

# Cardiovascular Risk After Bariatric Surgery for Obesity

John A. Batsis, MD<sup>a,b,\*</sup>, Michael G. Sarr, MD<sup>c</sup>, Maria L. Collazo-Clavell, MD<sup>b,d</sup>, Randal J. Thomas, MD, MS<sup>b,e</sup>, Abel Romero-Corral, MD, MSc<sup>e</sup>, Virend K. Somers, MD, PhD<sup>b,e</sup>, and Francisco Lopez-Jimenez, MD, MSc<sup>b,e</sup>

Obese patients have an increased prevalence of cardiovascular (CV) risk factors, which improve with bariatric surgery, but whether bariatric surgery reduces long-term CV events remains ill defined. A systematic review of published research was conducted, and CV risk models were applied in a validation cohort previously published. A standardized MEDLINE search using terms associated with obesity, bariatric surgery, and CV risk factors identified 6 test studies. The validation cohort consisted of a population-based, historical cohort of 197 patients who underwent Roux-en-Y gastric bypass and 163 control patients, identified through the Rochester Epidemiology Project. Framingham and Prospective Cardiovascular Munster Heart Study (PROCAM) risk scores were applied to calculate 10-year CV risk. In the validation cohort, absolute 10-year Framingham risk score for CV events was lower at follow-up in the bariatric surgery group (7.0% to 3.5%,  $p < 0.001$ ) compared with controls (7.1% to 6.5%,  $p = 0.13$ ), with an intergroup absolute difference in risk reduction of 3% ( $p < 0.001$ ). PROCAM risk in the bariatric surgery group decreased from 4.1% to 2.0% ( $p < 0.001$ ), whereas the control group exhibited only a modest decrease (4.4% to 3.8%,  $p = 0.08$ ). Using mean data from the validation study, the trend and directionality in risk was similar in the Roux-en-Y group. The test studies confirmed the directionality of CV risk, with estimated relative risk reductions for bariatric surgery patients ranging from 18% to 79% using the Framingham risk score compared with 8% to 62% using the PROCAM risk score. In conclusion, bariatric surgery predicts long-term decreases in CV risk in obese patients. © 2008 Elsevier Inc. All rights reserved. (Am J Cardiol 2008;102:930–937)

Cardiovascular (CV) risk assessment using decision tools allows the early identification of patients requiring changes in lifestyle and therapeutic interventions for the primary prevention of CV disease.<sup>1</sup> The Framingham risk score (FRS)<sup>1</sup> was derived using an American cohort and has been extensively validated and adapted for application in diverse populations.<sup>2–4</sup> Because its applicability to European cohorts has been challenged,<sup>5,6</sup> the Prospective Cardiovascular Munster Heart Study (PROCAM) risk score has also gained wide acceptance.<sup>7</sup> Bariatric surgery, an approved weight loss therapy,<sup>8</sup> is increasingly being used<sup>9</sup> in reducing medical co-morbidities and improving CV risk factors.<sup>10</sup> However, its long-term impact on CV events and mortality is still poorly defined.<sup>11</sup> In the present study, we used familiar CV risk models, such as the FRS and the PROCAM risk score, to test the predicted CV risk reduction in a validation cohort<sup>12</sup> using patient-level data and subsequently used the mean data of this study and those obtained from a systematic search of published research to examine whether overall CV risk trends are altered after bariatric surgery.

## Methods

We performed a broad search of publications paralleling the Quality of Reporting of Meta-Analyses statement<sup>13</sup> related to bariatric surgery, obesity, and CV risk factors using MEDLINE (from 1950 to the cut-off date of April 8, 2008) using the following search terms: “obesity surgery,” “gastroplasty,” “gastric bypass,” “bariatric surgery,” “obesity” (surgery), “anastomosis,” and “Roux-en-Y gastric bypass.” We independently combined these terms and “obesity” with “gastric banding,” “biliopancreatic diversion,” or “jejuno-ileal bypass,” thereby providing us with a total of 12,018 citations. We limited these studies to any of the following criteria for type of publication: retrospective studies, randomized controlled trials, longitudinal studies, prospective studies, cohort studies, case-control studies, clinical trials, comparative studies, or follow-up studies, resulting in 4,346 citations. We subsequently combined these citations with any of the following Keywords: “diabetes mellitus;” “glucose intolerance;” “metabolic syndrome;” “hyperlipidemia;” “hypertension;” “hypertriglyceridemia;” “hypercholesterolemia;” “risk factors;” “CV risk factors;” and “comorbidity.” We excluded nonhuman studies and pediatric studies and limited our search to reports in English; resulting in 656 citations.

