

Avoidance of Complications in Older Patients and Medicare Recipients Undergoing Gastric Bypass

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Hypothesis: Perioperative morbidity and mortality do not increase in carefully evaluated and managed Medicare and elderly patients undergoing gastric bypass.

Design: Retrospective review of a prospectively maintained bariatric database.

Setting: Academic tertiary care medical center.

Patients: We reviewed our database of 928 consecutive patients who underwent gastric bypass from March 24, 1998, through May 31, 2006. Of these patients, 36 underwent revision surgery and were excluded. The remaining 892 patients were separated into 4 groups by age and Medicare status. Group 1 consisted of 46 patients 60 years or older at the time of gastric bypass (range, 60-66 years). Group 2 consisted of 846 patients 59 years or younger at the time of gastric bypass (range, 18-59 years). Group 3 consisted of 31 Medicare recipients (age range, 31-66 years). Group 4 consisted of 861 non-Medicare recipients (age range, 18-64 years).

Main Outcome Measures: Groups were compared in terms of demographics, morbidity, and mortality.

Results: No differences were found in outcomes between older vs younger and Medicare vs non-Medicare patients for any postoperative complication or mortality.

Conclusions: Bariatric surgery can be performed in carefully selected Medicare recipients and patients 60 years or older with acceptable morbidity and mortality. No difference was found in the occurrence of complications in Medicare patients, patients younger than 60 years, or patients 60 years and older. We believe that these results reflect careful patient selection, intensive preoperative education, and expert operative and perioperative management. Our results indicate that bariatric surgery should not be denied solely based on age or Medicare status.

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OBESITY HAS BECOME THE leading cause of preventable death in the United States. Obesity may cause the first decline in life expectancy in the United States in this century.¹ Rates of obesity have continued to climb in the last decade across all age groups.² Surgery for morbid obesity is currently the most effective treatment.³ Guidelines for the surgical management of morbid obesity were first published in 1991 after the National Institutes of Health Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity. This panel did not recommend an age restriction.⁴ In 1977, before the consensus conference, Printen and Mason⁵ reported high mortality rates in patients older than 50 years and advised against bariatric surgery for these individuals.

This advice was followed by many bariatric surgeons for nearly 2 decades.

The success of bariatric surgery in the treatment of morbid obesity and its comorbid conditions has spurred surgeons to expand this therapy for patient populations not previously served. Medicare has recently issued a National Coverage Determination for obesity surgery, acknowledging bariatric surgery as safe and effective. However, a recent review of the Medicare database by Flum et al⁶ reported significant mortality rates in all Medicare recipients undergoing bariatric surgery, especially elderly patients. Consequently, we have undertaken this study to critically review our experience with Medicare patients and elderly patients undergoing gastric bypass and have compared the results of these 2 groups with the remainder of our bariatric database population.

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Study approval was obtained from the institutional review board at University Hospitals Case Medical Center for a retrospective medical record review. This review of our prospectively maintained bariatric database of 928 consecutive patients was conducted from March 24, 1998 (the start of our program), through May 31, 2006. Of the 928 patients, 36 patients had undergone revision surgery and were excluded from analysis. The remaining 892 patients were divided into 4 groups. Group 1 consisted of 46 patients 60 years or older at the time of gastric bypass (range, 60-66 years). Group 2 consisted of 846 patients 59 years or younger at the time of gastric bypass (range, 18-59 years). Group 3 consisted of 31 Medicare recipients (range, 31-66 years). Group 4 consisted of 861 non-Medicare recipients (range, 18-64 years). Age, sex, and body mass index (BMI) (calculated as weight in kilograms divided by the square of height in meters) were documented from the patient's initial history and physical examination. Operating room (OR) time was recorded from official OR sheets and represents time from incision until completion of closure. Length of stay was reported as the time in days from admission to the hospital to the time of the discharge order.

Complications were defined as follows. Death was defined as death from any cause within 30 days, 90 days, or 1 year after gastric bypass surgery. Pulmonary embolism was defined as a vascular filling defect on a spiral computed tomographic scan or ventilation-perfusion scan interpreted as high probability, with associated clinical suggestion of a pulmonary embolism. Anastomotic leakage was considered present when a radiologic study demonstrated extravasation of contrast material or subsequent exploration in the OR documented disruption of the anastomosis with visualization of gastrointestinal contents or soiling around the anastomosis. Postoperative bleeding was defined as either the need for 1 U or more of blood transfusion or return to the OR for hemoperitoneum. Pneumonia was defined as an infiltrate apparent on the chest x-ray film, with associated productive sputum, fever, or elevated white blood cell count.

