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Original article

Early morbidity and mortality of laparoscopic sleeve gastrectomy and gastric bypass in the elderly: a NSQIP analysis

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Abstract

Background: Even though the U.S. population is aging, outcomes of bariatric surgery in the elderly are not well defined. Current literature mostly evaluates the effects of gastric bypass (RYGB), with paucity of data on sleeve gastrectomy (SG). The objective of this study was to assess 30-day morbidity and mortality associated with laparoscopic SG in patients aged 65 years and over, in comparison to RYGB.

Methods: The National Surgical Quality Improvement Program (NSQIP) database was queried for all patients aged 65 and over who underwent laparoscopic RYGB and SG between 2010 and 2011. Baseline characteristics and outcomes were compared. P value $<.05$ was considered significant. Odds ratios (OR) with 95% confidence interval (CI) were reported when applicable.

Results: We identified 1005 patients. Mean body mass index was 44 ± 7. SG was performed in 155 patients (15.4%). The American Society of Anesthesiology physical classification of 3 or 4 was similar between the 2 groups (82.6% versus 86.7%, $P = .173$). Diabetes was more frequent in the RYGB group (43.2% versus 55.6%, $P = .004$). 30-day mortality (0.6% versus 0.6%, OR 1.1, 95% CI .11–9.49), serious morbidity (5.2% versus 5.6%, OR .91, 95% CI .42–0.96), and overall morbidity (9% versus 9.1%, OR 1.0, 95% CI .55–1.81) were similar.

Conclusion: In elderly patients undergoing laparoscopic bariatric surgery, SG is not associated with significantly different 30-day outcomes compared to RYGB. Both procedures are followed by acceptably low morbidity and mortality. (Surg Obes Relat Dis 2014;▮:00–00.)

Keywords: Bariatric surgery; Elderly; Sleeve gastrectomy; NSQIP; Safety

The U.S. population has been steadily aging since the beginning of the previous century. The elderly, aged 65 and over, increased by 15.1% from 2000–2010, compared to 9.7% for the total population, reaching over 40 million by the end of this period [1]. The older population is projected to double from 36 million in 2003 to 72 million in 2030, representing 20% of the total population (compared to 12% for 2003) [2]. Obesity affects 35.9% of the U.S. adult population, while excess weight is reported in 69.2% [3]. The elderly are equally affected by the obesity epidemic, with 34.6% of people aged 65 and over being obese [4]. Between 1999 and 2010, the prevalence of obesity in elderly males has significantly increased to 41.5% from 31.6%, with a similar increase in the prevalence of diabetes [5]. With increasing population age, obesity prevalence, and associated morbidity, obesity in the elderly is likely to evolve into a large public health burden.

Bariatric surgery has proven to be the most effective way to treat obesity and associated co-morbidities [6,7], and its

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safety of bariatric surgery in the general population has been well established [8]. Vertical sleeve gastrectomy (SG) has emerged as the most recent single-step surgical option for metabolic surgery. In 2012, laparoscopic SG represented 36.3% of all bariatric procedures performed in academic medical centers, compared to .9% in 2008 [9]. Large reports on the general population show low perioperative mortality and morbidity for patients undergoing SG [10,11].

Data on the safety of bariatric surgery in the elderly have demonstrated varying results. Original reports of alarmingly high mortality [12], were followed by many single-center studies demonstrating acceptable results, and a recent systematic review reported .3% mortality for laparoscopic gastric bypass (RYGB) [13]. Even though multiple studies have demonstrated an association of advanced age with worse outcomes [14–16], there has been a significant increase in the number of elderly patients undergoing bariatric surgery in recent years [17]. Large prospective population studies of patients undergoing SG, report on patient population with a mean age of 47, and their results cannot be extrapolated to elderly patients [10,11]. There are a few single-institution studies reporting outcomes of SG in the elderly, but they seem limited by small sample sizes [18–21].

The objective of this study was to assess the early morbidity and mortality associated with laparoscopic SG in elderly patients, aged 65 years and over. Additionally, we sought to compare perioperative safety with patients undergoing laparoscopic RYGB.