Among these 656 citations, the primary investigator (JAB) reviewed the individual abstracts and further excluded case reports, letters, reviews, or commentaries that may have eluded our initial search ( $n = 43$ ). Studies with  $< 6$  months of follow-up ( $n = 252$ ), those unrelated to bariatric surgery ( $n = 113$ ), and those with  $< 100$  patients

<sup>a</sup>Division of Primary Care Internal Medicine, <sup>b</sup>Department of Medicine, <sup>c</sup>Department of Surgery, and Divisions of <sup>d</sup>Endocrinology and Metabolism and <sup>e</sup>Cardiovascular Diseases, Mayo Clinic College of Medicine, Rochester, Minnesota. Manuscript received January 26, 2008; revised manuscript received and accepted May 4, 2008.

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\*Corresponding author: Tel: 507-284-5278; fax: 507-266-0036.

E-mail address: john.batsis@gmail.com (J.A. Batsis).

Table 1  
Studies examined using systematic review

Study	Year Performed	Year Published	Country	Type of Bariatric Surgery	No. of Patients	Mean Follow-Up (yrs)
Pontiroli et al <sup>14</sup>	1996	2002	Italy	Laparoscopic adjustable gastric banding	143	1.0
Busetto et al <sup>15</sup>	1993–2000	2004	Italy	Gastric banding	650	1.3
Stoopen-Margain et al <sup>16</sup>	2000–2002	2004	Mexico	Laparoscopic Roux-en-Y	100	1.7
He and Stubbs <sup>17</sup>	1990–2002	2004	New Zealand	Roux-en-Y	310	1.0*
Batsis et al <sup>12</sup>	1990–2003	2007	United States	Roux-en-Y	163/197 <sup>†</sup>	3.3
Sjostrom et al <sup>10</sup>	1994–2004	2004	Sweden	Vertical band gastroplasty	1,660/1,845 <sup>†</sup>	2.0
				Vertical band gastroplasty	627/641 <sup>†</sup>	10.0

\* Follow-up extended to 3.5 years, but data used in our study were obtained at 1 year.

<sup>†</sup> Patient numbers represent controls/surgical patients.

(n = 104) were omitted. We excluded follow-up studies performed at the same institution (n = 4). Of the 140 remaining citations, we excluded those without mention of CV risk factors: diabetes, hypertension, hypercholesterolemia, and weight change (n = 65).

We reviewed the entire manuscripts of the remaining 75 citations and excluded studies whose data were presented in descriptive or nonnumeric form (n = 30); cost studies (n = 5); studies providing no data on CV risk factors (n = 4); those dated earlier than 1980 (n = 7); brief reports, including a letter, a commentary, and an editorial (n = 3); quality-of-life studies (n = 3); studies with <100 patients (n = 7); studies that used the FRS in their analysis (n = 2); 1 study with follow-up of <1 year and 1 study with >20% of patients with incomplete follow-up; and studies involving reanalyzed data from previously published studies (n = 3). Four studies had missing numeric data for hypertension or hypercholesterolemia. We contacted the investigators in an attempt to obtain these data from the primary sources. One investigator supplied the missing data, 1 responded but did not have the data available, and 2 did not respond to our request. Six studies fulfilled all of our inclusion criteria, including our own population-based study (Table 1).<sup>10,12,14–17</sup>

The selection of the validation cohort has been previously published.<sup>12</sup> Briefly, we performed a historical, population-based study examining all Olmsted County, Minnesota, residents referred for Roux-en-Y gastric bypass surgery to the Mayo Clinic Nutrition Center from 1990 to 2003 using the Rochester Epidemiology Project, a medical record linkage system. All medical records are available for review, allowing the complete ascertainment of patients' histories. Our final study cohort consisted of 197 surgical patients and 163 nonoperative patients. To validate our previously published risk model,<sup>12</sup> we applied the FRS and PROCAM risk score<sup>17</sup> to this cohort. We included only patients with complete data to calculate risk scores. For the FRS, complete data were available on 182 surgical and 158 control patients, whereas for the PROCAM risk score, complete data were available for 173 surgical and 141 control patients.