Comorbidities were determined from the initial visit and any investigation performed before the patient's operation. Because of database constraints, we identified the comorbidities in a 50% random sample of groups 2 and 4. Comorbidities were identified for all patients in groups 1 (older patients) and 3 (Medicare patients).

Adhering to 1991 National Institutes of Health consensus conference criteria, we required all patients to have undergone supervised nonsurgical weight loss attempts before gastric bypass. The BMI requirements were 40 or higher or 35 or higher with at least 1 significant obesity-related comorbidity. The patients were initially seen by 1 of our 3 bariatric surgeons (P.T.H., T.A.S., and J.J.J.) and a bariatric nurse coordinator (M.S. or K.G.). In addition, all patients were evaluated before surgery by a board-certified pulmonologist. The cardiology department was consulted for patients 60 years and older and if clinically indicated in patients younger than 60 years. Most patients had an overnight polysomnogram performed to assess for occult sleep apnea. All patients subsequently underwent either a laparoscopic or open Roux-en-Y gastric bypass. When we started our program, we limited the laparoscopic approach to female patients with BMIs less than 50, without diabetes mellitus, and with no prior upper abdominal operations. As our experience with the laparoscopic approach has increased, we have limited our restrictions. We now offer a laparoscopic approach to most patients. Statistical analysis was performed with GraphPad Prism (GraphPad software Inc, San Diego, Calif). A *t* test was used

for parametric data, and the Fisher exact test was performed for nonparametric data. Results were considered statistically significant if $P \leq .05$.

RESULTS

Demographic data comparing patients 60 years or older (group 1) with patients younger than 60 years (group 2) are presented in **Table 1**. Group 1 comprised 46 patients aged 60 to 66 years, and group 2 comprised 846 patients aged 18 to 59 years. As expected, the mean ages between the groups are highly statistically significant. Male-female ratios and BMIs were similar between the 2 groups. Length of stay was a half a day longer for the elderly patients, but this difference was not statistically significant ($P = .04$). The OR time for the elderly group was statistically significant, with a mean time 17 minutes less than that of the younger group. The mean American Society of Anesthesiologists (ASA) scores for group 1 and group 2 were similar at 3 and 2.9, respectively.

Postoperative complications for group 1 (patients 60 years or older) and group 2 (patients 59 years and younger) are listed in **Table 2**. No statistically significant difference was found between the 2 groups for any postoperative complication or mortality. No mortality was seen in the older group (group 1) at 30 days, 90 days, or 1 year. Three deaths occurred within 30 days in the younger group (group 2), with 1 additional death within 1 year. This last death was a homicide.

We identified 32 patients as Medicare beneficiaries in our database from July 1, 2000, until May 31, 2006. We were unable to obtain insurance provider data before 2000. One patient underwent a revision operation and was excluded from this analysis. Demographic data are represented in **Table 3**. The age range for Medicare patients was 31 to 66 years, with a mean age of 47.7 years (group 3). In the non-Medicare group, the age range was 18 to 64 years, with a mean age of 43.1 years (group 4). The age differences between these groups were statistically significant ($P = .01$). Only 2 patients (6.5%) from group 3 were eligible for Medicare based on their age; the remaining patients qualified for Medicare based on disability. The mean BMI and OR times between groups 3 and 4 were statistically significant ($P < .001$ and $P = .03$, respectively). The Medicare patients (group 3) had a statistically significantly greater mean BMI of 56 ($P = .001$) and a significantly longer mean OR time ($P = .03$). The ASA scores for the Medicare and non-Medicare groups were 3.1 and 2.8, respectively ($P = .01$). The length of stay was not statistically significant ($P = .07$), with the Medicare patients spending an average of a day and a half longer in the hospital.

Postoperative complications and mortality for group 3 (Medicare patients) and group 4 (non-Medicare patients) are listed in **Table 4**. No significant difference was found between the 2 groups for any postoperative complication or mortality. No deaths occurred at 30 days, 90 days, or 1 year in the Medicare patients (group 3). In the non-Medicare patients, 3 deaths occurred within 30 days and 1 additional death within 1 year.

