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Fatal Complications of Bariatric Surgery

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Background: Bariatric surgery is an increasingly used method to treat morbid obesity. The mortality rate among patients undergoing bariatric operations is generally quoted as between 0.05-2.0%. Our focus was not on mortality rates but rather on the reasons patients die following the procedures. In New York City, deaths that are due to predictable complications of appropriate therapy are certified as therapeutic complications.

Methods: We retrospectively reviewed all deaths investigated by the Office of the Chief Medical Examiner in New York City between 1997 and 2005 in which bariatric surgery had been performed. We report the fatal complications, the interval between surgery and death, the type of procedure, and co-existing morbidities.

Results: Autopsies were performed on 95% of these fatalities. There were 97 deaths due to therapeutic complications of the operations. The interval between the initial surgery and death ranged from several hours to years. The most common complication was an anastomotic leak with subsequent infection. A high percentage of deaths occurred after discharge (40%) and/or >30 days after surgery (37%). There were 8 deaths from complications of bariatric surgery that occurred >1 year after surgery.

Conclusions: Studies that report the mortality rate during hospitalization or within 30 days of surgery, underestimate the actual incidence. Bariatric surgery carries both short- and long-term risks.

Key words: Morbid obesity, bariatric surgery, complication, mortality, fatality

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Introduction

Obesity is a major and often underestimated cause of death and morbidity in the United States.^{1,2} Bariatric surgery (from G. *baros*, weight) offers long-term weight reduction for morbidly obese patients and amelioration of some co-morbidities.^{3,4} Specific criteria have been developed to determine whether a patient is a candidate for the procedure. The recommended criteria from an NIH consensus conference (1991) are based upon the body mass index (BMI) and co-existing obesity-related morbidities.⁵ The degree of obesity and the morbidities must justify the risk of the surgical procedure.⁶ The types of bariatric surgery include restrictive (gastric banding or vertical banded gastroplasty), malabsorptive (jejunoileal bypass), and combination types (Roux-en-Y gastric bypass, biliopancreatic diversion).⁷⁻¹¹

The mortality rate among patients undergoing bariatric surgical procedures is generally quoted as between 0.05-2.0%.^{6,12,13} Recent studies, however, have demonstrated higher incidences, particularly with advanced age.¹⁴ In addition, there is an inverse relationship between hospital/surgical bariatric surgery volume (experience) and surgical morbidity and mortality.¹⁴ The number of deaths due to complications of bariatric surgery examined by the New York City Office of Chief Medical Examiner (NYC OCME) have increased over the past 7 years. This increase has paralleled the national increase in the number of bariatric operations performed. Our goal was to examine the mechanisms and immediate causes of these deaths.

Materials and Methods

The NYC OCME investigates all unexpected, violent, and suspicious deaths in New York City. In addition, all deaths that occur during diagnostic or therapeutic procedures (or from complications of such procedures) must be reported to the NYC OCME. The NYC OCME routinely takes jurisdiction of deaths that are suspected complications of diagnostic or therapeutic procedures. Of the reported bariatric deaths, the medical examiner's office did not refuse to perform an autopsy on any. There were 5 deaths in which the family requested that an autopsy not be performed and one autopsy that was done at the hospital. These 6 deaths were investigated and certified by the medical examiner's office and are included in this study. In a typical year, the NYC OCME investigates and certifies 8,500-9,000 deaths. Of these, approximately 400-500 are therapeutic complications and 5,000 are natural. The remainder includes accidents, homicides, suicides, and undetermined manners of death.

We performed a retrospective review of all deaths reported to the NYC OCME between January 1997 and August 2005 that occurred following bariatric surgery. The deaths were identified by a computer search of autopsy report and death certificate computer databases. Of these deaths, 90% (97/107) died due to complications of the bariatric procedure; this is the cohort which was studied. Autopsy, hospital, and investigation reports were reviewed. Data concerning cause of death, contributing conditions, age, race, sex, co-morbidities, interval between surgery and death, and BMI were extracted. The surgeries included gastric bypass (open and laparoscopic) and gastric banding. The gastric bypass procedures included: Roux-en-Y procedure, biliopancreatic diversion (with and without duodenal switch), and enteric bypass (jejunal-ileal anastomosis). The gastric bypass surgeries were not subclassified into proximal or long-limb procedures. Liposuction, breast reduction surgeries, and abdominoplasty surgeries were excluded.