Methods

The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database was used for the purposes of this study. The database includes prospectively collected data, entered by trained clinical reviewers, from over 250 hospitals around the U.S. Data are validated and audited for accuracy. These include preoperative patient demographic characteristics, co-morbidities, laboratory values, intraoperative details, and 30-day postoperative morbidity and mortality. The clinical reviewers perform a 30-day follow-up and search hospital and public records to ensure data completeness. The public use files including patients from January 2010 to December 2011 were combined, and patients were identified using the primary current procedural terminology codes for laparoscopic RYGB (43644, 43645) and SG (43775). The study population consisted of all patients aged 16 years or over who underwent laparoscopic RYGB or SG, defined by the use of one of the current procedural terminology codes as their primary procedure. Patients 90 years of age or older, were coded in NSQIP as being 89 years of age. This was a NSQIP limitation by design, but still allowed to identify elderly patients. The patients 65 years of age and older formed the study population. Patients were compared based on procedure performed.

Co-morbidities were grouped into 6 categories, as previously described by others (cardiac, vascular, pulmonary, hepatic, renal, and neurologic) [22]. Body mass index (BMI) was calculated based on the documented height and weight. The American Society of Anesthesiology physical classification system (ASA) was used as a baseline characteristic (ASA 1, healthy patient; ASA 2, mild systemic disease; ASA 3, severe systemic disease; ASA 4, severe systemic disease that is constant threat to life; ASA 5, moribund patient who is not expected to survive without the operation). Procedures listed as emergent, including patients with an ASA of 5 were excluded from the study. Patients were grouped based on severity of disease (ASA 1 and 2, versus ASA 3 and 4). Diabetes, history of active smoking, wound classification, weight loss >10% within 6 months, and chronic steroid use were analyzed individually.

The primary outcome was overall 30-day morbidity, and secondary outcomes included 30-day serious morbidity and mortality. Serious morbidity was defined as the postoperative occurrence of cardiac arrest requiring cardiopulmonary resuscitation, myocardial infarction, bleeding requiring transfusions, cerebrovascular accident, coma lasting over 24 hours, pulmonary embolism, ventilatory dependence over 48 hours, organ space infection, wound dehiscence, progressive or acute renal failure, sepsis or septic shock. Overall morbidity included the occurrence of any event mentioned previously, as well as urinary tract infection, deep venous thrombosis, unplanned intubation, pneumonia, peripheral nerve injury, and superficial or deep surgical site infection (SSI). When SSI was analyzed individually, organ space infections and superficial and deep SSI were included in the analysis. Septic complications included the development of sepsis or septic shock. Occurrences were also grouped per organ system and analyzed separately.

Approval for this study was obtained from the NSQIP administration and the Dartmouth Committee for the Protection of Human Patients. Data analysis was performed using SPSS for Macintosh version 21 (IBM, Somers, NY). Nominal and ordinal variables were compared using the Pearson X^2 or Fisher's exact test, and continuous variables were compared using the Mann-Whitney U test. Results were reported as mean (± standard deviation) for continuous variables and frequency for nominal and ordinal variables. Odds ratios (OR) with 95% confidence intervals (CI) were reported when applicable. Two-tailed P value $<.05$ was considered significant. Multivariate binary logistic regression was performed using all variables with significance level of $P < .1$ on univariate analysis. When the surgical procedure was entered in a regression model as a covariate, OR was reported for RYGB.

Results

We identified 1005 elderly patients who underwent laparoscopic bariatric stapling procedures. Laparoscopic

Table 1
Baseline characteristics in elderly patients undergoing laparoscopic stapling bariatric surgery

Variable	RYGB (n = 850)	SG (n = 155)	*P* value	OR (95% CI)
Male gender	260 (30.3%)	50 (33.1%)	.567	1.1 (.77–1.6)
BMI ≥ 50	152 (17.9%)	30 (19.4%)	.662	1.01 (.71–1.7)
Cardiac comorbidities	92 (13.7%)	15 (13%)	.856	0.95 (.53–1.7)
Vascular comorbidities	740 (90.8%)	131 (89.1%)	.521	0.83 (.47–1.47)
Pulmonary comorbidities	45 (6.6%)	4 (3.4%)	.192	0.51 (.18–1.44)
Renal comorbidities	1 (.1%)	1 (.6%)	.285	5.51 (.34–88.61)
Diabetes	473 (55.6%)	67 (43.2%)	.004	0.61 (.43–0.86)
Tobacco smoking	25 (2.9%)	5 (3.2%)	.799	1.1 (.42–2.92)
Chronic steroid use	10 (1.2%)	1 (.6%)	1.0	0.54 (.07–4.29)
ASA 3 or 4	737 (86.7%)	128 (82.6%)	.173	0.73 (.46–1.15)

ASA = American Society of Anesthesiology class; BMI = body mass index; RYGB = gastric bypass; SG = sleeve gastrectomy.

