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ORIGINAL CONTRIBUTIONS

Incidence and Risk Factors for Mortality Following Bariatric Surgery: a Nationwide Registry Study

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Abstract
Background Although bariatric surgery (BS) is considered safe, concern remains regarding severe post-operative adverse events and mortality. Using a national BS registry, the aim of this study was to assess the incidence, etiologies, and risk factors for mortality following BS.
Methods Prospective data from the National Registry of Bariatric Surgery in Israel (NRBS) including age, gender, BMI, comorbidities, and surgical procedure information were collected for all patients who underwent BS in Israel between June 2013 and June 2016. The primary study outcome was the 3.5-year post-BS mortality rate, obtained by cross-referencing with the Israel population registry.
Results Of the 28,755 patients analyzed (67.3% females, mean age 42.0 ± 12.5 years, and preoperative BMI 42.14 ± 5.21 kg/m^2), 76% underwent sleeve gastrectomy (SG), 99.1% of the surgeries were performed laparoscopically, and 50.8% of the surgeries were performed in private medical centers. Overall, 95 deaths occurred during the study period (146.9/100,000 person years). The 30-day rate of post-operative mortality was 0.04% (n = 12). Male gender (HR = 1.94, 95%CI 1.16–3.25), age (HR = 1.06, 95%CI 1.04–1.09), BMI (HR = 1.08, 95%CI 1.05–1.11), and depression (HR = 2.38, 95%CI 1.25–4.52) were independently associated with an increased risk of all-cause 3.5-year mortality, while married status (HR = 0.43, 95%CI 0.26–0.71) was associated with a decreased risk.
Conclusion Mortality after BS is low. Nevertheless, a variety of risk factors including male gender, advanced age, unmarried status, higher BMI, and preoperative depressive disorder were associated with higher mortality rates. Special attention should be given to these "at-risk" BS patients.

Keywords Bariatric surgery · Registry · Mortality

Nasser Sakran and Shiri Sherf-Dagan contributed equally to this work.

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Introduction

Bariatric surgery (BS) is effective for reducing obesity-related comorbidities, as well as achieving major long-term weight loss [1]. Moreover, when compared to severely obese non-BS patients, BS is associated with a reduction in long-term overall mortality [2–4]. According to a recently published nationwide registry study from Finland, mortality rates following BS were lower than those following other common elective surgeries [5]. Presently, several BS procedures are available including adjustable gastric banding (AGB), sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion (BPD) with or without duodenal switch (DS) [6], and single anastomosis gastric bypass (SAGB) [7].

The choice of proceeding with BS, and then the decision between surgery types, is influenced by the available evidence regarding weight loss results, durability of the procedure, and the associated short- and long-term adverse events, notably mortality [8, 9]. Reported mortality rates following BS procedures vary widely across patient cohorts, hospitals, and surgeons [10, 11]. Only a few population-based studies have provided data on mortality rates following different types of BS [5, 8, 10, 12–15]. Most published data report mortality rates following only a specific BS procedure and are limited to small patient cohorts or short-term follow-up periods [4, 11, 16–18].

During 2015, 9308 patients underwent BS in Israel [19], and at the present time, Israel performs the second highest number of BS per capita in the world [20].

The preoperative identification of high-risk BS candidates can assist in improved patient selection and counseling regarding BS options and treatment optimization [16]. Thus, utilizing the Israel Nationwide Registry of Bariatric Surgeries (NRBS), the aim of this study was to assess the incidence, causes, and risk factors for mortality following different types of BS.

Methods

Data Collection

Data were obtained from the Israel NRBS. This is a mandatory surgical registry initiated in June 2013, by a joint steering committee of the Israeli Ministry of Health, the Israeli Surgical Society, and the Israeli Endocrinology Society. All hospitals in Israel which perform BS ($n = 31$) are required on a monthly basis to submit specific and detailed data to the registry in order to maintain bariatric surgical privileges and receive BS procedure payment. These data are collected according to a structured electronic form and are transferred by each hospital to the national registry database where regular, routine quality controls are performed in order to ensure accurate data. Patient anonymity is maintained in the registry database.

Data collected from the Israel NRBS for this present study included age, gender, body mass index (BMI), comorbidities, hospital type (public vs. private), operative data (surgery type, surgical approach, primary vs. secondary BS, and length of hospital stay), and mortality. All patients who underwent BS in Israel between June 2013 and June 2016 were included in this study. The main study outcome was mortality. Mortality data were obtained by cross-referencing the NRBS with the Israel Population Registry reports. Cause of death was obtained from the Israel Ministry of Health mortality reports. Patient survival time was defined as the time between BS to either date of death or date of last follow-up (February 28, 2017). Cause of death was judged by the authors as directly or indirectly caused by surgery based on a case by case discussion and consensus.