The cause of death is defined as the etiologically specific disease and/or injury responsible for initiating the lethal sequence of events. A competent cause of death includes the *proximate* (underlying) cause, defined as that which in a natural and contin-

uous sequence, unbroken by any efficient intervening cause, produces the fatality and without which the end result would not have occurred. The manner of death is determined from the cause and circumstances of death. The manners of death include: natural, therapeutic complication (TC), accident, suicide, homicide, and undetermined. A natural death is exclusively due to natural disease; neither medical therapy nor injury plays a role in causing or contributing to the death. A therapeutic complication death is due to a predictable complication of appropriate therapy (e.g., anaphylaxis to a prescribed medication). The "but for" test may be used to distinguish natural from TC deaths. This is done by asking the question: "But for the procedure/treatment, would the patient likely have died at that time?" If the answer is "no", then the manner of death is certified as therapeutic complication instead of natural. Deaths due to unanticipated complications and/or inappropriate therapies are certified as accidents (e.g., inadvertent administration of too much medication).

Results

Between January 1997 and August 2005, there were 107 deaths of patients who had undergone bariatric surgery. Of these, 97 deaths were due to complications of the bariatric operation. Autopsies were performed on 95% (92/97) of these fatalities. The causes of the remaining 10 deaths were not due to complications of the bariatric surgery (e.g., suicidal ingestion). These 97 deaths due to surgical complications are the cohort which was studied.

The types of surgeries included open (71) and laparoscopic (21) techniques, and are listed in Table 1. At least three open laparotomies began as laparoscopic procedures. The surgeries included Roux-en-Y gastroenterostomy ("gastric bypass"), biliopancreatic diversion procedure with and without duodenal switch, gastric banding, and elective revision/reversal surgeries. Two deaths followed elective revisions, of which one followed reversal of a prior gastric bypass and the other followed removal of a gastric band. Due to reoperations, lack of some operative reports, and distorted anatomy at autopsy, the types of procedures were unknown in 12 instances.

Table 1. Known types of procedures in complication deaths

Bariatric Procedure (n=97)	Number (%)
Gastric bypass (Roux-en-Y gastroenterostomy)	71 (73%)
Biliopancreatic diversion with duodenal switch	4 (4%)
Gastric banding, NOS*	3 (3%)
Biliopancreatic diversion	3 (3%)
Elective revision of enteric bypass and Roux-en-Y	2 (2%)
Elective reversal of Roux-en-Y	1 (1%)
Elective reversal of gastric banding	1 (1%)
Unknown	12 (13%)
Surgical Approach	
Laparoscopic procedure	21 (22%)
Open procedure	68 (70%)
Laparoscopic followed by open procedure	3 (3%)
Unknown	5 (5%)

*NOS = not otherwise specified

There were 68 women and 29 men with 42 White, 35 African-American, 20 Hispanic, and no Asian. The mean age was 44.8 years (range 18-70). Of these 97 deaths due to therapeutic complications, 61 patients died within 30 days of surgery (Figure 1) and 39 died after discharge from the hospital. The interval between the initial surgery and death was between 6 hours to 3,680 days including 36 deaths that occurred within the first 9 days after surgery. The interval for one death was unknown. The BMI at autopsy ranged from 25-120 (mean 54) for 95

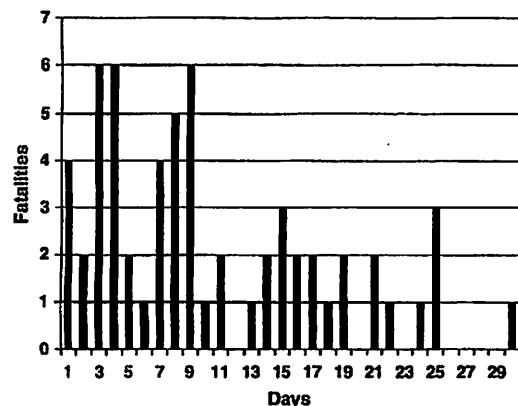


Figure 1. 30-day mortality: number of days between surgery and death (n=60). Note: One additional patient died within 30 days of surgery but the exact interval was not known.