The FRS is the most commonly used CV risk tool in the United States. Many other risk scores are derived from the FRS and hence were not considered in this study. The predicted score is based on a community-based cohort of 5,345 patients aged 30 to 74 years at the time of the initial Framingham examination. Follow-up was 12 years, with a total of 610 patients experiencing cardiac events. The latest

version<sup>1</sup> was used to compute 10-year risk for fatal or nonfatal coronary events using the following variables in this model: gender, age, total and high-density lipoprotein cholesterol, systolic blood pressure, smoking (yes or no), and a diagnosis of diabetes mellitus (yes or no).

The PROCAM score<sup>7</sup> was used because many of our included studies were of European origin. The study was performed in German government and company workers from 1979 to 1985, with 96% follow-up. These investigators developed a 10-year CV prediction score to estimate the global risk for fatal and nonfatal coronary events on the basis of an actual 325 acute coronary events in the 5,389 men followed from 35 to 65 years of age at the time of recruitment. Variables included were age, low-density lipoprotein, high-density lipoprotein, triglycerides, systolic blood pressure, smoking (yes or no), diabetes (yes or no), and a family history of a myocardial infarction (yes or no).

We decided not to use other commonly known risk assessments. The United Kingdom Prospective Diabetes Study (UKPDS) and its risk equation<sup>18</sup> are limited specifically to patients with only diabetes mellitus and would not be applicable in our cohort. The Systematic Coronary Evaluation (SCORE) risk score<sup>19</sup> focuses on CV and non-CV deaths, not events. Its computed score in younger patients (aged <65 years) on the basis of the risk assessment charts would be very low, and therefore it was not used.

The Framingham and PROCAM risk tables were used to compute 10-year risk for our validation cohort and for the individual studies. For the validation cohort, we calculated 10-year risks separately by gender on the overall cohort and when the patients' age was standardized at 55 years. We used the mean values for the required risk function variables to calculate the FRS and the PROCAM risk score. A composite score was obtained and converted into 10-year CV risk using their respective data. The purpose was to delineate the directionality of CV risk after surgical intervention, using studies obtained from our systematic review, not to assess 10-year risk precisely. The Friedewald formula was used in studies (n = 3) that did not measure low-density lipoprotein directly. For studies that did not provide information about specific CV risk factors, including smoking status or family history of myocardial infarction, we used data previously

Table 2  
Characteristics of patients in selected studies

Variable	Pontiroli et al <sup>14</sup>		Stoopen-Margain et al <sup>16</sup>		Busetto et al <sup>15</sup>		He and Stubbs <sup>17</sup>	
	Initial (n = 143)	Follow-Up (n = 143)	Initial (n = 100)	Follow-Up (n = 100)	Initial (n = 650)	Follow-Up (n = 650)	Initial (n = 310)	Follow-Up (n = 310)
Follow-up (yrs)	1	—	1.67	—	1.28	—	1	—
Age (yrs)	43	44	31	33	38	39	42	43
Women	81%	81%	63%	63%	76%	76%	77%	77%
Body mass index (kg/m <sup>2</sup> )	45	37	50	36	47	38	46	N/A*
Systolic blood pressure (mm Hg)	133	128	155	123	146	131	144	125
Diastolic blood pressure (mm Hg)	83	81	97	79	94	87	85	82
Diabetes mellitus	46%	21%	24%	14%	11%	4%	17%	1%
Total cholesterol (mg/dl)	201	205	204	179	209	203	244	208
High-density lipoprotein cholesterol (mg/dl)	48	53	32	53	46	46	36	52
Low-density lipoprotein cholesterol (mg/dl)	123	131	123	95	132	134	145	131
Triglycerides (mg/dl)	151	106	246	153	151	115	315	129
Smokers	39%	39%	39%	39%	39%	39%	39%	39%

All values are rounded to the nearest whole number.

