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Long-term incidence of serious fall-related injuries after bariatric surgery in Swedish Obese Subjects

Lena M.S. Carlsson,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden

Kajsa Sjöholm,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden

Sofie Ahlin,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden; Catholic University of the Sacred Heart, Rome, Italy

Peter Jacobson,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden

Johanna C. Andersson-Assarsson,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden

Linda Karlsson Lindahl,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden

Cristina Maglio,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden; Wallenberg Centre for molecular and translational medicine, University of Gothenburg, Gothenburg, Sweden

Cecilia Karlsson,

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Correspondence to: Associate professor Kajsa Sjöholm, SOS Secretariat, Vita Stråket 15, Sahlgrenska University Hospital, S-413 45 Gothenburg, Sweden. kajsa.sjoholm@medic.gu.se, Telephone: +46 733 680308.

Author contributions:

Study concept and design: LMSC, KS, PAS, MP. Acquisition, analysis, or interpretation of data: LMSC, KS, SA, PJ, JCAA, LKL, CM, CK, SH, MT, PAS, BC, MP. Drafting of the manuscript: LMSC, KS, MP. Critical revision of the manuscript for important intellectual content: SA, PJ, JCAA, LKL, CM, CK, SH, MT, BC, PAS. Statistical analysis: MP. Obtained funding: LMSC, KS, SA, CM. Technical or material support: LMSC, KS, SA, PJ, JCAA, LKL, CM, CK, SH, MT, PAS, BC, MP. Study supervision: LMSC, MP. KS had full access to the data in the study and final responsibility for the decision to submit for publication.

Conflict of Interest Disclosures: LMSC has obtained lecture fees from AstraZeneca, Johnson&Johnson and MSD. BC and CK are employed by AstraZeneca and hold stocks in the same company. SH holds stocks in AstraZeneca. MT holds stocks in Umeocrine AB, and has a patent licensed to Umeocrine AB. No other conflict of interest relevant to this study was reported.

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Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden; Global Medicines Development, AstraZeneca Gothenburg, Mölndal, Sweden

Stephan Hjorth,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden

Magdalena Taube,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden

Björn Carlsson,

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden; CVMD Translational Medicine Unit, Early Clinical Development, IMED Biotech Unit, AstraZeneca Gothenburg, Mölndal, Sweden

Per-Arne Svensson, and

Institute of Medicine, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden; Institute of Health and Care Sciences, the Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden

Markku Peltonen

National Institute for Health and Welfare, Helsinki, Finland

Abstract

Obesity increases risk of falling, but the effect of bariatric surgery on fall-related injuries is unknown. The aim of this study was therefore to study the association between bariatric surgery and long-term incidence of fall-related injuries in the prospective, controlled Swedish Obese Subjects study. At inclusion, body-mass index was 34 kg/m² in men and 38 kg/m² in women. The surgery per-protocol group (n=2007) underwent gastric bypass (n=266), banding (n=376) or vertical banded gastroplasty (n=1365), and controls (n=2040) received usual care. At the time of analysis (December 31, 2013), median follow-up was 19 years (maximal 26 years). Fall-related injuries requiring hospital treatment were captured using data from the Swedish National Patient Register. During follow-up, there were 617 first-time fall-related injuries in the surgery group and 513 in the control group (adjusted hazard ratio (adjHR) 1.21, 95% CI, 1.07 to 1.36; P=0.002). The incidence differed between treatment groups (P<0.001, log-rank test) and was higher after gastric bypass than after usual care, banding and vertical banded gastroplasty (adjHRs 0.50-0.52, P<0.001 for all three comparisons). In conclusion, gastric bypass surgery was associated with increased risk of serious fall-related injury requiring hospital treatment.

Introduction

Obesity is associated with premature mortality and increased risk for serious diseases such as type 2 diabetes, cardiovascular disease and cancer.¹ In addition, studies have shown associations between obesity and falls in older and middle-aged adults,²⁻⁵ as well as in younger adults with obesity.⁶ While it is well established that bariatric surgery promotes

sustained weight loss and improves several obesity-related comorbidities,⁷ it is not known whether it affects the long-term risk of a fall-related injury.

In the short term, bariatric surgery improves functional capacity⁸ and balance control,⁹ suggesting that the risk of falling may be reduced; however, to date there are no studies that support this hypothesis. On the contrary, a small, two-year, randomized controlled study in individuals with obesity and type 2 diabetes reported seven serious falls in those who had undergone gastric bypass but only three serious falls in the lifestyle group, suggesting that the risk of falling may in fact be increased after bariatric surgery.¹⁰

Fall-related injuries often infer large costs for both society and the affected individuals, and the long-term consequences can be extensive and seriously affect independence and quality of life.^{4, 11, 12} The aim of this study was therefore to examine whether the long-term risk of fall-related injury is altered after gastric bypass, banding or vertical banded gastroplasty compared to conventional obesity care.