Older patients (group 1) vs younger patients (group 2) had a higher incidence of hypertension (75.6% vs

Table 1. Demographic Data for Patients 60 Years and Older vs Patients 59 Years and Younger

Demographic Characteristic	Group 1 (Age ≥60 y) (n = 46)	Group 2 (Age ≤59 y) (n = 846)	P Value
Age, mean ± SD (range), y	61.6 ± 1.44 (60-66)	42.3 ± 9.4 (18-59)	<.001
Male/female, No. (%)	6/40 (13/87)	110/736 (13/87)	>.99
BMI, mean ± SD	50.4 ± 7.45	50.5 ± 8.1	.90*
OR time, mean ± SD, min	148.1 ± 38.8	164.8 ± 54.3	.04*
ASA score, mean ± SD	3.0 ± 0.3	2.9 ± 0.4	.15*
LOS, mean ± SD, d	3.7 ± 5.2	3.2 ± 3.9	.40*

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); LOS, length of stay; OR, operating room.

*t Test.

Table 2. Postoperative Complications in Patients 60 Years and Older vs Patients 59 Years and Younger

Complication	No. (%) of Patients		P Value
	Group 1 (Age ≥60 y) (n = 46)	Group 2 (Age ≤59 y) (n = 846)	
Pulmonary embolism	2 (4.3)	9 (1.1)	.11
Leak	1 (2.2)	15 (1.5)	.58
Fistula	1 (2.2)	9 (1.1)	.41
Bleeding	0	17 (2.0)	>.99
Pneumonia	1 (2.2)	8 (1.0)	.38
Bowel obstruction within 30 days	1 (2.2)	6 (0.7)	.31
Death within 30 days	0	3 (0.4)	>.99

38.5%; $P < .001$), diabetes (48.9% vs 17.8%; $P < .001$), and gastroesophageal reflux disease (55.6% vs 38.8%; $P = .04$). The incidence of sleep apnea (64.4% vs 48.5%; $P = .06$), arthritis (84.4% vs 74.3%; $P = .15$), and hyperlipidemia (26.7% vs 18.8%; $P = .23$) was similar. The average total number of comorbidities for groups 1 and 2 was 6 and 5, respectively ($P < .001$). In Medicare vs non-Medicare patients, a higher incidence of diabetes (51.7% vs 20.1%; $P < .001$) and hyperlipidemia (31.0% vs 19.5%; $P = .005$) was found. The incidence of hypertension (65.5% vs 41.8%; $P = .09$), sleep apnea (69.0% vs 51.1%; $P = .08$), gastroesophageal reflux disease (55.6% vs 42.9%; $P = .25$), and arthritis (77.9% vs 72.4%; $P = .49$) was similar. The average total number of comorbidities for groups 3 and 4 was also 6 and 5, respectively ($P < .001$).

COMMENT

The number of obese older persons has markedly increased because of an increase in both the total number of older persons and the percentage of the older population that is obese.⁷ From 1991 to 2000, the prevalence of obesity in persons aged 60 to 69 years increased 56%, from 14.7% to 22.9%.² It has been estimated that in the United States, obesity accounts for at least 300 000 deaths annually and is now a stronger predictor of mortality than smoking.^{8,9} One recent report has estimated that obesity may reverse the progression in life expectancy seen in this century and may even cause a decrease in life ex-

pectancy of up to 5 years.¹ The Framingham Heart Study found that obese adults lived 6 to 7 years less than normal-weight adults.¹⁰

In 1977, Printen and Mason⁵ reported an 8% 30-day mortality rate in patients older than 50 years vs 2.8% in patients younger than 50 years undergoing gastric bypass. At the time, they recommended not performing bariatric surgery in patients older than 50 years. Since that time, many surgeons have restricted gastric bypass to younger patients. Surgeons today have been able to lower the 30-day mortality rate for all bariatric patients to an astounding 0.3% to 0.5%. This improvement in mortality rates coupled with an epidemic rise in obesity rates across all age groups has led surgeons to expand bariatric surgery to groups not previously served, such as adolescent and elderly patients. Debate still exists about increased mortality in older patients. Livingston et al¹¹ noted a 3-fold higher rate of mortality for patients 55 years or older. Flum et al,⁶ in their review of the national Medicare database, noted a mortality rate of 4.8% vs 1.7% in patients older than 65 years vs younger patients. They also noted a striking 19.1% mortality rate in patients older than 75 years. An occasional exception to this prohibitive mortality rate has been noted, such as that reported by Sugerman et al¹² and Macgregor and Rand.¹³ The Medical College of Virginia (Richmond) series had no early postoperative deaths in 80 patients 60 to 74 years old.¹²