\* This information was not available (N/A) but was not needed for the analysis.

published from the risk model's original study cohort to impute these values. For the FRS, we assumed that 39% of all patients were smokers at baseline and follow-up in both genders. We assumed that 21.6% had positive family histories in calculating the PROCAM risk score in studies with missing variables. The proportion of diabetics in the Swedish Obesity Study was calculated using the reported percentage of patients recovered from diabetes along with the number of patients with diabetes at follow-up.<sup>10</sup> For the individual studies, the proportion of patients with diabetes or smokers was multiplied by the number of risk points for that entity. Separate estimates were calculated by gender. Because the FRS consists of 2 separate tables by gender, we estimated the scores separately, first assuming that all patients were men and subsequently considering all patients to be women. Because all reports contained the demographic mix by gender, we calculated an overall score using the proportional mix of genders and each individual score. In studies with a control group, the  $\Delta$  value between baseline and follow-up was obtained to determine the difference in CV risk for patients who had undergone bariatric surgery compared with control patients.

For the validation cohort, continuous data are presented as mean  $\pm$  SD. For comparisons within each cohort between baseline and follow-up, we used the 2-sided paired Student's *t* test and Wilcoxon's signed rank test. We compared the changes between groups with a 2-sample Student's *t* test of unequal variances and Wilcoxon's rank-sum test. A *p* value <0.05 was considered statistically significant. Descriptive statistics were provided only to describe the risks from the mean scores. All analyses were performed using JMP for SAS for Windows version 7.0.0 (SAS Institute Inc., Cary, North Carolina).

## Results

The patient characteristics of each study are listed in Table 2. Table 3 lists the absolute 10-year risks for CV disease using our validation cohort for patients' actual ages and for age standardized to 55 years. The results consistently demonstrate a lower risk after bariatric surgery. The risk reduction was more pronounced after standardizing all patients' ages to 55 years, likely because these risk prediction rules are heavily dependent on age.

Comparing our validation cohort with the mean individual data presented in our study (Table 4), the trends were consistent, demonstrating a decrease in risk after bariatric surgery. The risk analysis using mean values shows changes in CV risk in the same direction as the individual patient-level data and maintain a proportional difference between surgical and nonsurgical groups. The absolute risk, however, was clearly underestimated when using the mean values.

Examining the 10-year FRS and PROCAM risk score using group data demonstrated reductions in CV risk after bariatric surgery<sup>14–16</sup> (Table 4). Interestingly, the study by Sjostrom et al,<sup>10</sup> which primarily used the vertical banded gastroplasty procedure, demonstrated consistent increases and decreases in the risk for CV events in the control and surgical groups, respectively, at 2 years; however, at 10 years, CV risk was greater in the 2 groups, although the absolute CV risk was 2.2% lower in the bariatric surgery group. Determination of an age-independent FRS using the baseline age at follow-up confirmed directionality whereby the follow-up risk was consistently less in the bariatric surgery group (data not shown).

## Discussion

The present study demonstrates that clinically important weight reduction by bariatric surgery can lead to major

Table 2  
(continued)

Batsis et al <sup>12</sup>				Swedish Obesity Study <sup>10</sup>							
				Controls		Surgery		Controls		Surgery	
Controls		Operative		2 Years		2 Years		10 Years		10 Years	
Initial	Follow-Up	Initial	Follow-Up	Initial	Follow-Up	Initial	Follow-Up	Initial	Follow-Up	Initial	Follow-Up
163	163	197	197	1,660	1,660	1,845	1,845	627	627	641	641
3.3	163	3.3	197	2	—	2	—	10	—	10	—
43	47	44	47	49	51	47	49	48	58	47	57
73%	73%	80%	80%	70%	70%	71%	71%	69%	69%	69%	69%
44	44	50	34	40	40	42	32	40	41	42	35
133	128	134	121	138	138	144	137	138	145	144	145
77	76	80	72	85	85	89	84	86	84	90	87
24%	32%	32%	11%	19%	15%	74%	21%	15%	13%	29%	18%
207	193	199	154	217	217	226	220	223	209	233	220
45	49	45	55	46	48	46	57	46	51	46	57
121	109	117	77	135	131	140	134	140	120	146	129
227	176	188	111	178	189	198	144	188	192	204	171
20%	20%	13%	13%	20%	20%	24%	24%	21%	21%	25%	257%

improvements in predicted CV risk, regardless of the method used to calculate risk. By using studies with long-term follow-up of detailed patient information on CV risk factors, these results confirm and expand the results of previous analyses performed in individual cohorts.<sup>12</sup>