Statistical Analysis

Statistical analysis was performed using the SAS package (version-9.1, SAS, Cary, NC). Results are expressed as mean ± standard deviation (SD) and/or percentage. For continuous variables, differences in means between mortality and non-mortality groups were assessed by the independent samples t test. The chi-square test was applied for categorical variables. Multivariable Cox proportional hazard regression analysis adjusted for covariates was used to estimate hazard ratios (HRs) and 95% confidence intervals (CIs) of patient death during the study period. To estimate the probability of death over time, a Kaplan-Meier curve was constructed. Incidence rate of mortality using person-years was calculated as the number of incident cases of death divided by the amount of person-time (the sum of total time in years contributed to the study by all subjects under observation) at risk. This calculation was done only for the overall mortality rate up to 3.5 years, whereas for the 30-day post-surgery mortality rate, all the study sample was under observation. $P < 0.05$ was considered statistically significant for all analyses.

Results

Study Participants

During the study period, 28,755 adult patients (67.3% females) who underwent BS were identified in the Israel NRBS. Mean age and preoperative BMI were 42.0 ± 12.5 years (range 18.0–79.4 years) and 42.14 ± 5.21 kg/m^2, respectively. Most of the BS procedures were SG (76.0%) and almost all were performed laparoscopically (99.1%). Surgeries were evenly distributed between private (50.8%) and public (49.2%) hospitals.

Incidence and Causes of Death

The number of patients available during the follow-up period and the number of deaths are shown in Table 1. Patient survival following BS is shown in Fig. 1. Patients were followed for anywhere from 6 months to 3.5 years post-BS, with a median follow-up of 1.9 years. Overall, during the follow-up period, 95 deaths (146.9/100,000 person-years) occurred. The mortality rates according to the procedures performed were 89.6/100,000 ($n = 5$), 138.7/100,000 ($n = 70$), 216.0/100,000 ($n = 17$), and 405.8/100,000 ($n = 3$) person-years for AGB, SG, RYGB/SAGB, and all other BS types, respectively.

In addition, 12 deaths (0.04%) were identified in the first 30 days after surgery (Table 1). Anastomotic leak was the most common mortality-associated short-term (≤ 30 days) post-operative adverse event ($n = 5$, 42% of early deaths). Late mortality (> 30 days after surgery) was due to malignancies ($n = 22$), cardiac-related events ($n = 10$), and suicide ($n = 6$) (Table 2). Among the six patients who committed suicide, 4 (66%) were women, only one was married (17.1%), and their mean age was 37.8 ± 10.9 years. The suicides occurred on average 626 ± 424 days (range 201–1126 days) post-surgery. Malignancy-associated deaths were due to pancreatic ($n = 6$, all non-diabetics), lung ($n = 4$), and breast ($n = 2$) cancers and one case each of prostate, ovarian, kidney, liver, colorectal, esophagus, adrenal, lymphoma, multiple myeloma, and unknown origin cancers.

Deceased versus surviving patient's characteristics are presented in Tables 3 and 4. Univariate analysis showed that mortality was significantly associated with male gender (50.5 vs. 32.6%, $P < 0.001$), age (52.8 ± 12.1 vs. 41.9 ± 12.5 years, $P < 0.001$), unmarried status (51.6 vs. 36.0%, $P < 0.001$), higher BMI (44.0 ± 7.9 vs. 42.1 ± 5.2 kg/m^2, $P < 0.001$), type 2 diabetes mellitus (58.0 vs. 26.3%, $P < 0.001$), hypertension (62.3 vs. 29.8%, $P < 0.001$), sleep apnea (25.0 vs. 13.8%, $P = 0.007$), depression (19.1 vs. 6.9%, $P < 0.001$), open surgical procedure (4.4 vs. 0.9%, $P < 0.001$), and surgery at a public hospital (67.4 vs. 49.2%, $P < 0.001$) (Tables 3 and 4). Demographic and clinical characteristics, type of bariatric surgical procedures, and operative data stratified by hospital type (public vs. private) are detailed in Supplementary Table 1.