As Flum et al⁶ noted from the Medicare database, more than 90% of patients who underwent bariatric surgery were younger than 65 years. Our program demonstrates a similar patient demographic, with 94% of our Medicare patients younger than 65 years. Only those with a significant disability are eligible for Medicare at younger than 65 years. One may hypothesize that the presence of a significant disability could increase the risk to these patients when undergoing bariatric surgery. Our data tend to support this hypothesis. The Medicare patients had a greater number of comorbidities; higher incidence of hypertension, diabetes, sleep apnea, gastroesophageal reflux disease, and hyperlipidemia; larger BMI; higher ASA score; longer operative time; and longer length of stay. Despite these risk factors, our Medicare population had no postoperative mortality up to 1 year after surgery. This finding contrasts directly with the report on the Medicare database in which the lowest mortality rate in any group is 1.2%. These differences are undoubtedly mul-

Table 3. Demographic Data for Medicare Patients vs All Non-Medicare Patients

Demographic Characteristic	Group 3 (Medicare Patients) (n = 31)	Group 4 (Non-Medicare Patients) (n = 861)	P Value
Age, mean ± SD (range), y	47.7 ± 10.2 (31-66)	43.1 ± 10.1 (18-64)	.01*
Male/female, No. (%)	2/29 (6/94)	121/740 (14/86)	.29
BMI, mean ± SD	56.0 ± 1.6	50.3 ± 8.0	<.001*
OR time, mean ± SD, min	178.2 ± 40.6	163.9 ± 53.2	.03*
ASA score, mean ± SD	3.1 ± 0.3	2.9 ± 0.4	.01*
LOS, mean ± SD, d	4.5 ± 6.4	3.0 ± 1.4	.07

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); LOS, length of stay; OR, operating room.

*t Test.

Table 4. Postoperative Complications in Medicare Patients vs All Non-Medicare Patients

Complication	No. (%) of Patients		P Value
	Group 3 (Medicare Patients) (n = 31)	Group 4 (Non-Medicare Patients) (n = 861)	
Pulmonary embolism	0	11 (1.3)	.10
Leak	2 (6.4)	14 (1.6)	>.99
Fistula	0	10 (1.1)	>.99
Bleeding	0	17 (2.0)	>.99
Pneumonia	1 (3.2)	8 (0.9)	.27
Bowel obstruction within 30 days	0	7 (0.8)	>.99
Death within 30 days	0	3 (0.3)	>.99

tifactorial. Possible explanations include patient selection, surgeon experience, perioperative evaluation and management, preoperative and postoperative education, and program philosophies regarding smoking cessation, exercise, and preoperative weight management. In our program, all patients must be smoke free for 3 months before surgery. Patients must be exercising at least 4 days a week, consisting of a walking, swimming, or biking program. We mandate that patients cannot gain weight from the time of their initial office visit until surgery. Before surgery all patients are evaluated by a pulmonologist. Currently, all patients undergo preoperative sleep study evaluation. We recently investigated the prevalence of obstructive sleep apnea in our bariatric population, finding that 91% of patients had obstructive sleep apnea. All patients with diagnosed obstructive sleep apnea are treated with continuous positive airway pressure therapy before undergoing gastric bypass.¹⁴ We have previously reported that these aggressive measures have resulted in a significant decrease in length of stay.¹⁵ These measures most likely also contribute to the low mortality rate in all of our patients, especially in elderly and Medicare patients.

The 46 patients 60 to 66 years old and the 31 Medicare patients who have successfully undergone gastric bypass in our program with no mortality and acceptable morbidity compare favorably with the series of Sugarman et al¹² of 80 patients aged 60 to 74 years with no early mortality.

