



Original article

First report from the American Society of Metabolic and Bariatric Surgery closed-claims registry: prevalence, causes, and lessons learned from bariatric surgery medical malpractice claims

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Abstract

Background: Bariatric surgery has demonstrated sustained improvements in quality. Malpractice closed claims have been offered as a means of assessing quality. Few studies have investigated malpractice closed claims and opportunities for improvement in bariatric surgery.

Objectives: To examine the prevalence and causes of malpractice claims with examination of prospects for quality improvement.

Setting: University hospital, United States; private practice.

Methods: Four national malpractice insurers participated in the closed-claims registry. Data regarding patients, staff, procedures, and hospital status were gathered from closed-claims files. Following data collection, a clinical summary of each closed claim was collected and later assessed by an expert panel on the basis of the following: contributing diagnosis and treatment events; whether complications were potentially preventable by the surgeon; the role of language, fatigue, distraction, workload, or teaching hospital/trainee supervision; communication concerns; and final care determination.

Results: A total of 175 closed claims were collected from index bariatric surgeries within the period from 2006–2014. Of these, 75.9% of surgeons were board certified and 43.3% of the hospitals were accredited for bariatric surgery. Most clinical complications after bariatric surgery that led to malpractice lawsuits were mortality (35.1%) and leaks (17.5%). While they were not the common cause for malpractice suits, bleeding (5.3%), retained foreign body (5.3%), and vascular injury (4.4%) occurred at higher rates than national averages.

Conclusion: Prevalence of malpractice claims regarding bariatric surgery is low. Failure to diagnose, delay in treatment, postoperative care, and communication domain responses indicate future

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Key words: Bariatric; Complications; Insurance; Closed claims

The landmark Institute of Medicine Report, “To Err is Human: Building a Safer Health System,” highlighted the societal need to improve patient safety [1]. Three strategies were emphasized in the report: preventing, recognizing, and lessening any injuries caused by medical errors. The report especially stresses the importance of implementing strategies to prevent error, which is deemed to have the greatest effect on patient safety. Medical malpractice claims often offer a method of addressing lapses in patient care and provide an opportunity to enhance the quality of medical care.

The alarming increase of obesity among both children and adults in the United States has led to the rise in bariatric surgery procedures [2,3]. More than 30% of adults and 17% of adolescents have obesity in the United States in 2012 [4]. The increase in bariatric surgery procedures prompted a need for national standards to guarantee patient safety [5]. Complications occurred at a high rate after surgery in the early 2000s, inciting the establishment of Centers of Excellence in Bariatric Surgery [6]. The field of bariatric surgery has since experienced a tremendous improvement in patient outcomes [7] owing in part to accreditation [8], fellowship training [9,10], and changes in procedure practice.

Despite bariatric surgery’s current excellent patient safety profile, malpractice coverage for bariatric surgery malpractice was initially difficult to obtain. Very few studies have analyzed medical malpractice in bariatric surgery [11]. Additionally, no closed-claims registry has been created for bariatric surgery. A bariatric surgery closed-claims registry affords the opportunity to review specific episodes of care that may have opportunities for improvement. To our knowledge, this study presents the first bariatric surgery closed-claims registry designed to examine prevalence and causes of malpractice claims with examination of prospects for quality improvement.

Methods

Four of the nation’s major malpractice insurers agreed to participate in the American Society for Metabolic and Bariatric Surgery’s (ASMBS) Closed Claims Registry (Coverys, The Doctors Company, Medical Centre Insurance Company, NORCAL). These malpractice carriers represent 4 of the largest medical malpractice firms in the United States [12]. The ASMBS Closed Claims Taskforce obtained primary data from direct abstraction on-site of insurance company’s closed-claims files. Data abstraction included the following variables: age, preoperative body mass index

(BMI), sex, number of comorbidities, surgeon board certification, hospital accreditation status, types of procedures and complications, monetary awards and lawsuit expenses. After data abstraction, a structured clinical summary of each closed claim was provided to all ASMBS Closed Claims Expert Panel members. Members of the ASMBS Closed Claim Expert Panel provided assessment of the clinical summary on basis of the following categories: diagnosis and treatment events; surgeon’s preoperative, intraoperative, postoperative, global assessment of care; complication preventable by surgeon during preoperative, intraoperative, postoperative care; the role of language, informed consent, fatigue, distraction, workload, clinical performance issues, equipment, or teaching hospital/trainee supervision; communication concerns; cause determination by provider, system and/or disease; and care determination. Members of the ASMBS Closed Claims Expert Panel represented 8 prior ASMBS presidents with over 20 years of experience and 4000 cases performed on average. The clinical summaries were reviewed by the entire Expert Panel and initial assessment was documented. Interrater reliability was 90%, and final determination was confirmed by group discussion and final anonymous assessment.