Methods

Study design and treatment

The SOS study has previously been described (for details see Supplementary Appendix).¹³ In brief, the surgery group consists of 2010 subjects who chose surgical treatment, and the control group consists of 2037 individuals matched for 18 variables. The study groups had identical inclusion and exclusion criteria. The inclusion criteria were an age of 37-60 years and a body-mass index (BMI) of 34 kg/m^2 in men and 38 kg/m^2 in women before or at the time of the matching examination. The exclusion criteria were those that were relevant for the participants' suitability for surgery. Seven regional ethics review boards (Gothenburg, Lund, Linköping, Örebro, Karolinska Institute, Uppsala, Umeå) approved the study, and written or oral informed consent was obtained from all participants. The study has been registered at ClinicalTrials.gov (NCT01479452).

In this study, data were analyzed per protocol. The intended surgical intervention was not performed in four patients. Three of these patients never underwent surgery and in the per-protocol analyses used in the current study they are therefore included in the control group. One patient was scheduled for a vertical banded gastroplasty but instead underwent a gastric bypass procedure and is therefore included in the gastric bypass group in per-protocol analyses. In the surgery per-protocol group (n=2007), participants underwent gastric bypass (n=266), banding (n=376) or vertical banded gastroplasty (n=1365). The control per-protocol group (n=2040) received the customary treatment for obesity at their primary health care centers (see Table 1 in Supplementary Appendix).

Outcomes and follow-up

During follow-up, fall-related injury events were identified by searching the Swedish National Patient Register, which contains information on hospital stays and hospital-based outpatient care, using International Classification of Diseases (ICD) 8/9 (E826, E880-E888) and 10 codes (V01-V19, W00-W19).¹⁴ Fall-related injuries before entering the study were

identified by searching for falls treated in hospital in the 12 months before inclusion.¹⁴ At the time of register linkage, the register was complete until December 31, 2013.

Statistical methods

Mean values and standard deviations were used for baseline characteristics of the participants. Differences between group means and proportions were analyzed with analysis of covariance (continuous variables) and logistic regression (dichotomous variables).

Time to first fall-related injury event was calculated from the date of inclusion into the study. Those who were never assigned a fall-related ICD code were censored at Dec 31, 2013, at date of emigration, or at date of death. Time of progression to first event after inclusion in the different treatment subgroups was compared with Kaplan-Meier estimates of cumulative incidence rates. Log-rank test was used to analyze differences in cumulative incidence. Cox proportional-hazards models were used to evaluate differences between groups while adjusting for preselected baseline risk factors (fall-related injuries during 12 months prior to inclusion, age, sex, diabetes, alcohol use smoking and depression). Total event rate taking into account recurrent falls (defined as hospitalizations more than 30 days apart) were evaluated with time to event methods.

Participants who underwent surgery during follow-up were identified using the National Patient Register and SOS questionnaires (at baseline and after 0.5, 1, 2, 3, 4, 6, 8, 10, 15 and 20 years) and censored at the time of surgery if it resulted in change of treatment group. All P values are two-sided, and P values of less than 0.05 were considered to indicate statistical significance. All statistical analyses were performed using Stata (version 12.1).

Results

Baseline characteristics and weight changes during follow-up

Patients in the surgery group were one year younger than the patients in the control group, while most metabolic risk factors were worse in the surgery group. Among surgical subgroups, patients in the gastric bypass group were heavier, had higher cholesterol levels and higher systolic blood pressure and higher rates of type 2 diabetes than those in the vertical banded gastroplasty and banding groups, while there was no significant difference in fall-related injuries in the year before study start (Table in Supplementary Appendix).

On the date of analysis, the follow-up time was up to 26 years, with a median of 19 years (interquartile range 15-21 years). During follow-up, two participants in the surgery group withdrew consent and were censored immediately after the date of inclusion. In addition, 23 patients in the control group and 26 in the surgery group emigrated and were censored at the date of emigration.

At the two-year follow-up the relative weight loss in the gastric bypass, vertical banded gastroplasty and banding subgroups were 31.6, 22.4 and 21.1 %, respectively. The weight change in the control group was minimal (weight increase 0.1%).

Incidence of fall-related injuries during follow-up

There were 513 first-time fall-related injuries in the control group and 617 in the surgery group during follow-up (Figure 1A), and the unadjusted hazard ratio with surgery was 1.19 (95% CI, 1.06 to 1.33; P=0.004). After multivariable adjustments, the hazard ratio was 1.21 (95% CI, 1.07 to 1.36; P=0.002).