Recently, 3 large administrative database studies^{6,16,17} have evaluated bariatric surgery in elderly patients; 2 of these 3 also addressed bariatric surgery in Medicare recipients. Large administrative database studies can alert

us to possible concerns about adverse outcomes; however, these studies tell us nothing about what led to the adverse outcomes or how to improve them. Single institutional studies may have the shortcoming of limited numbers but nonetheless provide details about patient selection, evaluation, and management that can help explain superior outcomes. These qualities are invaluable to bariatric surgeons and referring physicians and simply cannot be obtained from large administrative databases. Thus, we believe that there is a complementary role for database studies with large numbers but inadequate specific patient data and institutional studies such as ours with relatively small numbers but specific patient and management information.

Single or multiple institutional case studies^{5,12,13,18-20} have relatively small numbers of elderly patients or Medicare patients, similar to our study. However, our study is unique for the following reasons. To date, to our knowledge, no other institutional case study has attempted to evaluate both elderly and Medicare patients and compare these 2 groups with their respective cohort of bariatric patients. Insurance status has been addressed in administrative database studies but rarely in publications from single institutions.²¹⁻²³ The publication we identified that addressed insurance status from a single program reviewed patients undergoing vertical banded gastroplasty, not gastric bypass.²⁴

In our experience, bariatric surgery can be performed in carefully selected and evaluated patients 60 years and older and in Medicare beneficiaries with acceptable morbidity and mortality. Despite evidence that the Medicare patients were sicker than the group as a whole, their outcomes were comparable. We believe that

these results in both groups reflect careful patient selection, intensive preoperative education, perioperative management, and surgical expertise. Our results indicate that bariatric surgery should not be denied to patients based solely on age or Medicare status.

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REFERENCES

1. Olshansky SJ, Passaro DJ, Hershow RC, et al. A potential decline in life expectancy in the United States in the 21st century. *N Engl J Med.* 2005;352:1138-1145.
2. Mokdad AH, Bowman BA, Ford ES, et al. The continuing epidemics of obesity and diabetes in the United States. *JAMA.* 2001;286:1195-1200.
3. Livingston EH. Obesity and its surgical management. *Am J Surg.* 2002;184:103-113.
4. Gastrointestinal Surgery for Severe Obesity: NIH Consensus Development Conference Consensus Statement 1991 March 25-27. *Am J Clin Nutr.* 1992;55 (suppl):615S-619S.
5. Printen KJ, Mason EE. Gastric bypass for morbid obesity in patients more than fifty years of age. *Surg Gynecol Obstet.* 1977;144:192-194.
6. Flum DR, Salem L, Elrod JAB, Dellinger EP, Cheadle A, Chan L. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA.* 2005;294:1903-1908.
7. Villareal DT, Apovian CM, Kushner RF, Klein S. Obesity in older adults: technical review and position statement of the American Society for Nutrition and NAASO, The Obesity Society. *Am J Clin Nutr.* 2005;82:923-934.
8. Bouldin MJ, Ross L, Sumrall C, et al. The effect of obesity surgery on obesity comorbidity. *Am J Med Sci.* 2006;331:183-193.
9. Allison DB, Fontain K, Manson J, et al. Annual deaths attributable to obesity in the United States. *JAMA.* 1999;282:1530-1538.
10. Peeters A, Barendt J, Willenkens F, et al. Obesity in adulthood and its consequences for life expectancy: a life table analysis. *Ann Intern Med.* 2003;138:24-32.
11. Livingston EH, Huerta S, Arthur D, et al. Male gender is a predictor of morbidity and age a predictor of mortality for patients undergoing gastric bypass surgery. *Ann Surg.* 2002;236:576-582.
12. Sugerman HJ, DeMaria EJ, Kellum JM, et al. Effects of bariatric surgery in older patients. *Ann Surg.* 2004;240:243-247.
13. Macgregor AM, Rand CS. Gastric surgery in morbid obesity: outcome in patients aged 55 years and older. *Arch Surg.* 1993;128:1153-1157.
14. Hallowell PT, Stellato TA, Schuster M, et al. Potentially life threatening sleep apnea is unrecognized without aggressive evaluation. *Am J Surg.* 2007;193:364-367.
15. Stellato TA, Hallowell P, Crouse C. Two-day length of stay following open Roux-En-Y gastric bypass: is it feasible, safe and reasonable? *Obes Surg.* 2004;14:27-34.