Results

A total of 175 closed claims were identified from index bariatric surgeries within the period from 2006–2014. Patients were on average 44.4 ± 1.0 years of age and had a mean preoperative BMI of 48.0 ± 0.9 kg/m², and 70.2% were women. Close to half of the patients (41.8%) had super obesity with a BMI >50 kg/m². Most of the procedures performed were laparoscopic Roux-en-Y gastric bypasses (45.6%), followed by laparoscopic gastric band placements (18.1%), open bariatric surgery (13.4%), and sleeve gastrectomies (8.1%). Nonstandard procedures accounted for 3.4% of all procedures, and 75.9% of surgeons were board certified. Less than half of the hospitals (43.3%) were hospital accredited for bariatric surgery (Table 1).

The most common clinical complication that was followed by malpractice lawsuits was mortality (27.1%). Leaks constituted another major clinical complication (16.7%). Other significant complications were bowel obstructions (8.3%), surgical technical errors (6.9%), wound infections (6.9%), bleeding (6.3%), perforations (6.3%), and nutrient deficiencies (4.9%). The mean monetary award was $\$293,499.83 \pm \$100,434.60$, ranging from \$0 to \$10,400,000. The mean total expense for lawsuits was

Table 1
Preoperative study population demographics and hospital characteristics

Patients (n)	175
Age (mean ± SE), yr	44.4 ± 1.0
BMI (mean ± SE), kg/m ²	48.0 ± 0.9
BMI >50 kg/m ² (%)	41.8
Female sex (%)	70.2
Co-morbidities (mean ± SE)	2.86 ± 0.2
Type of procedure (%)	
LRYGB	45.6
Lap band	18.1
Open surgery	13.4
Sleeve gastrectomy	8.1
Revision surgery	4.0
Nonstandard procedures	3.4
Band removal	2.7
BPD/DS	2.7
Band to BPD/DS	2.0
Surgeon board certified (%)	75.9
Hospitals accredited (%)	43.3

SE = standard error; BMI = body mass index; LRYGB = laparoscopic Roux-en-Y gastric bypass; BPD = biliopancreatic diversion; DS = duodenal switch.

\$91,835.54 ± \$12,111.40, ranging from \$0 to \$850,000 (Table 2).

Upon assessment of the clinical summaries, the ASMBS Closed Claims Expert Panel discovered the following issues. A total of 60.8% of diagnostic events contained misinterpreted tests, misdiagnoses, or other diagnostic issues, and 70.9% of treatment events included technical misadventures, delayed treatments, incorrect treatments, and failed treatments. In overall clinical performance, delays or inappropriate diagnosis accounted for 22.8% of clinical performance issues, and delays or inappropriate treatment accounted for 34.7%. The panel judged that 58.1% of all complications were preventable by the surgeon, especially through better postoperative care; improved postoperative

Table 2
Clinical complications and malpractice expenses

Clinical complications (%)	
Mortality	27.1
Leak	16.7
Bowel obstruction	8.3
Surgical technical error	6.9
Wound infection/dehiscence	6.9
Bleeding	6.3
Perforation	6.3
Nutrient deficiencies	4.9
Retained foreign body	4.2
Intra-abdominal abscess	3.5
Vascular injury	3.4
Prolonged nausea/abdominal pain	2.8
Ulcers/stricture	2.1
Myocardial infarction	0.7
Monetary awards (mean ± SE)	\$293,499.83 ± \$100,434.60
Expenses for lawsuits (mean ± SE)	\$91,835.54 ± \$12,111.40

SE = standard error.

care could have prevented complications in 45.1% of all postoperative cases. Cause determination was mainly provider-related. Many communication issues were also discovered in these cases. Forty percent of cases contained team communication concerns, and 27.8% had insufficient communication with the patient or the family of the patient. Only 19.5% of cases contained appropriate communication performances. Other issues were also identified as having a role in the malpractice lawsuits, such as informed consent, concerns regarding trainee supervision in a teaching hospital, issues with coverage and handoff, and nonstandard weight loss operations. Finally, only 20.9% of overall care determination was deemed appropriate; 47.8% contained human error with opportunity for improvement; 23.5% had at-risk behavior (preventable errors), which requires significant education to prevent reoccurrence; and 7.9% of cases comprised inappropriate (preventable) care suggesting reckless disregard of surgeon's duty to patient through gross negligence, incompetence, or actual intent to provide substandard care (Table 3).