RYGB was performed in 850 (84.6%) and SG in 155 (15.4%). Mean BMI was 44 ± 7, and 30.8% of patients were male. ASA classification of 3 or 4 was assigned to 865 (86.1%) patients. There was a significant increase in the performance of laparoscopic SG from 2010–2011 (13% versus 17.7%, OR 1.44, 95% CI 1.02–2.04, *P* = .038). Comparison of baseline characteristics between the patients who underwent laparoscopic RYGB and SG is presented in Table 1. The presence of diabetes preoperatively was more frequent in patients who underwent laparoscopic RYGB, compared to SG (55.6% versus 43.2%, *P* = .004).

Thirty-day complication rates in this cohort were not significantly different between patients who underwent laparoscopic RYGB and SG (Table 2). In examining system-based occurrences, there was no significant difference in cardiovascular (5.2% versus 3.5%, *P* = .327), pulmonary (2.1% versus 0.6%, *P* = .338), renal (0.8% versus 0, *P* = .604), or neurologic (0.2% versus 0, *P* = 1.0) complications between the 2 groups. Mortality, overall morbidity, and serious morbidity were not significantly different after laparoscopic RYGB and SG. After controlling for the preoperative presence of diabetes with regression modeling, there was no significant effect of the surgical procedure on mortality (OR .85, 95% CI .1–7.41, *P* = .884), overall (OR 1.0, 95% CI .55–1.82, *P* = .991) and serious morbidity (OR 1.1, 95% CI .51–2.38, *P* = .806).

Independent variables associated with postoperative complications were identified through backward stepwise regression of preoperative risk factors achieving statistical significance in the comparison of elderly patients with or without postoperative occurrences (pulmonary co-morbidities and history of steroid use). Only the use of steroids was independently associated with overall morbidity (OR 3.86, 95% CI 1.0–14.82, *P* = .049).

Discussion

The number of bariatric procedures performed in the elderly is increasing. Older studies using administrative data and single-institution series report that <3% of the patients undergoing bariatric surgery were over the age of 60 [23]. However, more recent NSQIP data show that the proportion of bariatric procedures in patients ≥65 years of age significantly increased from 1.9% in 2005 to 4.8% in 2009 [17]. Similarly, analyzing the trends of bariatric surgery in U.S. academic medical centers, Nguyen et al. [9] demonstrated that from 2008–2012 the use of laparoscopic SG increased from .9%–36.3%, while the use of laparoscopic adjustable gastric banding (LAGB) and RYGB both decreased (from 23.8%–4.1%, and 66.8%–56.4%, respectively). With the increasing number of elderly patients undergoing bariatric surgery and the adoption of

Table 2
Univariate analysis of elderly patients undergoing laparoscopic stapling bariatric surgery

Variable	RYGB (n = 1791)	SG (n = 155)	*P* value	OR (95% CI)
Mortality	5 (.6%)	1 (.6%)	1.0	1.1 (.13–9.49)
Serious morbidity	48 (5.6%)	8 (5.2%)	.808	0.91 (.42–1.96)
Overall morbidity	77 (9.1%)	14 (9%)	.992	1 (.55–1.81)
Postoperative bleeding	19 (2.2%)	4 (2.6%)	.77	1.16 (.39–3.45)
Organ space infection	8 (.9%)	0	.617	—
Pulmonary embolism	6 (.7%)	2 (1.3%)	.356	1.84 (.37–9.2)
Reoperation	33 (3.9%)	5 (3.2%)	.693	0.83 (.32–2.15)
SSI	24 (2.8%)	2 (1.3%)	.409	0.45 (.11–1.92)
Septic occurrences	15 (1.8%)	2 (1.3%)	1.0	0.73 (.17–3.21)

RYGB = gastric bypass; SG = sleeve gastrectomy; SSI = surgical site infection

SG, it is imperative that the outcomes of this procedure on this subgroup are closely evaluated.