16. Livingston EH, Langert J. The impact of age and Medicare status on bariatric surgical outcomes. *Arch Surg.* 2006;141:1115-1120.
17. Varela JE, Wilson SE, Nguyen NT. Outcomes of bariatric surgery in the elderly. *Am Surg.* 2006;72:865-869.
18. Quebbemann B, Engstrom D, Siegfried T, Garner K, Dallal R. Bariatric surgery in patients older than 65 years is safe and effective. *Surg Obes Relat Dis.* 2005;1:389-393.
19. Nelson LG, Lopez PP, Haines K, et al. Outcomes of bariatric surgery in patients ≥ 65 years. *Surg Obes Relat Dis.* 2006;2:384-388.
20. Frutos MD, Lujan J, Hernandez Q, et al. Results of laparoscopic gastric bypass in patients ≥ 55 years old. *Obes Surg.* 2006;16:461-464.
21. Carbonell AM, Lincourt AE, Matthews BD, et al. National study of the effect of patient and hospital characteristics on bariatric surgery outcomes. *Am Surg.* 2005;71:308-314.
22. Poulouse BK, Griffin MR, Zhu Y, et al. National analysis of adverse patient safety events in bariatric surgery. *Am Surg.* 2005;71:406-413.
23. Livingston EH, Ko CY. Socioeconomic characteristics of the population eligible for obesity surgery. *Surgery.* 2004;135:288-296.
24. Durkin AJ, Bloomston M, Murr MM, et al. Financial status does not predict weight loss after bariatric surgery. *Obes Surg.* 1999;9:524-526.

DISCUSSION

Ravi Moonka, MD, Seattle, Wash: This is really 2 studies in 1. They are looking at 2 patient cohorts: patients older than 60 and patients who are insured by Medicare. There is a lot of overlap between the 2 groups. You can be older than 60 and be privately insured, and you can have Medicare insurance not on the basis of being older than 65 but just based on being chronically disabled.

The study is a response, I believe, to that landmark study published about a year ago that looked at all 16 000 Medicare patients operated on between 1997 and 2002. The 90-day mortality in those 16 000 patients after bariatric surgery was 2.8%. If you limited that evaluation to patients over age 65, the 90-day mortality was 6.9%. These were high numbers, alarmingly high numbers, which I think were an offense to the sensibilities of many bariatric surgeons. I think the group at Case Western took it upon themselves to demonstrate that that did not necessarily need to be the case, and I think that they have succeeded.

There is much to praise in this study and not much to quibble with. However, if I were to quibble, it would be with the relatively small number of patients in the study cohort. I think for patients over 65 there were 46; for Medicare patients there were 31. If by chance there had been a death in that cohort, then the conclusions from the paper would have been dramatically different. I don't think that that is an acknowledged way of performing a statistical analysis, but it does show that when you are dealing with, thankfully, rare events in small populations, it is a hard thing to study.

The fact of the matter is that death did not occur. That is the point of the study. I certainly eagerly anticipate a study with similar outcomes looking at hundreds of Medicare patients. In the absence of that study, this is the best we have, and it is quite good. I think it is valuable because it provides reassurance to those of us who operate on this patient population and, for lack of a better word, cover.

I think it is valuable for another reason as well, which is that if we are sincerely interested in improving our outcomes after gastric bypass surgery, then it is going to be papers like this one that lead the way. This new generation of papers that look at large administrative databases are helpful in informing the surgery community that we need to do better, but they do not necessarily show us how to do that. This paper does because it not only talks about their outcomes, but it talks about some of the things that may be related to those better outcomes. With that in mind, my questions mostly focus on maybe further elucidating why your outcomes are so good.

I am convinced, as are you, that your rigorous selection criteria help explain your outcomes in older patients. There is nothing about an older patient that is inherently technically more difficult than a younger patient. You obviate that liability by operating on physiologically younger patients. Certainly that is intuitively attractive, but why do you not also exclude patients based on body mass index or sex, which are, I think, well-established risk factors for mortality after this operation?

Your leak rate I feel is very respectable at 1.8%. I think that is especially true, since your average BMI is 50, and correct me if I am wrong, but the study covers a period when you have converted from an open approach to a laparoscopic approach. Nonetheless, just based on the number of patients you have operated on, you have a fair number of leaks. It doesn't seem like many of those patients died. Do you have any insights for us on early diagnosis and appropriate treatment of those leaks?