Discussion

Bariatric medical malpractice gained interested with the rise of bariatric surgery cases [13]. However, it is not completely understood if the increase in lawsuits is consistent with the increase in bariatric surgery procedures. Few studies exist to characterize bariatric surgery malpractice claims. This is the first study to create a bariatric surgery closed-claims registry. This registry is crucial to comprehend the prevalence and causes of malpractice claims. Its potential also lies in the improvement of patient safety in the bariatric surgery field. Detailed, de-identified case summaries of the closed claims will be provided for research purposes.

This study finds a low prevalence of malpractice claims in bariatric surgery from 2006–2014. When compared with the national demographics norms of bariatric surgery through the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), the percentage of males was higher and the mean of preoperative BMI was greater in malpractice claims. This outcome is consistent with previous studies demonstrating that the male gender and preoperative BMI were statistically significant risk factors for complications in bariatric surgery [14,15]. Additionally, surgeons who were involved with malpractice claims were less often board-certified than national norms. Similarly, hospitals involved with malpractice suits had a much lower accreditation rate in comparison with national norms. Of note, sleeve gastrectomy represented only 8% of claims while representing >70% of primary bariatric procedures with the caveat that during this time frame sleeve gastrectomy was emerging and not yet dominant. Malabsorptive and nonstandard procedures were over-represented in

Table 3
Summary of clinical assessment of patient care

Diagnosis events (%)	
Misinterpreted tests	15.1
Misdiagnosis	28.2
Other diagnostic issue	13.3
Any “diagnostic event” occurred	4.2
No diagnostic event	39.2
Treatment events (%)	
Technical misadventure	22.2
Delayed treatment	26.2
Failure to treat	13.8
Wrong treatment	8.7
Outside scope of established practice	3.4
Medication issue	2.4
Equipment issue	3.2
Anesthesia event	2.1
Retained foreign body	3.3
Any “other event” occurred	5.1
No treatment issue	9.6
Clinical performance issues (%)	
Delay/inappropriate diagnosis	22.8
Delay/inappropriate treatment	34.7
Supervision/delegation	7.0
Goals of care not addressed	1.7
Omission of procedure	1.9
Procedure incorrectly performed	15.2
Case selection	5.8
Appropriate clinical performance	11.0
Communication issues (%)	
Insufficient communication with team	40.0
Insufficient communication with patient and/or patient’s family	29.8
Disclosure process inadequate	5.9
Incomplete documentation	4.9
Appropriate communication performance	19.5
Care determination (%)	
Not preventable (care appropriate)	20.9
Human error (practitioner improvement opportunity)	47.8
At-risk behavior (preventable error) care	23.5
Inappropriate (preventable) care	7.9

malpractice claims in comparison with the MBSAQIP procedure rates; however, it must be considered that patients with higher BMI are often referred to these procedures. While mortality was the most common cause for malpractice suits, bleeding, retained foreign body, and vascular injury occurred at higher rates than national averages. Overall care determination found 31.4% of cases to be either preventable error or preventable. Failure to diagnose, delay in treatment, postoperative care, and communication domain responses from expert panel indicate future opportunities for improvement along with specific recommendations for prevention of retained foreign bodies and vascular injury following trocar placement. There is a clear opportunity to provide a quality improvement curriculum based

on these findings. Technical instruction on specific issues could lead to prevention of complications including prevention of leaks, proper laparoscopic access, removal of nasogastric/temperature tubes during surgical stapling, and consensus for hernia management during bariatric surgery. There is a clear need for standardized hand-offs between surgeons and opportunity for better communication. Many claims centered on lack of knowledge of the clinical status of patient by all members of the team. Home monitoring of vital signs could also provide another means of preventing complications particularly with the advent of telehealth. There were numerous instances of patients reporting alterations in vital signs that did not result in a clinical assessment. The disproportionate representation of nonstandard procedures in these malpractice claims indicates a continuing need for assessment of approved procedures. The nonstandard procedures are defined by those not listed by ASMBS as endorsed procedures [16]. It should be noted that a malpractice claim does not necessarily indicate a gap in quality. One large national study found that over 37% of claims did not involve error [17].

This study contains limitations. The victor of the malpractice lawsuit was never revealed in the responses gathered in this study; therefore, the final legal outcomes were unknown. Additionally, the assessment and classifications provided by the ASMBS Closed Claims Expert Panel members may not be fully representative of the ASMBS community or the rest of the bariatric surgery community, though 80% of the ASMBS Closed Claims Expert Panel was composed of former ASMBS presidents.

Conclusion

While the prevalence of malpractice claims regarding bariatric surgery is low, the malpractice claims offer great potential in improving the safety of bariatric surgery. Hospital accreditation, further standardization in procedures, quality improvement education, and increased training in bariatric surgery may decrease the rates of complications following bariatric surgery, as well as malpractice claims in the field.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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