGAL PERSPECTIVE

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 Abstract

There has been a steady increase in the number of medicolegal claims following bariatric surgery. This is due to a number of factors including high patient expectation, the technical demands of surgery itself and the requirement for on-going lifelong follow-up. In order to avoid medicolegal pitfalls it is essential to have a robust consenting process; perform well-documented and technically proficient surgery and provide a comprehensive follow up strategy. In addition there is an increasing burden on the non-specialist surgeon to manage bariatric surgical emergencies. Although the medicolegal standard applied to such non-specialists is lower than that expected from a specialist unit, close collaboration with a specialist centre is strongly advised to prevent successful medicolegal claims.

Introduction

Despite advances in the peri-and post-operative management of bariatric surgical patients, bariatric procedures are still associated with a significant incidence of early post-operative and long term morbidity. As a consequence of this and other factors, there has been a steadily increasing rate of medical negligence claims in bariatric surgery - a fact which has reflected in steadily rising insurance premium for bariatric surgeons worldwide. In this chapter, we will explore some of the issues underlying bariatric surgical litigation, analysing the legal principles underpinning such claims as well as a potential medical legal pitfalls associated with bariatric surgery. This chapter will also attempt to define the role of the general surgeon and the medicolegal ramifications of looking after post-bariatric surgery patients who are admitted with complications. Given the wide variations in legal tradition and statutes and in individual jurisdictions, we have chosen to use template of English law in this chapter in order to illustrate the wider principles associated with bariatric medical legal claims.
LEGAL PRINCIPLES

In most jurisdictions, with the exception of gross clinical negligence, the vast majority of clinical negligence claims comes under the purview of civil litigation. In English law, all clinical negligent cases are considered under the principles of tort law. For any clinical negligence case to be successful, the plaintiff must demonstrate that:

1) The doctor or hospital had a duty of care
2) This duty of care was breached
3) That this breach in turn materially contributed towards harm which was both foreseeable and quantifiable
4) But for the breach of duty, this harm could have been avoided.

With particular reference to bariatric surgery, the main areas of contention surrounding most medico-legal cases centre around the validity of the patient's consent; the performance of surgery itself and the management of the patient following surgery. With respect to question of what constitutes the valid and informed consent different jurisdictions apply different rules. For example many states in the USA, applied the so-called “prudent patient test” - in other words for consent to be valid, the patient would need to be given all material information necessary for a “prudent patient” to make an appropriate decision. By contrast, consent under English law has been governed by the so-called “Bolam principle”- namely that provided a body of medical practitioners would agree with the consenting process, it would be deemed to be of an acceptable standard.

Moreover this principle not only applies to consent, but all aspects of pre-, intra- and post-operative management. This approach of peer validation has been criticised as allowing too much leeway to medical practitioners and it should noted in the majority of legal jurisdictions do have higher standards which medical practitioners need to attain in order to prevent successful claims of negligence.
BARIATRIC SURGERY 
AND THE MEDICOLEGAL ENVIRONMENT

Despite the general reduction in peri-operative morbidity and mortality following elective surgery seen in the Western world in the last 20 years, there has been an increase in the number of claims in the bariatric surgery. Indeed, in the United Kingdom, bariatric surgery is now classed one of the highest litigation risks by the major medical insurance companies. The reasons for this are multifactorial, but include:

1. Patient expectation: Bariatric patients have a high incidence of depression and psychological disorders as compared to the general population. This can lead to unrealistic expectations of what surgery can offer to them. This consequence of this, these patients may have an increased tendency to seek legal redress should these expectations not be met. In addition, bariatric patients tend to be better informed about their operations than patients undergoing most other forms of surgery typically due to the high level of information and support groups available on the Internet. Finally, in most countries with a predominantly state-funded health care system, there is often an underprovision of bariatric surgery in the publically-funded hospitals. As a consequence of this, a large number of patients are forced to pay these operations privately and as such tend to have a lower threshold for complaining should something go wrong.

2. Nature of surgery: Bariatric surgery is a relatively new, technically-demanding and rapidly developing branch of surgery. Although, there are now established fellowship programmes to allow junior surgeons to develop their skills under appropriate supervision and mentorship, a significant proportion of bariatric surgery is performed by surgeons whose primary training and experience is in resectional upper gastrointestinal surgery. Although a large number of these skills are transferable to bariatric surgery, some surgeons (particularly those trained in the era of open as opposed to laparoscopic surgery) may not have the training necessary to perform laparoscopic bariatric surgery to a high level. Similarly, bariatric operations pose considerable challenges to anaesthetists, many of whom may not have the familiarity and experience to deal with particular medical issues associated with the morbidly obese. Finally, many hospitals do not
have the specialist equipment needed to deal with challenges of managing bariatric patients (eg CT scanners capable of coping with the weight of the morbidly obese).