The present study provides insight into the use of multiple CV risk prediction in patients who undergo bariatric surgery. Two other studies using the FRS have demonstrated decreases in predicted CV risk.<sup>20,21</sup> Vogel et al<sup>20</sup> demonstrated an overall reduction of 6% to 4% ( $p < 0.001$ ) in patients who underwent laparoscopic Roux-en-Y gastric bypass surgery. However, this study did not have a comparison control group, had a short follow-up period of only 17 months, and defined diabetes as receiving antidiabetic medications and/or a glycosylated hemoglobin level  $>6\%$ , because the investigators' data did not include fasting blood glucose concentrations. Torquati et al,<sup>21</sup> in their analysis of 500 Roux-en-Y patients, similarly had no control group, and their cohort was not population based. Their actual rate of CV disease was substantially less at 1% than their predicted risk. Moreover, they excluded patients with preliminary diagnoses of CV disease, thereby underestimating the true decrease in CV risk at follow-up.

To obtain accurate risk assessments, the patient populations should be similar to the population in which the risk function was derived. The mean body mass indexes in the PROCAM study were 26 and 24 kg/m<sup>2</sup> in men and women, respectively, markedly less than those observed in the previously described studies.<sup>22</sup> Schulte et al<sup>22</sup> observed that the interaction of body mass index with other risk variables in PROCAM did not emerge as an independent risk factor in their multivariate analysis, suggesting that this algorithm can account fully for the contribution of body mass index to the risk for CV disease through intermediate pathophysiologic mechanisms, even in patients with obesity. Interest-

ingly, body mass index was found to have an independent effect on coronary risk in the Framingham study,<sup>23</sup> the mean body mass index of which was 28 kg/m<sup>2</sup>. We believe that body mass index likely has a significant role in predicting CV events, likely underestimating the crude rates observed using the FRS in this study.

Our data suggest that bariatric surgery offers significant reductions in predicted CV risk. Recently, 2 studies demonstrated a mortality benefit after bariatric surgery. In 1 study with a 7.1-year mean follow-up period, long-term mortality from any cause was decreased by 40% compared with controls, and mortality from CV disease was decreased by 56%.<sup>24</sup> Not only did this study rely on death certificates for cause of death, known to often be inaccurate, but the cohort's baseline health status was largely unknown. The Swedish Obesity Study<sup>11</sup> demonstrated similar directionality, with an adjusted hazard ratio for death of 0.71 ( $p = 0.01$ ) compared with controls. Our results suggest that risk models may indeed be applied to bariatric surgery patients to inform them of their future risk for CV events and all-cause death.

Our validated data set comprises a geographically constrained population from Olmsted County. Previous epidemiologic studies have demonstrated excellent external validity to most of the United States white population.<sup>25</sup> The results derived from our previous study<sup>12</sup> have been validated in this study using the FRS and the PROCAM risk score. The use of a systematic publication search not only limited bias in identifying and rejecting studies but ensured that all studies had complete and sufficient follow-up pertinent to the study scope. Using mean study results confirmed the directionality of CV risk. Furthermore, CV risk after bariatric surgery was substantially less in controls, in studies with such a group. In light of the paucity of studies examining CV outcomes after bariatric surgery,<sup>11,24</sup> we

Table 3  
Absolute 10-year risk for cardiovascular disease after bariatric surgery using risk prediction models in the study by Batsis et al<sup>12</sup>