patients (two were unknown). Of the seven patients with a BMI <35, all were at least 135 days from surgery (range 135-875 days). The mean BMI of patients who died within 30 days of surgery (61 patients) was 56 (range 35-120) and 1 year after surgery (eight patients) was 38 (range 28-53). There were eight patients in whom the original hospital was unknown. Among the other 89 patients, the surgeries occurred at 31 different hospitals in the NYC metropolitan area. In 2003, there were 21 deaths that occurred in 15 different hospitals (Figure 2).

For all 97 fatalities, the proximate cause of death was obesity and the manner of death was therapeutic complication. The complications that resulted in this certification are listed in Table 2. Two patients had more than one complication (anastomotic leak and pulmonary embolus (PE), short gut syndrome with anastomotic leak on subsequent revision). Because these are predictable complications of appropriate surgical therapy, the manner is therapeutic complication as opposed to natural or accident.

The most common complication was an anastomotic leak with infection (Table 2 and Figure 3).

Table 2. Complications of Bariatric Surgery (n=97)

	Total	Percentage
Technical		
Anastomotic leak	35	36%
Hemorrhage at surgical site	8	8%
Biliary leak (cholecystectomy)	1	1%
Non-Technical		
Pulmonary embolism	12	12%
Cardiac mechanisms	9	9%
Postoperative infection	9	9%
Coagulopathy (generalized hemorrhage)	3	3%
Respiratory complication	2	2%
Ulcer at anastomosis	1	1%
Ileus	1	1%
Carotid artery thrombosis	1	1%
Late/Delayed		
Adhesions/obstruction	9	9%
Ventral/incisional hernia	3	3%
Malnutrition	3	3%
Fistula	1	1%
Intestinal ulcer/hemorrhage	1	1%
Re-operation	53	55%

Note: Two patients had more than one complication.

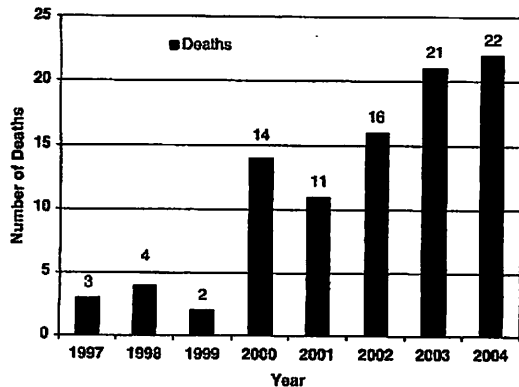


Figure 2. Number of deaths by year, 1997-2004 (n=93).

Three patients had generalized hemorrhagic complications ("oozing"), two of whom had cirrhosis. Among the fatalities, 12 (13%) died from a PE of which one had a vena caval filter (five others had filters placed but did not die from PE). The average heart weight was 528 gm (range 230-1250 gm), and 46 patients (50%) had heart weights ≥ 500 gm. At least one co-morbidity was found in 89% of the therapeutic complication fatalities (Table 3).

Ten (10/107) deaths were not due to complications of the bariatric operation. Among these, eight were certified as natural, one was a suicide (by toxic ingestion), and one was an accident (blunt injury due to a fall). Most of these deaths were remote (>3

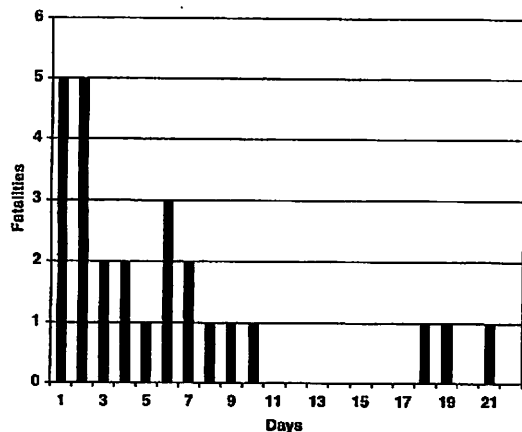


Figure 3. Number of days between surgery and diagnosis of anastomotic leak (n=26). Note: The interval was not known in 9 patients.