Based on the assessment of a nationwide audited prospective database, our study demonstrates that elderly patients aged 65 years and over undergoing laparoscopic stapling bariatric procedures have low morbidity and mortality, regardless of the type of surgical procedure. In this cohort, laparoscopic RYGB and SG were not associated with significantly different morbidity and mortality. To our knowledge, this is the first study to compare safety in this age group between the 2 most common bariatric procedures. In a systematic review of 15 randomized trials comparing SG with other bariatric procedures, the mean age of patients undergoing bariatric surgery ranged between 26 and 49 years, much younger than our study population [24]. Two large previous database analyses have shown that laparoscopic SG is associated with decreased morbidity compared to RYGB [11,25]. However, the patient population in these studies is younger (mean age of 46 and 47, respectively), and the applicability of these results on the elderly population is equivocal.

Data from the NSQIP demonstrates that laparoscopic SG can be safely performed in selected elderly patients, with .6% mortality (1 patient) and $<10\%$ morbidity, despite the high severity of chronic disease in this patient population. Small retrospective single-institution studies have attempted to assess the safety of this procedure in the elderly. The first study reported on 12 patients aged 60 and over with a median BMI of 49, and although perioperative mortality was 0, major morbidity (mostly bleeding) was 42% [20]. Similarly low mortality was reported in another study of 12 patients aged ≥ 65 years, but overall morbidity was 25% in this age group [19]. The authors concluded that SG is safe in older patients, but underlined the need for comparison studies with RYGB. The Cleveland Clinic group from Florida reported on 42 patients over the age of 69 with a mean BMI of 44 who underwent bariatric surgery [18]. Twenty elderly patients underwent stapling procedures with nil mortality; 12 patients had SG and 8 RYGB, with 25% and 12.5% overall morbidity rate, respectively. Although the authors did not compare SG and RYGB directly, the only significant difference in the complication rate between older and younger patients was noted in the SG group. A subsequent study by the same group, focused on 35 patients aged 60 and over with a mean BMI of 46 who underwent laparoscopic SG [21]. There were no perioperative mortalities in this group, and overall morbidity was 8.4%, similar to the present study. All of these studies conclude that laparoscopic SG is a safe procedure in the elderly patients, but suffer from small sample size. Our NSQIP study attests to the safety of this procedure, in comparison to laparoscopic RYGB in the elderly population.

Our study is limited by the retrospective nature of our methods. The NSQIP represents a highly accurate audited database of patients who underwent surgery, but there are no data on patients who were evaluated but were deemed ineligible for bariatric surgery. Even though this cohort of elderly patients undergoing laparoscopic RYGB or SG was not low risk (as evident by the high rate of ASA 3 and 4 patients), we assume that selection bias is inherent in the study design. Additionally, it was decided to only include laparoscopic stapling procedures; LAGB procedures were excluded, as their incidence has dramatically decreased over the past years [9]. Open surgery was also not included in this analysis, as these operations are uncommon and declining incidence, and their inclusion would potentially influence the effect of the actual procedure (RYGB versus SG) on outcomes. The most important limitation to our study is that the NSQIP is not a bariatric-specific database. As such, there are no long-term data available on weight loss, late morbidity, and co-morbidity resolution.

Conclusion

We conclude that in elderly patients aged 65 and over undergoing laparoscopic stapling surgery, SG is not associated with significantly different 30-day complication rates compared to RYGB. Both stapling procedures are associated with low morbidity and mortality and appear to be equally safe. Further studies in the perioperative safety and the long-term outcomes of these procedures in the elderly patients are required to determine the optimal approach and proper patient selection.

Disclosures

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References

[1] US Census Bureau [homepage on the Internet]. Werner: Census briefs, C2010 BR-09. The older population: 2010. Available from: http://www.census.gov/prod/cen2010/briefs/c2010 br-09.pdf.

[2] US Census Bureau [homepage on the Internet]. Current population reports, P23-209. He W, Sengupta M, Velkoff VA, DeBarros KA. 65+ in the United States: 2005. Available from: https://www.census.gov/prod/2006 pubs/p23-209.pdf.

[3] Centers for Disease Control and Prevention, National Center for Health Statistics [homepage on the Internet]. Hyattsville: Health, United States, 2012: with special feature on emergency care. Available from: http://www.cdc.gov/nchs/data/hus/hus12.pdf.