3. Postoperative care: Unlike traditional resectional gastrointestinal surgery where the vast majority of clinical input occurs in the immediate postoperative period, bariatric patients tend to require continued longer-term follow-up and supervision. For example patients with gastric bands require multiple band adjustments whilst patients undergoing gastric bypass and duodenal switch require multivitamin supplementation for life and regular monitoring of their micronutrient levels. In addition, a significant number of patients represent with emergency complications related to their bariatric procedures many years following their original surgery, a subject that will be discussed later in this chapter. For example patients with gastric bands may present with acute band slippage whilst gastric bypass patients may present with intestinal obstruction secondary to internal hernia. The management of these conditions can be a source of medicolegal claims, particularly as the late diagnoses of these problems can result in significant long-term ongoing morbidity. Finally, a significant portion of patients regain weight in the longer term following surgery and this can be a source of dissatisfaction and potential litigation.

**BURDEN OF MEDICAL LEGAL CLAIM IN BARIATRIC SURGERY**

Despite the obvious importance of medicolegal claims in bariatric surgery, there is surprisingly little in medical literature on this subject. In the largest study on this topic, Cotta et al [1] reviewed the case notes of 100 consecutive bariatric lawsuits. The most common adverse events initiating litigation were leaks followed by intra-abdominal abscess, bowel obstruction, major airway events, organ injury and pulmonary embolism. In terms of clinical outcomes, 32 patients had a documented intra-operative complication and 72 required additional surgery. A total of 53 of the patients died and 28 had a full recovery with remainder having minor or major disability. Analysis by a medical malpractice lawyer found potential negligence in 28% of cases - the most common cause of negligence being delay in diagnosis of a complication or misinterpretation of vital signs.
Interestingly, surgeons with a low level of experience (i.e., less than one year of experience in bariatric surgery) were most likely to be involved in lawsuits. It should be noted that this analysis was performed on cases performed between 1997 and 2005 and as such included a significant number of operations which are which are no longer routinely undertaken such as vertical banded gastroplasty and open gastric bypass. In addition, none of the patients in the cohort underwent gastric band insertion which again probably reflects the timeframe during which this study was conducted. In a similar study Bruguera et al. [2] reviewed the case files of 49 medicolegal bariatric cases presented to the Professional Liability Department of the Catalanian Medical Colleges Council from 1992 to 2009. In 47% of the cases the patients died, 21% made a complete recovery and the remainder had some residual impairment. The most frequent causes of death were peritonitis due to suture dehiscence (48%), and respiratory complications. Malpractice was considered to have occurred in 20% of cases and interestingly in 6% of cases the surgeons were convicted in criminal court of criminal negligence.

In both of these studies, the finding of negligence was typically based on the failure to detect complications in a timely fashion as supposed to the complications themselves. It should also be noted that both studies focused on early postoperative complications associated with bariatric surgery and did not analyse litigation associated with late complications following surgery.

**AVOIDING MEDICOLEGAL PITFALLS IN BARIATRIC SURGERY**

Given the rising burden of the medicolegal claims, the obvious question for any bariatric surgeon is how these can be avoided. Although there are no hard and fast rules on this subject, the following principles should be useful in reducing and mitigating medicolegal claims following surgery:

1. **Consenting:** It is critical that bariatric patients undergo a fully informed consenting process. This consists of pre-operative counseling preferably by the operating surgeon as to the risks and benefits of bariatric surgery. Although individual patient’s medical co-morbidities must be taken into consideration in counseling patients as to the risks of surgery, the following generic risks should be emphasised:
a) Laparoscopic gastric band insertion- In terms of the significant and serious risks of this procedure, these include bleeding, deep vein thrombosis and pulmonary embolism and collateral injury to the surrounding structures during port insertion. The patient should be made aware that the band will require multiple adjustments and be counseled as to the risks of infection of the band, tubing and the port site as well as the risk of the band tubing fracturing or disconnecting leading to a loss of fluid and hence restriction in the band. Finally, the patient must be aware of the long term risks of band slippage and erosion necessitating revision surgery.

b) Laparoscopic sleeve gastrectomy- The risks of this procedure include bleeding, infection, collateral injury to the surrounding structures and staple line leakage. Overall, the mortality rate from this procedure estimated to be 1 in 1000. The procedure is irreversible and there is at present limited long-term data on the outcomes in terms of weight regain.

c) Laparoscopic gastric bypass- The immediate postoperative risks of this procedure include bleeding, infection, deep vein thrombosis and pulmonary embolism and anastomotic leak. The overall mortality rate for this procedure is approximately 1 in 200. In addition, the patients need to be aware that there is a long term risk of internal herniation and they will require vitamin supplementation and regular blood test monitoring for life.

All patients should be counseled that there is a significant chance of weight regain after any bariatric procedure and their expected weight loss will be determined by a number of factors including the technical performance of the operation and the patient’s willingness to alter their behaviour in terms of the dietary intake following surgery. All patients should also be warned that they will have a significant risk of loose overhanging skin after surgery which may require plastic surgical intervention.

Following surgical consultation patients should be discussed in a multidisciplinary team environment with the involvement of dietitians, psychologists, anaesthetists and physicians. The purpose of the multidisciplinary team involvement is to assess suitability of the patient for bariatric surgery and also in conjunction with the patient to decide which bariatric operation best suits each individual patient. The patient should also be
given a written summary of the risks and benefits of each of the bariatric operations and allowed a cooling period prior to surgery to allow them to take stock of their options before written consent is reconfirmed.