Table 3. Co-morbidities in therapeutic complication fatalities (n=97)

Co-morbidities	Total	Percentage
Total number of deaths with one or more co-morbidities	86	89%
Atherosclerotic and/or hypertensive cardiovascular disease	53	55%
Diabetes mellitus	28	29%
Respiratory disease (asthma)	14	14%
Hepatic steatosis	64/91	70%
Sleep apnea	12	12%
Arthritis	11	11%

months) from surgery. Four of the natural deaths, however, occurred 3, 34, 60, and 63 days after gastric bypass surgery. There was no evidence at autopsy for a directly attributable cause due to the surgery (e.g., PE or leak); therefore, these deaths were certified as natural (heart disease due to obesity). Although there was no anatomic immediate cause or mechanism of death, it is possible that physiologic and metabolic alterations and/or stress following surgery may have played a role in the deaths.

Discussion

We report 97 deaths due to complications of bariatric surgery performed for morbid obesity. By examining the mechanisms and immediate causes of death, we hope to provide information to clinicians that may assist in the prevention of such deaths and to pathologists to assist in the examination of these deaths. Our focus was not on how many patients died per procedure performed, but rather *why* they died.

In our study, anastomotic leaks were the most common fatal postoperative complication. Leaks are due to mechanical/tissue causes or rarely an ischemic mechanism.¹⁵ It is postulated that early leaks (1-3 days following surgery) are due to technical factors and leaks that occur later (7-10 days following surgery) are related to local ischemic issues (see Figure 3). In either instance, the intraluminal pressure exceeds the strength of the tissue and the staple-line, resulting in a leak. Intrinsic dysfunction of the stapler or misuse of the stapler (e.g., incorrect selection of staple size) may also play a

role and can be difficult to discern at autopsy.

In a study by Fernandez et al¹⁶ of 3,073 patients who underwent gastric bypass surgery, 3.2% developed a leak. Overall, their leak-associated mortality was nearly 17%. Independent risk factors for leak included age, male gender, a history of sleep apnea, and procedure type. Independent risk factors for death included leak, weight, procedure type, and hypertension. Many of our fatalities had at least one co-morbidity, which may have made them a higher surgical risk.

A previous study by Melinek et al¹⁷ found that eight of the ten patients who died following gastric bypass surgery had microscopic evidence of pulmonary emboli (PE), although the cause of death was PE in only three. This is not surprising because obesity and abdominal surgery are risk factors for deep venous thrombosis and PE.¹⁸⁻²⁰ Some surgeons insert prophylactic inferior vena caval filters prior to gastric bypass surgery. Among our fatalities, 12% died from a PE of which one had a vena caval filter (five others had filters placed but did not die from PE). The differences in the incidences of the fatal PE in these two studies may be related to the differences in group size and a selection bias (hospital-based study vs medical examiner study).

Other non-technical complications include cardiac mechanisms which accounted for 9% of the fatalities. Hypertensive disease is a common co-morbidity of obesity. At autopsy, cardiac hypertrophy is a common sign of hypertension. The normal heart weight is based upon body weight with a typical normal upper limit of 500 gm. The risk of cardiac arrhythmias increases with increasing abnormal heart size. In general, a heart weight >500 gm, regardless of the patient's body weight, is at increased risk for arrhythmia. The average heart weight was 528 grams (range 230-1250 gm), and 46 patients (51%) had heart weights ≥500 gm. However, obesity, per se, does not appear to be the sole determinant of cardiac hypertrophy. For example, a patient with a 760-gm heart had a body weight of 151 kg and a second patient who weighed 171 kg had a heart weight of 390 gm. However, the high prevalence of cardiac hypertrophy in the obese population should be considered as a potential risk for fatality.