During follow-up, there was a significant difference in the incidence of first-time fall-related injuries between treatment groups (P<0.001, log-rank test) with higher incidence after gastric bypass compared to the other two surgical groups and controls (Figure 1B, Table 1). Compared to the gastric bypass group, the adjusted hazard ratio for the control group was 0.50 (P<0.001) and 0.51-0.52 (P<0.001) for the other two surgical groups (Table 1).

When also considering recurrent falls during follow-up, the adjusted hazard ratios for control, banding and vertical banded gastroplasty groups compared to the gastric bypass group were 0.38, 0.34 and 0.41, respectively (Table 1).

Sensitivity analysis

The gastric bypass group had a higher rate of type 2 diabetes at baseline and previous studies suggest an increased risk of falling in patients with type 2 diabetes.¹⁵ We therefore examined the incidence of fall-related injuries in groups of patients with or without type 2 diabetes at baseline (Figure 1 in Supplementary Appendix). This analysis showed that the incidence of fall-related injuries was higher in the gastric bypass group compared to other treatment groups regardless of diabetes status at baseline.

Discussion

In this prospective controlled long-term study, we showed that bariatric surgery, compared with usual obesity care, was associated with increased incidence of fall-related injuries severe enough to cause hospital visits. However, the risk of suffering a first-time fall-related injury was doubled in obese patients treated by gastric bypass compared to controls. By contrast, the risk of suffering a fall-related injury was not changed in patients who underwent banding or vertical banded gastroplasty, suggesting that weight loss *per se* does not alter the risk of falling and that the risk of falling remains higher compared to normal weight individuals even after substantial weight loss. Our study confirms and extends observations from an earlier very small study showing that serious falls are more common after gastric bypass surgery compared to intensive lifestyle treatment of diabetes,¹⁰ and is also consistent with reports suggesting that gastric bypass patients have an increased risk of dying from external causes such as accidents.¹⁶⁻¹⁸

Bariatric surgery procedures have changed over time and gastric bypass, which has long been considered to be the gold standard, is being gradually replaced by the sleeve gastrectomy technique. Nevertheless, a very large number of patients worldwide have undergone this procedure. It is unclear why fall risk is increased after gastric bypass, however, compared to restrictive procedures, it is associated with higher risk of micronutrient deficiency-related neurological complications,¹⁹ hypoglycemia,²⁰ and dependence syndromes, in particular alcohol use disorders.^{16, 21}

The SOS study and our analysis have some limitations. The SOS study was not randomized and fall-related injury was not a pre-specified endpoint. The Swedish National Patient Register used to trace fall-related injuries only contains inpatient data and for this reason, we could have missed minor fall-related injuries treated in primary care. Despite these limitations, the study is, to our knowledge, the best available source of data for evaluation of rare, long-term side effects after bariatric surgery.