Table 1 Number of patients and number of deaths by follow-up period

Time since operation	Number of patients available for follow-up (N)	Number of deaths, $N = 95$ (n, %)[a]
< Week[b]	28,755	6 (6.3)
≥ 1 week–1 month	28,755	6 (6.3)
≥ 1–3 months	28,755	12 (12.6)
≥ 3–6 months	28,755	6 (6.3)
≥ 6–9 months	28,141	10 (10.5)
≥ 9–12 months	25,891	12 (12.6)
≥ 12–18 months	21,829	8 (8.4)
≥ 18–24 months	16,797	10 (10.5)
≥ 24–36 months	7760	17 (17.9)
≥ 36–45 months	2720	8 (8.4)

[a] Represents the number and the percentage of cases of deaths for each term since operation

[b] Including 0–7 days post-surgery

Risk Factors for Post-BS Mortality

After adjusting for covariates, we found a significantly increased risk of all-cause mortality up to 3.5 years associated with male gender (HR = 1.94, 95%CI 1.16–3.25), age (HR = 1.06, 95%CI 1.04–1.09), higher BMI (HR = 1.08, 95%CI 1.05–1.11), and preoperative depressive disorder (HR = 2.38, 95%CI 1.25–4.52). We also found a significantly decreased risk of mortality in those patients who were married (HR = 0.43, 95%CI 0.26–0.71). Marginal significance was found for type 2 diabetes mellitus and open surgical procedure and in those patients undergoing BS at a public hospital (Table 5).

Discussion

We found that the 30-day and overall mortality rates following BS were similar or lower than those reported in other national registry or large cohort studies [8, 10–14, 16, 21–28]. During the short-term post-operative period (≤ 30 days), anastomotic leak was the most common post-operative adverse event associated with mortality. Post-operative anastomotic leak is one of the most serious and feared adverse events in BS and may lead to prolonged hospitalization, sepsis, chronic fistula formation, hemodynamic instability, multiorgan dysfunction, and ultimately patient demise [29–31]. Most leaks occur following patient discharge, occurring between a few days to several weeks post-operatively [29, 30]. The leading cause of death during the latter post-operative period (> 30 days after surgery) was malignancy, which occurred between 0.2 and 3.1 years post-surgery. Metastatic pancreatic cancer was the most frequent, though the reason for this is unclear as this is a rather rare malignancy, especially in this patient age group. Obesity is an established risk factor for obesity-related cancers (breast, prostate, colorectal, endometrial, renal, pancreatic, gallbladder, and esophageal) [32], and cancer may take up to 20 to 30 years to develop [33]. Thus, it is possible that the long lead time for the appearance of cancer explains some of the cancer cases which were observed in this present study [34]. With respect to the general adult population (age ≥ 20 years) in Israel in 2014, the standardized mortality ratio (SMR) due to cancer was 0.40 (95%CI 0.25–0.59), a lower number of observed deaths than expected. This result is in line with that of previous studies which found that BS appears to decrease the risk of cancer compared to non-operated obese individuals, and this association is more marked among women than that among men [32, 34].