[4] Centers for Disease Control and Prevention, National Center for Health Statistics [homepage on the Internet]. Hyattsville: Fakhouri TH, Odgen CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity among older adults in the United States, 2007–2010. NCHS data brief, no 106. Available from: http://www.cdc.gov/nchs/data/databriefs/db106.htm.

[5] Centers for Disease Control and Prevention [homepage on the Internet]. Atlanta: National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Available from: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf.

[6] Schauer PR, Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. N Engl J Med 2012;366:1567–76.

[7] Mingrone G, Panunzi S, De Gaetano A, et al. Bariatric surgery versus conventional medical therapy for type 2 diabetes. N Engl J Med 2012;366:1577–85.

[8] Flum DR, Belle SH, King WC, et al. Perioperative safety in the longitudinal assessment of bariatric surgery. N Engl J Med 2009;361: 445–54.

[9] Nguyen NT, Nguyen B, Gebhart A, Hohmann S. Changes in the makeup of bariatric surgery: a national increase in the use of laparoscopic sleeve gastrectomy. J Am Coll Surg 2013;216:252–7.

[10] Birkmeyer NJ, Dimick JB, Share D, et al. Hospital complication rates with bariatric surgery in Michigan. JAMA 2010;304:435–42.

[11] Hutter MM, Schirmer BD, Jones DB, et al. First report from the American College of Surgeons Bariatric Surgery Center Network: laparoscopic sleeve gastrectomy has morbidity and effectiveness positioned between the band and the bypass. Ann Surg 2011;254: 410–20.

[12] Printen KJ, Mason EE. Gastric bypass for morbid obesity in patients more than fifty years of age. Surg Gynecol Obstet 1977;144:192–4.

[13] Lynch J, Belgaumkar A. Bariatric surgery is effective and safe in patients over 55: a systematic review and meta-analysis. Obes Surg 2012;22:1507–16.

[14] Flum DR, Salem L, Elrod JA, Dellinger EP, Cheadle A, Chan L. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. JAMA 2005;294:1903–8.

[15] Nguyen NT, Masoomi H, Laugenour K, et al. Predictive factors of mortality in bariatric surgery: data from the Nationwide Inpatient Sample. Surgery 2011;150:347–51.

[16] Livingston EH, Langert J. The impact of age and Medicare status on bariatric surgical outcomes. Arch Surg 2006;141:1115–20.

[17] Dorman RB, Abraham AA, Al-Refaie WB, Parsons HM, Ikramuddin S, Habermann EB. Bariatric surgery outcomes in the elderly: an ACS NSQIP study. J Gastrointest Surg 2012;16:35–44.

[18] Ramirez A, Roy M, Hidalgo JE, Szomstein S, Rosenthal RJ. Outcomes of bariatric surgery in patients >70 years old. Surg Obes Relat Dis 2012;8:458–62.

[19] van Rutte PW, Smulders JF. de Zoete JP, Nienhuijs SW. Sleeve gastrectomy in older obese patients. Surg Endosc 2013;27:2014–9.

[20] Leivonen MK, Juuti A, Jaser N, Mustonen H. Laparoscopic sleeve gastrectomy in patients over 59 years: early recovery and 12-month follow-up. Obes Surg 2011;21:1180–7.

[21] Soto FC, Gari V, de la Garza JR, Szomstein S, Rosenthal RJ. Sleeve gastrectomy in the elderly: a safe and effective procedure with minimal morbidity and mortality. Obes Surg 2013;23:1445–9.

[22] Mason RJ, Moazzez A, Sohn HJ, Berne TV, Katkhouda N. Laparoscopic versus open anterior abdominal wall hernia repair: 30-day morbidity and mortality using the ACS-NSQIP database. Ann Surg 2011;254:641–52.

[23] Varela JE, Wilson SE, Nguyen NT. Outcomes of bariatric surgery in the elderly. Am Surg 2006;72:865–9.

[24] Trastulli S, Desiderio J, Guarino S, et al. Laparoscopic sleeve gastrectomy compared with other bariatric surgical procedures: a systematic review of randomized trials. Surg Obes Relat Dis 2013;9: 816–29.

[25] Carlin AM, Zeni TM, English WJ, et al. The comparative effectiveness of sleeve gastrectomy, gastric bypass and adjustable gastric banding procedures for the treatment of morbid obesity. Ann Surg 2013;257:791–7.