	Nonoperative Group					Operative Group					Intergroup	
	Initial	Follow-Up	Δ Risk	Relative Risk Reduction	p Value	Initial	Follow-Up	Δ Risk	Relative Risk Reduction	p Value	Δ Risk	p Value
Individual data												
FRS												
Men	12.0 ± 9.0	10.2 ± 7.7	-1.8	15	0.04	10.7 ± 6.5	4.5 ± 3.1	-6.2	58	<0.001	-4.4	<0.001
Women	5.2 ± 5.5	5.1 ± 4.9	-0.1	1.3	0.85	6.1 ± 6.2	3.3 ± 3.3	-2.9	47	<0.001	-2.8	<0.001
Overall	7.1 ± 7.3	6.5 ± 6.2	-0.6	8	0.13	7.0 ± 6.5	3.5 ± 3.3	-3.5	50	<0.001	-3.0	<0.001
PROCAM risk score												
Men	6.1 ± 6.0	4.7 ± 4.5	-1.3	22	0.10	5.5 ± ± 5.6	2.7 ± 3.2	-2.8	51	<0.001	-1.5	0.04
Women	3.8 ± 4.9	3.4 ± 3.9	-0.4	9	0.34	3.8 ± 4.1	1.8 ± 1.8	-2.0	52	<0.001	-1.6	<0.001
Overall	4.4 ± 5.3	3.8 ± 4.0	-0.6	14	0.08	4.1 ± 4.5	2.0 ± 2.2	-2.1	52	<0.001	-1.5	<0.001
Age standardized at 55 years												
FRS												
Men	17.3 ± 9.2	13.1 ± 6.4	-4.2	24	<0.001	17.0 ± 7.5	5.8 ± 3.5	-11.1	66	<0.001	-7.0	<0.001
Women	9.4 ± 5.4	8.0 ± 4.5	-1.5	16	0.01	9.8 ± 6.0	4.4 ± 2.9	-5.5	56	<0.001	-4.0	<0.001
Overall	11.6 ± 7.5	9.4 ± 5.6	-2.2	19	<0.001	11.2 ± 6.9	4.7 ± 3.1	-6.5	58	<0.001	-4.3	<0.001
PROCAM risk score												
Men	12.5 ± 8.7	7.7 ± 4.5	-4.8	38	<0.001	11.2 ± 6.8	3.6 ± 3.1	-7.6	68	<0.001	-2.8	0.02
Women	8.6 ± 6.4	7.1 ± 6.0	-1.6	18	0.01	8.4 ± 6.5	2.8 ± 1.9	-5.6	67	<0.001	-4.0	<0.001
Overall	9.6 ± 7.2	7.2 ± 5.6	-2.4	25	<0.001	8.9 ± 6.6	3.0 ± 2.2	-6.0	67	<0.001	-3.6	<0.001

All risks are represented as 10-year risk (%) ± SD. The calculation of Δ risk was based on unrounded values. A negative value of Δ risk represents an improvement at follow-up compared with baseline. A negative value of intergroup Δ risk represents the difference between surgical and controls, in favor of the surgical group. Numbers have been rounded to the nearest whole number.

Table 4  
Absolute 10-year risk for cardiovascular disease after bariatric surgery using mean group values

Variable	Batsis et al <sup>12</sup>																	
	Nonoperative				Operative				Intergroup Δ Risk									
	Initial	Follow-Up	Δ Risk	Relative Risk Reduction	Initial	Follow-Up	Δ Risk	Relative Risk Reduction										
FRS																		
Men	6.8	5.1	-1.7	25	6.8	2.5	-4.3	64										
Women	3.4	4.7	+1.3	-39	3.0	2.7	-0.3	10										
Overall	4.3	4.8	+0.5	-12	3.8	2.7	-1.1	29										
PROCAM	1.9	2.8	+0.9	-51	1.8	1.0	-0.7	37										
	Pontioli et al <sup>14</sup>				Stoopen-Margain et al <sup>16</sup>				Busetto et al <sup>15</sup>				He and Stubbs <sup>17</sup>					
	Initial	Follow-Up	Δ Risk	Relative Risk Reduction	Initial	Follow-Up	Δ Risk	Relative Risk Reduction	Initial	Follow-Up	Δ Risk	Relative Risk Reduction	Initial	Follow-Up	Δ Risk	Relative Risk Reduction		
FRS																		
Men	7.7	5.4	-2.3	30	8.5	3.0	-5.5	65	7.0	4.9	-2.2	31	13.4	4.8	-10.6	79		
Women	4.0	3.0	-1.0	25	2.0	1.0	-1.0	50	2.2	1.8	-0.4	18	5.5	2.8	-2.7	49		
Overall	4.7	3.5	-1.2	26	4.4	1.7	-2.7	61	3.4	2.6	-0.8	24	7.3	3.3	-4	55		
PROCAM	2.2	2.0	-0.2	8.3	<1.0	<1.0	—	—	1.9	1.5	-0.4	19	5.1	2.3	-2.8	55		
	Swedish Obesity Study <sup>10</sup>																	
	Controls: 2-Year Data				Surgical Group: 2-Year Data				Intergroup Δ Risk	Controls: 10-Year Data				Surgical Group: 10-Year Data				
	Initial	Follow-Up	Δ Risk	Relative Risk Reduction	Initial	Follow-Up	Δ Risk	Relative Risk Reduction		Initial	Follow-Up	Δ Risk	Relative Risk Reduction	Initial	Follow-Up	Δ Risk	Relative Risk Reduction	
FRS																		
Men	7.8	9.4	+1.6	-21	12.9	7.9	-5.0	39	-6.6	7.7	15.1	+7.3	-95	10.2	12.6	+2.4	-23	-5.0
Women	5.5	8.0	+2.8	-55	10.4	4.3	-6.1	59	-9.0	5.0	11.0	+5.9	-118	6.6	11.5	+4.9	-74	-1.0
Overall	5.9	8.4	+2.5	-42	12.2	5.4	-6.8	56	-9.3	5.9	12.3	+6.4	-108	7.7	11.8	+4.1	-54	-2.2
PROCAM	4.1	6.4	+2.3	-55	7.1	2.7	-4.4	62	-6.6	4.1	7.6	+3.5	-86	5.9	5.1	-0.9	15	-4.4