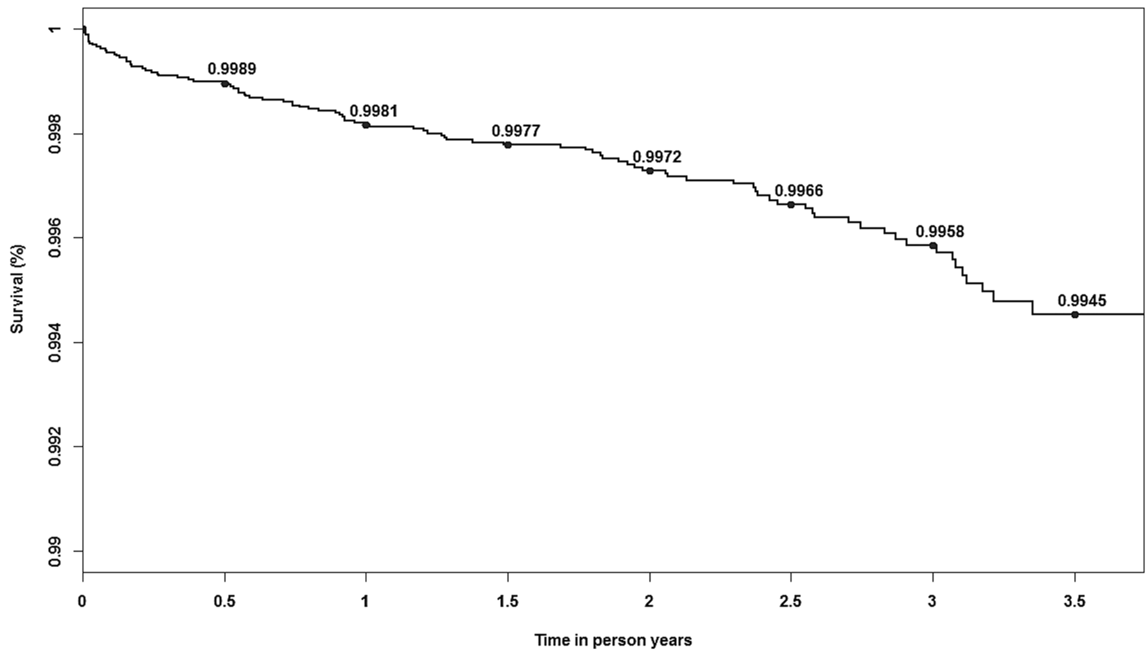

Fig. 1 Survival rates of patients after bariatric surgery up to 3.5 years monitoring period

Table 2 Underlying cause of death in the study cohort

Causes of death	0–30 days (*n*, %)	> 30 days (*n*, %)
Directly caused by surgery		
Anastomotic leak	5 (5.3)	5 (5.3)
Sepsis/infection	2 (2.1)	1 (1.1)
Cardiac	2 (2.1)	1 (1.1)
Pulmonary embolism	2 (2.1)	–
Bleeding	1 (1.1)	–
Respiratory insufficiency	–	1 (1.1)
Starvation	–	1 (1.1)
Indirectly caused by surgery		
Malignancy	–	22 (23.2)
Cardiac	–	10 (10.5)
Suicide	–	6 (6.3)
Sepsis/infection	–	5 (5.3)
Thrombosis	–	3 (3.2)
Renal disease	–	2 (2.1)
Bleeding	–	1 (1.1)
Acute liver failure	–	1 (1.1)
Lithium toxicity	–	1 (1.1)
Amyloidosis	–	1 (1.1)
Adverse event due to other surgeries	–	1 (1.1)
Accident	–	1 (1.1)
Unknown	–	20 (21.1)

The relatively low mortality rates observed in this present study may be partially explained by several factors. This includes the high volume of BS performed in Israel and the dominant use of a laparoscopic surgical approach. In Israel, there are a limited number of bariatric surgeons, who altogether perform approximately 9000 bariatric surgeries per year [35]. Moreover, all hospitals performing BS must be approved by the Israel Ministry of Health. This approval is only granted to centers that meet specific standards, among which are performance of at least 100 BS cases per year, the availability of an intensive care unit, diagnostic and interventional radiology, gastroenterology/endoscopy capabilities, and a dedicated multidisciplinary bariatric team [36]. In addition, BS has become a routine laparoscopic operation [37], and open surgeries are performed only in selected cases [13]. Although open surgery was found to have only marginal impact on an increased risk of all-cause mortality, the dominant use of laparoscopic surgeries (> 99%) in our cohort may also explain the low rates of post-operative mortality in Israel. Previous studies have demonstrated lower rates of mortality for laparoscopic versus open surgery [8, 21].

Others have reported that mortality following BS is related to the bariatric surgeon's skill, hospital volume, institution-available facilities, operative time, selection of type and approach of operation, older age, male gender, higher BMI, android body habitus, and presence of significant comorbidities (including type 2 diabetes and hypertension, known risk factors for pulmonary embolism, low serum albumin, and functional dependence) [8, 10, 11, 13, 16, 21, 23, 24, 38].

Statistical significance for increased risk of all-cause 3.5-year mortality was found for male gender, older age, unmarried status, higher BMI, and preoperative depressive disorder,

Table 3 Demographic and clinical characteristics of the cohort population at baseline stratified by non-mortality group and mortality group