Finally, and I think you alluded to this a little bit, but the study period spans 8 years. How did your processes change over time as you learned about this operation? In particular, you seem very concerned about sleep apnea in your patients. I wonder if you had some close calls with unrecognized induced hyperventilation that led to this problem.

Dr Stellato: There is no question that the small numbers in this study are a liability. I think what we really need to do is find a place where we can balance a study like this with the administrative surveys that we heard about with Dr Flum's paper (Flum DR, Salem L, Elrod JAB, Dellinger EP, Cheadle A, Chan L. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA*. 2005;294:1903-1908) and a more recent one that just came out in the November *Archives of Surgery* by Dr Livingston (Livingston EH, Langert J. The impact of age and Medicare status on bariatric surgical outcomes. *Arch Surg*. 2006;141:1115-1120). Dr Livingston looked at a Medicare population base, and, interestingly, he noted that there was no increase in mortality with Medicare patients if you looked at the comorbidities and balanced out the comorbidities, etc. I think our challenge is to find out what is the place for each type of study, the large database surveys and the individual institutional studies. Obviously, the small numbers in this paper are a problem, and we recognize that.

You asked a question about body mass index. We certainly do not exclude patients on the basis of body mass index. I am not sure it was in this paper, but the highest patient body mass index was actually 86. We have an exclusion on the basis of actual weight, which is interesting, and that is simply a function of the resources that we have in our hospital: operating room tables, radiology tables, etc. Consequently, we do not operate on patients who exceed 500 lb. We feel that if we cannot get someone in a computed tomographic (CT) scanner, we are not going to operate on them. If we can't manage their complications, then we are not going to offer them a gastric bypass. We have an exclusion on the basis of actual absolute weight, but not on the basis of body mass index.

You asked about early leaks and why our mortality may be so low. We have a philosophy, which I know is not held by all, that every single patient gets a swallow study the day after surgery. We use that for a couple of reasons. One, to identify leaks, but also to identify when we can safely begin liquids by mouth. Not uncommonly, we will see some edema at the anastomosis with a hold-up of contrast. With experience we have learned not to get overly concerned about that. We routinely do swallow studies on every patient. I think that has been helpful at times. We also are, as I think most bariatric surgeons are, exquisitely sensitive to the clinical findings of unexplained tachycardia. We have no hesitation to take someone back to the operating room before getting that swallow study if we see a patient with unexplained tachycardia or pain. I think this early surgi-

cal intervention may possibly be the reason why our mortality rate is so low despite the occasional leak from our gastrojejunal anastomosis.

Finally, you commented about obstructive sleep apnea and whether we had some close calls perhaps with opiate administration. Before routinely testing all patients, we had a rare occasion of respiratory depression in patients with unrecognized obstructive sleep apnea. We recently presented data at the annual meeting of the Midwest Surgical Association that we hope will be published in the *American Journal of Surgery*. We screened patients initially on the basis of clinical presentation and a sleep study survey and found that patients came in with a 21% incidence of obstructive sleep apnea. After testing patients on the basis of clinical symptoms and the sleep survey, the incidence was increased to 56%. However, when we started performing sleep studies routinely on every patient unselected, we realized that 91% of our patients had obstructive sleep apnea. This information made us recognize that a large number of patients had been coming to surgery with undiagnosed and thus untreated obstructive sleep apnea.

Leigh Anne Neumayer, MD, Salt Lake City, Utah: I believe your numbers are a little small, but if you risk adjusted your patients, your outcome would actually be much better than what the Medicare Administrative Database would show.

I noticed that you get pulmonary and cardiology consults on older patients. Were there any common themes or recommendations that we all might take home to think about? My cardiologists always say to avoid hypoxemia, hypotension, and hypovolemia, and that doesn't really help me.

Second, how did your perioperative processes change when sleep apnea was identified? Is there something different that you did in those patients? I think that is a really important take-home lesson for us as well.