In addition to hypertensive cardiovascular disease, other co-morbidities included diabetes mellitus, atherosclerosis, hepatic steatosis, and chronic lung disease (asthma, sleep apnea). These diseases may

make a patient more susceptible to a variety of operative and postoperative complications, including infection (urinary tract, bronchopneumonia), cardiac arrhythmias, and respiratory complications while under anesthesia or on mechanical ventilation. Because of the nature of the complex pathophysiological interactions of these processes, it is not always possible to determine the precise role or extent of an individual morbidity in the overall cause of death. The presence, however, of at least one co-morbid condition in 89% of the fatalities suggests that these patients may be more susceptible to succumbing to postoperative complications.

Among the delayed deaths, which accounted for 18% of the fatalities, most were due to complications of bowel obstruction and/or complications of repair of a ventral/incisional hernia. This is a risk with any abdominal surgery. Prompt diagnosis and treatment are important in preventing these deaths. Patients who have had prior abdominal surgery need to be aware of the symptoms of the complications in order to receive timely evaluation. Two patients died of direct complications of malnutrition and one from an anastomotic leak following surgical revision of a gastric bypass due to short gut syndrome which are known complications of some types of the malabsorptive procedures.²¹⁻²³

In 2002 in the USA, the percentage of bariatric surgical patients who underwent gastric bypass surgery (Roux-en-Y) was 88%.²⁴ Malabsorptive procedures, gastroplasty, and gastrectomy made up the remainder.²⁴ Although at least three procedures were converted intraoperatively from laparoscopic to open, laparoscopic procedures did not appear to be over- or under-represented among our fatalities. In a study in Virginia from 1992 to 2003, the laparoscopic approach accounted for 29% of their gastric bypass operations compared to 26% in our study. The procedure proportions of our fatalities are similar to the figures for types of bariatric surgical procedures performed in the United States. The incidence of the types of procedures performed in NYC is unknown, but comparison to the national data suggests that a particular surgical procedure is not over-represented among the NYC fatalities.

The mortality rate for gastric bypass surgery has been reported to range from 0.05% to 4.6%, depending upon how it was measured.²⁵ Santry et al,²⁴ using the NIS database, estimated the mortality

rate to be 0.1 to 0.2%. This rate was for postoperative deaths that occurred during hospitalization for the primary surgery. As our data demonstrate, 40% of patients died after discharge for the initial surgery. The majority of our decedents (61/96) died within 30 days following surgery. The study by Zingmond et al²⁶ that used California data, reported a total mortality rate at 30-days of 0.33%, which is similar to the 0.5% reported by Buchwald.¹³ Another study in Washington State reported a 30-day mortality rate of 1.9%,⁶ while a study of Medicare beneficiaries undergoing bariatric surgery reported a 30-day mortality rate of 2.0% and a 1-year rate of 4.6%.¹⁴ Our data showed that 35/96 patients (37%) died after 31 days following surgery. There were eight deaths from complications of bariatric surgery that occurred >1 year after surgery. This confirms that bariatric surgery carries both short- and long-term risks, which may actually be under-reported.

These deaths following bariatric surgery most likely underestimate the actual number of fatalities from complications of bariatric surgery performed in New York City. Among the complication deaths, 40% occurred after discharge from the hospital. Because of the range of time intervals between surgery and death, some of these deaths may not be recognized as due to delayed surgical complications. If not, then they may not have been reported to or accepted by the NYC OCME. This is one reason why the incidence of bariatric deaths in New York City is practically unknowable for us. Not only would it be difficult to find the number of bariatric operations performed in >30 hospitals over an 8-year period, but the numerator also is problematic. Some patients who undergo bariatric surgery in New York City are not New York City residents. Fatal complications that occur after discharge may not be accurately captured if the patient lives outside New York City. In this case, the investigation and certification of that death would be the responsibility of another jurisdiction. Indeed, one of the instances investigated by the NYC OCME died in New York City but underwent gastric bypass at a medical center outside of New York City.

We reviewed 107 deaths of patients who had undergone bariatric surgery. The vast majority of deaths (97) were due to complications of the surgery. Because we do not know the total number of

procedures that were performed during this time period, we can offer no comment on the rate of complications due to bariatric surgery. Other studies, as discussed, have examined that issue. There is, however, a high number of deaths that occur after discharge (40%) and/or >30 days after surgery (37%). Therefore, studies that have reported the mortality rate during hospitalization or within 30 days of surgery, underestimate the actual incidence.

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