Characteristics	Non-mortality group *n* (%) or mean ± SD	Mortality group *n* (%) or mean ± SD	*P* value
Demographic	$N = 28,660$	$N = 95$	
Gender (female)	19,303 (67.4)	47 (49.5)	*< 0.001*
Age (years, mean ± SD)	41.9 ± 12.5	52.8 ± 12.1	*< 0.001*
Age ≥ 65 years	842 (2.9)	16 (16.8)	*< 0.001*
Ethnicity			0.229
Jews	24,041 (83.9)	84 (88.4)	
Arabs	4618 (16.1)	11 (11.6)	
Marital status (married)	18,326 (64.0)	46 (48.4)	*< 0.001*
Current smokers	5367 (22.9)	15 (23.4)	0.938
Anthropometrics	$N = 27,169$	$N = 94$	
BMI (kg/m^2, mean + SD)	42.1 ± 5.2	44.0 ± 7.9	*< 0.001*
kg/m^2 BMI ≥ 50	2103 (7.7)	16 (17.0)	0.008
Comorbidities	$N = 23,651$	$N = 69$	
Hypertension	7020 (29.8)	43 (62.3)	*< 0.001*
Type 2 diabetes	6184 (26.3)	40 (58.0)	*< 0.001*
Sleep apnea	3232 (13.8)	17 (25.0)	*0.007*
Ischemic heart disease	395 (3.7)	2 (11.1)	0.094
Dyslipidemia	4047 (34.8)	10 (45.3)	0.304
NAFLD	6904 (59.5)	14 (63.6)	0.693
Previous CVA	183 (0.8)	2 (2.9)	*0.044*
Atherosclerosis	1043 (4.4)	14 (20.3)	*< 0.001*
Depression	1611 (6.9)	13 (19.1)	*< 0.001*
No. of comorbidities (%)[a]			
0–1	13,113 (55.1)	20 (29.0)	*< 0.001*
2–3	7760 (32.6)	29 (42.0)	
3<	2914 (12.3)	20 (29.0)	

BMI body mass index, *NAFLD* non-alcoholic fatty liver disease, *CVA* cerebrovascular accident

[a] All types of comorbidities

while type 2 diabetes, open surgery, and undergoing BS in a public hospital were found to be only marginally significant. Obese males typically have more intra-abdominal fat compared to obese females, possibly making operation technically more difficult [8, 39]. There are increasing numbers of elderly patients undergoing BS [40]. As compared to younger patients, older patients can present with more comorbidities, a longer duration of comorbidities, more sarcopenia, and a slower wound healing process which influence their baseline physical condition [40, 41]. These factors altogether might explain the higher mortality post-BS among older patients. However, BS represents an acceptable and effective treatment option in morbidly obese patients older than 60 years old; thus, older age alone should not be an absolute contraindication for BS [40, 42]. Data on how spousal relationships influence BS patient outcomes are scarce [43]. Previous studies have found that marital status is associated with health benefits including lower morbidity and mortality [43, 44]. However, it seems that the interactions and dynamics within the couple's relationship are the key to these influences [43]. Super obese individuals (BMI ≥ 50 kg/m^2) are more likely to have more complex health issues that might increase surgical risk [45]. The primary strategy for minimizing adverse events in these patients might be to decrease their BMI prior to surgery by a hypocaloric diet, drug therapy, intra-gastric balloon placement, or hospitalization [46, 47]. Extremely obese individuals are more vulnerable to depression, although the factors responsible for this susceptibility are unclear [48]. BS patients have higher suicide rates than the general population [3, 49]. It was reported that approximately 30% of the suicides occurred within the first 2 years and the remainder within 3 years post-surgery or later [50]. In this present study, there were six cases of suicide which occurred between 0.6 and 3.1 years post-surgery. According to the Israel Ministry of Health report on suicides in the general population in 2013, the age-standardized suicide rate was 6.3 per 100,000 individuals [51]. Important predictors for completed suicide post-surgery are suicide attempts in the past and a history of sexual abuse [49]. Candidates for BS should therefore be assessed preoperatively for depression and should be treated and

Table 4 Bariatric surgical procedures and operative data in the non-mortality group compared to those in the mortality group

Characteristics	Non-mortality group $N=28,660$ n (%) or mean ± SD	Mortality group $N=95$ n (%) or mean ± SD	P value
Type of surgery	$N=28,660$	$N=95$	
AGB	2326 (8.1)	5 (5.3)	0.309
SG	21,785 (76.0)	70 (73.7)	0.595
RYGB/SAGB	4278 (14.9)	17 (17.9)	0.272
Other (BPD-DS/BPD/VBG)	271 (1.0)	3 (3.2)	0.244
Surgery category	$N=24,054$	$N=68$	
Primary surgery Redo surgery	21,143 (87.9) 2911 (12.1)	60 (88.2) 8 (11.8)	0.931
Surgical approach	$N=23,876$	$N=69$	
Laparoscopic Open	23,667 (99.1) 123 (0.5)	66 (95.6) 1 (1.5)	*0.001*
Laparoscopic converted to open	86 (0.4)	2 (2.9)	
Hospital type	$N=28,656$	$N=95$	
Private Public	14,570 (50.8) 14,086 (49.2)	31 (32.6) 64 (67.4)	*< 0.001*
Length of stay (days)[a]	2.8 ± 3.2	5.4 ± 11.7	*< 0.001*