In conclusion, our results show that gastric bypass, but not banding or vertical banded gastroplasty, increases the risk for fall-related injury and suggest that post-surgery care needs to be optimized to reduce this risk.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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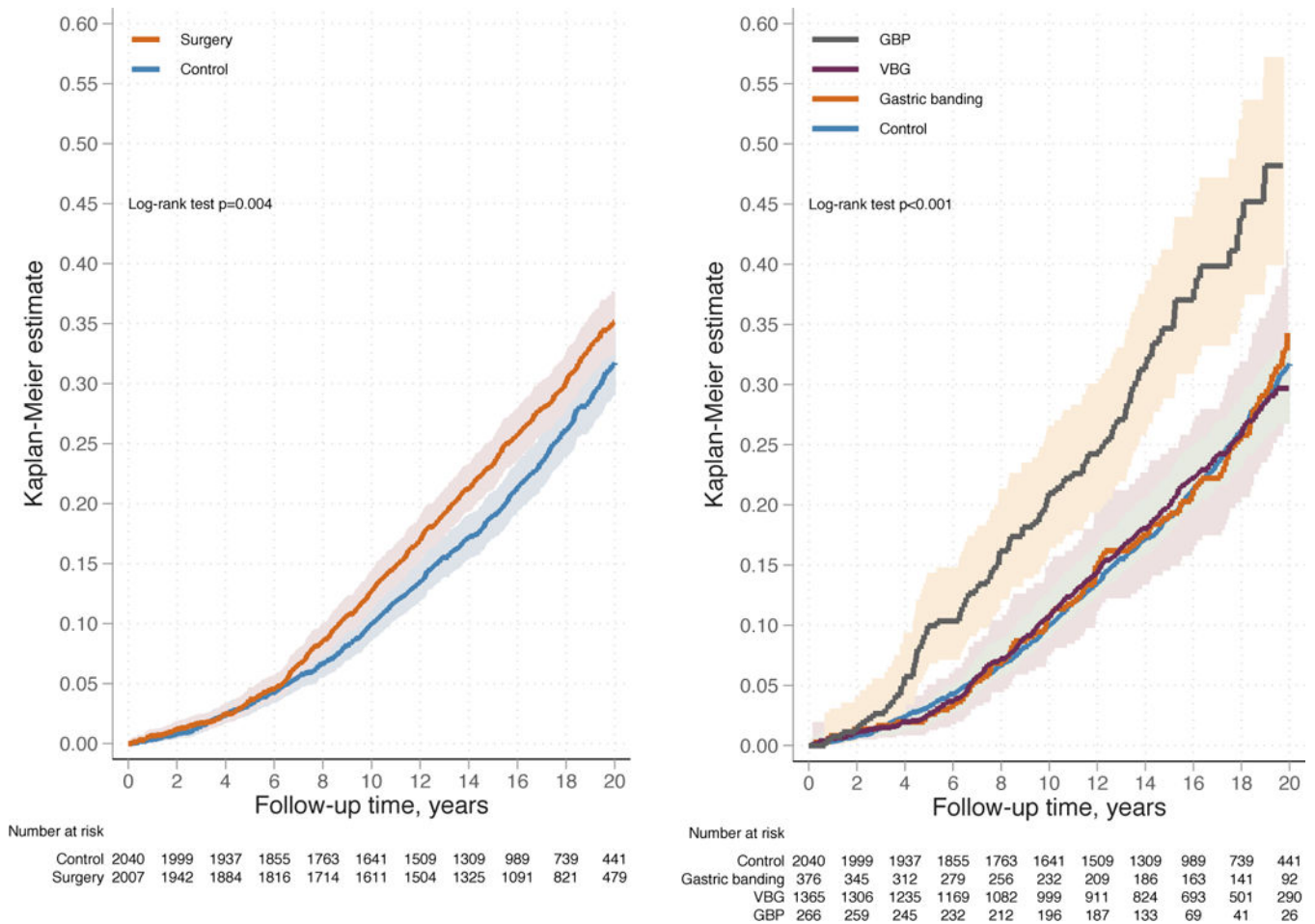


Figure 1. Cumulative incidence of first time fall-related injuries during follow-up in the bariatric surgery group and the control group (panel A) and divided by the method of treatment (panel B). Observations were censored at time of surgery if it resulted in change of treatment group (control patients who underwent bariatric surgery and patients in the surgery group who underwent surgical re-instatement during follow-up were censored at the time of surgery in panel A; reoperations resulting in change of surgical group were additionally censored in panel B). GBP, gastric bypass; VBG, vertical banded gastroplasty. The shaded areas represent the 95 percent confidence intervals.

Table 1

Hazard Ratios for the Incidence of Fall-Related Injuries.

	Control (N=2040)	Banding (N=376)^b	VBG (N=1365)^b	GBP (N=266)^b
Number of first fall events	513	84	324	100
Person-years	31148	4954	19742	3512
Incidence rate per 1000 person-years (95% CI)	16.5 (15.1-18.0)	17.0 (13.7-21.0)	16.4 (14.7-18.3)	28.5 (23.4-34.6)
HR, unadjusted (95% CI)	0.52 (0.42-0.65)	0.54 (0.40-0.72)	0.52 (0.42-0.66)	1.0 (reference)
HR, adjusted ^a (95% CI)	0.50 (0.40-0.62)	0.52 (0.39-0.69)	0.51 (0.41-0.64)	1.0 (reference)
Total number of fall events	886	128	600	235
Person-years	31949	5110	20328	3763
Incidence rate per 1000 person-years (95% CI)	27.7 (26.0-29.6)	25.1 (21.1-29.8)	29.5 (27.2-32.0)	62.5 (55.0-71.0)
HR, unadjusted (95% CI)	0.39 (0.30-0.51)	0.35 (0.25-0.49)	0.42 (0.32-0.55)	1.0 (reference)
HR, adjusted ^a (95% CI)	0.38 (0.29-0.49)	0.34 (0.24-0.47)	0.41 (0.31-0.54)	1.0 (reference)

^a Adjusted for fall-related injuries 12 months prior to inclusion, age, sex, diabetes, alcohol use and smoking and depression at baseline.

^b Censored at time of reoperation if it resulted in change of surgery group. CI, confidence interval; VBG, vertical banded gastroplasty; GBP, gastric bypass.