Dr Stellato: The second question first. That is pretty easy. When we identify obstructive sleep apnea, we insist that all patients be titrated with continuous positive airway pressure (CPAP) machines before their operations. They have a trial at home with CPAP, and we instruct all patients with obstructive sleep apnea to bring their CPAP machine to the hospital on the day of their surgery. If someone has had a sleep study but they haven't been titrated, we will postpone their surgery until they actually receive CPAP.

In terms of pulmonary and cardiology consultations, they have been helpful to us. Sometimes our pulmonary consultants have said, "These patients look like they may have pulmonary hypertension," and then we will do some more testing on those patients to see whether they are at more significant risk. We have a very great working relationship with our pulmonologists, and I think it has been helpful.

Kenneth J. Printen, MD, Wilmette, Ill: Thirty years ago when Ed Mason and I presented our data on gastric bypass patients who were older than 50, which at that time seemed to be horribly old but it is not old at all, we did not recommend this operation for people who were older than 50. We did that because in looking at our patients we found that people older than 50 didn't lose as much weight as their younger cohorts, and we had just come off a paper where we looked at complications of gastric bypass and found that in our patients older than 50 who had perhaps had symptoms of a leak for 24 hours before they were diagnosed, our survival rate with reoperation was zero. We actually figured that this operation wasn't going to benefit a lot of these elderly patients.

Some things obviously changed, if you look at the upswing in surgical procedures for obesity being performed nationwide, and on the elderly patients, even though they only represent about 10% of the patients who get gastric operations for the treatment of obesity. I think there are probably 3 things that will explain that.

First of all, as you have heard, the earlier recognition and treatment of anastomotic leaks. Now we have abdominal CT scanners. Forget about abdominal CT scanners that can take care of people who weigh up to 500 lb, we didn't have abdominal CT scanners when we started doing this operation.

We also didn't recognize that in these elderly patients who come with their saddlebags full of medical comorbidities, just a modest weight loss is going to make a tremendous improvement in most of those medical comorbidities and allow them to have a really much better handle on the activities of daily living.

Last of all, we didn't have laparoscopy, and I think we all would believe now that laparoscopic procedures provide less of a stress to the postoperative patient. With laparoscopic procedures, patients not only have fewer pulmonary complications, but they are able to ambulate better and quicker. Actually, in the early days, that was our only prophylaxis at the University of Iowa when we first started doing these operations for the treatment of the development of deep venous thromboembolic phenomena. We got the patients out of bed the same day they were operated on. They were too big to have antiemetic stockings, and we had so many wound complications that we were afraid to give them heparin, because we figured that at least 25% of them would develop hernias and require additional operation.

My own personal view of these patients in this age group, especially since the authors have made this operation so safe and well tolerated, is that the usual morbidly obese patient at 60 years-plus of age with his medical comorbidities is almost too sick to not operate on. That being the case, do you have uniform selection criteria for the elderly patients, and are they different from the patients who are of a younger age?

Second, how does mobility of the patient influence your patient selection? I notice that the patients must exercise, but when you get into the elderly patients, you are going to get into people

who have had strokes; they have some sequelae of strokes, and some of them don't even have all their legs. You have got to figure out some way to see if these people will actually benefit from the procedure.

Is there anything really specific about the workup in the patient older than 60 besides the cardiology consultation and the visit to the pulmonologist?

Dr Stellato: In terms of mobility, there is absolutely no question that we are somewhat stringent about the requirement for mobility. We also are somewhat selective in the elderly patients. We will not operate on a patient who is bedridden. We will operate on the occasional patient who is wheelchair bound but can get off that wheelchair and walk a few steps with a walker, but obviously that patient has to have a lot of other things going for him for us to consider him for surgery. We want patients to be able to walk at least a few steps. If patients are totally wheelchair bound, we have a lot of hesitation to take them into surgery.

That being said, we have also operated on a patient who is a bilateral amputee. However, that patient was walking with bilateral prostheses. In general we want our patients to be ambulatory. When we talk about exercise, we are relatively simple in what we want them to do. Walking, swimming, biking for a minimum of 5 minutes a day is all we ask for.

In terms of selection criteria, I am not sure that the selection criteria are really any different in someone older than someone who is younger. We are going to be more aggressive in terms of pulmonary evaluation, and everyone is going to get a cardiology consult. We ask them to jump through the same hoops that we have with all our other patients. There are so many hoops that these patients have to jump through that I think these are the selection criteria for these individuals.

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