AGB adjustable gastric banding, *SG* sleeve gastrectomy, *RYGB* Roux-en-Y gastric bypass, *BPD-DS* biliopancreatic diversion with or without duodenal switch, *SAGB* single anastomosis gastric bypass, *VBG* vertical banded gastroplasty, *CVA* cerebrovascular accident

[a] Data were available for $N=28,752$ (of these, 95 mortality events)

monitored prior to and following surgery [48]. It is important to mention that in Israel, as part of the multidisciplinary BS team, all patients must be evaluated and cleared by a social worker or psychologist [52]. In cases of active or untreated depression or other mental health problems, patients do not receive permission to undergo BS.

Type 2 diabetes is considered as a risk factor for mortality following BS [10] and other surgeries as well [53, 54]. Adequate preoperative glycemic control has the potential to minimize risk for adverse surgical outcomes and favorably influence post-operative diabetes remission rates [55].

Table 5 Adjusted hazard ratios for mortality among patients following bariatric surgery (Cox model)

Parameter	HR of death (95% CI)	P value
Age	1.06 (1.04–1.09)	*< 0.001*
Gender (male)	1.94 (1.16–3.25)	*0.011*
Marital status (married)	0.43 (0.26–0.71)	*0.001*
BMI	1.08 (1.05–1.11)	*< 0.001*
Hypertension	1.42 (0.76–2.66)	0.275
Type 2 diabetes	1.74 (0.96–3.14)	0.065
Sleep apnea	1.08 (0.59–1.97)	0.802
Depression	2.38 (1.25–4.52)	*0.008*
Previous CVA	1.57 (0.37–6.53)	0.535
Public hospital (compared to private)	1.71 (0.98–2.98)	0.059
Laparoscopy (compared to open access[a])	0.30 (0.09–1.03)	0.056
More than one chronic disease	0.68 (0.29–1.61)	0.0387
Recurrent surgery	0.72 (0.31–1.65)	0.445
Different types of surgery (SG compared to other types)	0.71 (0.40–1.25)	0.243

Data were available for $N=22,777$ (of them, 65 events of death)

HR hazard ratio, *BMI* body mass index, *SG* sleeve gastrectomy

[a] Included open and laparoscopic conversion to open procedures

We found that the BS cases were evenly distributed between private and public hospitals, but the volume of BS at private hospitals was higher. Others have previously reported that surgical case volume significantly affects mortality rates following BS [10, 38]. Thus, it is conceivable that this may partially explain the lower mortality rates we observed since BS case volume was higher at private hospitals in Israel. On the other hand, we found that public hospitals treated more complicated patients, which may also favorably impact mortality risk [21].

The major strengths of this current study include its large sample size, the relatively long-term follow-up period, and the use of a national BS patient registry that undergoes routine quality control measures. However, this study has several limitations. First, despite the use of national registry data that is regularly monitored for quality control, there still can be misclassification or missing patient data. However, there is no reason to believe that any such missing or misclassified data should be different between patients who survived compared to those who did not survive following surgery. Moreover, death certificate misclassification (in the Israel Population Registry reports) cannot be ruled out. Better training of physicians in standard International Classification of Diseases (ICD) death certification classification is needed in order to improve reporting quality for future national studies and health policy decisions [56]. Second, data for some parameters were not available for all patients (i.e., comorbidities, surgery category, and surgical approach). Third, study participants were followed for different lengths of time (i.e., 0.5–3.5 years with a median follow-up of 1.9 years). Therefore, we calculated and presented the long-term mortality rates in person-years using Cox proportional hazards modeling in order to derive hazard ratios. Fourth, no matched non-bariatric control group was available in this study. Furthermore, in Israel, SG was the most common BS [19]. This may affect the generalizability of our results, since restrictive bariatric procedures are known to have lower mortality rates compared to malabsorptive bariatric procedures [10, 13]. Nevertheless, SG is currently the most popular bariatric procedure worldwide [20], and the unselected population in a nationwide registry study should enhance generalizability to other settings [8].

Conclusion

Mortality following BS is low. However, different risk factors including male gender, advanced age, unmarried status, higher BMI, and preoperative depressive disorder were identified as impacting mortality. Special attention should be given to these "at-risk" BS patients prior to and following surgery.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in this study were approved by the institutional research committee and in accordance with the ethical standards of the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Statement of Informed Consent For this type of study, formal consent is not required.

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