2. Technical performance of the operation: There is surprisingly little in the literature on what constitutes an appropriate medicolegal standard in the performance of surgery. Clearly gross technical errors (eg the attachment of the biliary limb to the gastric pouch during gastric bypass surgery – the so-called Roux en O) are indefensible but these are relatively rare. As previously discussed, the most common cause of successful litigation is failure to detect and act on the complications in a timely manner. For example although a leak following gastric bypass surgery is not in itself an indicator of negligence, failure to detect and act upon this would be regard as a negligent error. This can be problematic as the signs of leak can be subtle and as such bariatric surgeons should have very low threshold for investigating patients whose clinical recovery appears to be delayed. In addition to surgical complications, it should be noted that bariatric patients often have significant co-morbidities which need to be optimally managed during their hospital stay. In particular, bariatric patients have a high risk of deep vein thrombosis and suitable thromboprophylaxis is an essential part of their care.

3. Post-discharge management: Following discharge from hospital, patients should be given written advice regarding their dietary intake in the immediate postoperative period and appropriate information regarding their vitamin supplementation. Although these patients should ideally be followed up for life by the bariatric team and this may not be logistically feasible, however if a patient is to be discharged it is incumbent on the bariatric surgeon to ensure that appropriate follow-up is arranged with their primary care physician.

**BARIATRIC MEDICOLEGAL ISSUES FOR THE NON-SPECIALIST**

There is an increasing burden of patients presenting to their primary care physician or emergency department requiring either routine follow-up or emergency management of complications related to bariatric surgery.
The reasons for this recent rise in the number of patients requiring clinical input from non-specialist, non-bariatric institutions are multifactorial and include:

1) As the number of patients who have had bariatric surgery grows, there is a growing pool of patients within the community susceptible to the potential long-term complications associated with bariatric surgery.

2) Given the specialist nature of bariatric surgery, there are relatively few bariatric centres and hence patients often have travel a long distance to have their surgery in these specialist hospitals. In addition, there is a large, well-advertised international market for bariatric operations and hence many patients do go abroad for their surgery. Both of these classes of patient are likely to access their local health services as opposed to their original institution.

3) Unlike patients undergoing resections for gastrointestinal cancer, bariatric patients are relatively young. As such there is a significant incidence of patient migration for work or personal reasons from the area where the original surgery was performed.

4) Sub-optimal follow-up by their bariatric surgical unit can result in patients presenting \textit{in extremis} with for example metabolic complications following a failure to monitor and adjust vitamin supplementation after gastric bypass.

Typical emergency presentations related to bariatric surgery include early post-operative complications such as late anastomotic leak as well as long-term complications many years following surgery (eg gastric band slippage and internal herniation following Roux-en-Y gastric bypass surgery). These patients present a particular clinical problem for institutions administering emergency care. For start patients presenting as emergencies will typically will go to their local Emergency Department, and these hospitals may not have surgeons with familiarity in bariatric surgery nor experience in dealing with post-bariatric surgical emergencies. In addition, the facilities in such hospitals may not be able to cater for the special needs of morbidly obese patients. The question which then arises is- what is the minimum medicolegal standard of care that these hospitals need to provide to such emergency bariatric patients? Although these standards can vary from jurisdiction to jurisdiction, under English law, the hospital will be expected to provide a standard of care provided by a reasonably competent general surgeon in a non-specialist hospital, as opposed to the optimum standard of care which would be afforded by a specialist bariatric unit. An important principle is that these patients
should be discussed at the earliest opportunity with a bariatric unit (ideally the institution where the surgery was originally performed) and, where possible and appropriate, early transfer of the patient should be arranged. However this should not delay treatment as the majority of complications after bariatric surgery tend to be general surgical complications (eg intestinal obstruction) and as such the management of these complications should be within the remit and capacity of a general surgeon covering the emergency take. Failure to recognise these problems early and intervene in a timely fashion is one of the most common causes of preventable, major long-term disability or death in bariatric surgical patients and hence such failures should be considered to be sub-standard provision of care.

CONCLUSION

Bariatric surgery is designed in conjunction with other behavioural modifications to improve the long-term functional outcome of patients. Unlike traditional resection of gastrointestinal surgery, bariatric surgery requires a different paradigm

with a truly multidisciplinary approach both pre- and post-operatively to improve the long-term functional outcomes of patients. This in turn creates a large number of medical legal pitfalls which, in ever more litigious society are likely to result in more legal claims. However with appropriate multidisciplinary involvement and robust protocols for the pre-, intra- and postoperative management of these patients these risks can be mitigated and reduced. Finally it should be noticed that we have so far focused exclusively on the medicolegal aspects of patients enrolled within a surgical programme. However, in countries such as the United Kingdom with a predominantly state-funded health care system, there is a growing problem with access to publically-funded bariatric surgery. For example in the United Kingdom, less than 1% of the patients who would benefit clinically from bariatric surgery are in fact funded for this operation. It is likely that this rationing of bariatric surgery will become a significant source of medicolegal claims in the future.
REFERENCES