All risks are represented as 10-year risk (%). The calculation of Δ risk was based on unrounded values. A negative value of Δ risk represents an improvement at follow-up compared with baseline. A negative value of intergroup Δ risk represents the difference between surgical patients and controls, in favor of the surgical group. Numbers may not add up because of rounding.

believe that this study will allow initial generalizability of using bariatric surgery as a means to decrease CV morbidity and mortality.

One study limitation is that the FRS was derived from a predominantly Caucasian cohort and cannot be applied to non-Caucasians.<sup>2</sup> Empana et al<sup>26</sup> showed poor estimation of absolute risk using the FRS and the PROCAM risk score in France and Northern Ireland, concluding that there is a need for population-specific risk functions. Other studies have demonstrated that the FRS and the PROCAM risk score show close agreement for average CV risk in Northern European populations.<sup>6</sup> Recent data have shown that recalibration and adaptation of the FRS to allow correlation with long-term CV outcomes is plausible.<sup>2</sup> Recalibration also prevents the overestimation of risk in low-risk European Mediterranean areas<sup>5</sup> and in British men.<sup>27</sup> Game and Jones<sup>28</sup> suggested that although there were no systematic calculated differences in CV risks between the FRS and the PROCAM risk score in patients with diabetes, PROCAM risk scores tended to underestimate CV risk in patients with low levels of risk but overestimate those at greater levels of risk. This study refutes the evidence presented in our present study, in which moderately high risk patients who underwent bariatric surgery had a lower calculated coronary risk using the PROCAM risk score than the FRS. Interestingly, a patient's CV risk may be overestimated when models derived from high-risk populations are applied to low-risk populations.<sup>29</sup> Whether the converse is true is unknown, yet possibly a recalibration of the FRS or PROCAM risk score equations may be needed in a bariatric surgery population, a matter that requires further investigation.

The CV risk tables of the FRS and PROCAM risk score were meant to be applied to an individual sample or patient, not to an entire sample mean. To the best of our knowledge, the PROCAM algorithm has not been validated in a female cohort, which may affect our results. Each study variable had significant standard errors or deviations, which were not accounted for in the crude analysis. Missing variables were imputed when required by the specific risk table, which would likely underestimate risk assessment, particularly because social habits often change after bariatric surgery. Obese patients assessed for surgery often have substantial co-morbidities and CV risk factors, at levels that may exceed the ceiling of these tables, and hence their 10-year scores may be inherently lower than they should be because the risk function approaches a range of nonlinearity. This approach allowed a "best-guess" estimate as to the directionality of CV risk after intentional weight loss. Our results may actually have understated the potential differences in CV risk between baseline and follow-up. Finally, further study would be required to ascertain the number of CV outcomes in our cohort to further validate these results.

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