**CLINICAL RESEARCH** 

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**Bariatric Surgery** ABCDEF 1 Justyna Domienik-Karłowicz Authors' Contribution: Study Design A DEF 2 Paweł Ziemiański Data Collection B Piotr Małkowski E 3 Statistical Analysis C BE 1 Maciej Kosieradzki Data Interpretation D Manuscript Preparation E BC 1 Piotr Pruszczyk Literature Search F ABCDEF 2 Wojciech Lisik Funds Collection G **Corresponding Author:** Justyna Domienik-Karłowicz, e-mail: jdomienik@tlen.pl Source of support: Departmental sources

**Background:** Controversy exists with regard to the effectiveness and reasons for bariatric procedures in patients older than 60 years. The goal of our study was to determine the reduction in risk of developing cardiovascular disease and type 2 diabetes mellitus after undergoing bariatric surgery in obese patients over age 60 at our institution.

Material/Methods:Patients with severe obesity (BMI >40 kg/m²) were retrospectively included in the study. Risk of cardiovascular<br/>disease and type 2 diabetes at baseline and their reduction during the follow-up period were evaluated with<br/>the following selected, currently preferred risk algorithms: (1) the Systemic Coronary Risk Evaluation (SCORE)<br/>scale; (2) the Framingham Risk Score (of myocardial infarction or coronary death) for patients with no prior<br/>history of diabetes, coronary heart disease, or intermittent claudication; and (3) the Framingham Offspring<br/>Diabetes Risk Score, which estimates the 8-year risk of developing type 2 diabetes.

Results: All 33 elderly patients (32 women and 1 man, mean age 62.3±2.7 (BMI 44.3±6.2 kg/m<sup>2</sup>) significantly reduced their risk levels. We observed a decrease in the 10-year risk of a first fatal cardiovascular event (3.5±0.5 vs. 2.4±0.5, absolute risk reduction [ARR] 1.0); reduced 10-year risk of myocardial infarction or death (5.0±1.6 vs. 3.25±1.6, ARR 1.7); and reduced predicted 8-year risk of developing type 2 diabetes (7.4±7.2 vs. 3.1±0.3, ARR 4.3). No intra- or postoperative complications were observed.

**Conclusions:** Our study showed a significant reduction in risk of developing cardiovascular diseases and type 2 diabetes, as measured by available risk scores, in elderly patients undergoing bariatric procedures.

MeSH Keywords: Bariatric Surgery • Cardiovascular Diseases • Health Services for the Aged • Risk Assessment

 Abbreviations:
 BMI – body mass index; SCORE – Systemic Coronary Risk Evaluation; ARR – absolute risk reduction; BS – bariatric surgery; % EWL – percentage of excess body weight loss; % EBMIL – excess BMI loss; WHR – waist-hip ratio; chol – total cholesterol; Tg – triglycerides; HDL – high-density lipoprotein; LDL – low-density lipoprotein

Units of measurement: Age (years); body mass index (kg/m<sup>2</sup>); total cholesterol (mg/dL); low-density lipoprotein (mg/dL); high-density lipoprotein (mg/dL); triglycerides (mg/dL); HbA<sub>1</sub>C (%); systolic blood pressure (mmHg); diastolic blood pressure (mmHg)

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# A Retrospective Study of 6-Month Reduction in Risk of Developing Cardiovascular Diseases and Type 2 Diabetes Mellitus in Severely Obese Patients Over 60 Years of Age Following Bariatric Surgery

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# Background

It is widely known that severe obesity and its comorbid diseases negatively affect patient health and quality of life [1]. Bariatric procedures are considered the most effective longterm obesity treatment in elderly patients [2,3]. Weight loss subsequent to bariatric surgery causes sustainable improvement or remission of hypertension and type 2 diabetes mellitus in severely obese patients [4-6]. However, controversy exists with regard to the effectiveness and reasons for bariatric surgery in elderly patients [7-9]. In the recent past, weight loss through surgery was not recommended for elderly patients and was limited to patients under 60 years old based on age-dependent increased surgical risks [10]. However, obesity causes a remarkable decline in quality of life and ability to perform activities of daily living [11]. The steady increase in life expectancy and the decline in quality of life associated with obesity, as well as other proven risks for cardiovascular disease and mortality, justify reconsideration of the recommendations for bariatric surgery in this specific and growing population of patients (due to aging of society), with particular attention to the decrease in cardiovascular risk and the type of surgery performed [8,12]. The significant decrease in body mass achieved by surgery is proven to improve survival in extremely obese patients [13]. Finally, it is important to emphasize that age does not increase the intraoperative or postoperative risks of surgical complications due to bariatric surgery and percentage excess weight loss at 6-month follow-up [14]. The goal of our study was to determine the 6-month reduction in risk of developing cardiovascular diseases and type 2 diabetes mellitus in severely obese patients over age 60 years following bariatric surgery (BS) at our institution [15, 16]. We assessed the effect of major weight loss (about one-third of initial body weight) on the risk of developing cardiovascular diseases and type 2 diabetes in a short period following BS.

# **Material and Methods**

We retrospectively included all patients aged 60 years and older who underwent bariatric procedures in our department. In accordance to applicable guidelines, all of our patients fulfilled the specific criteria for this type of surgery, especially BMI >40 kg/m<sup>2</sup> (defined as severe or morbid obesity) or BMI  $\geq$ 35 kg/m<sup>2</sup> with obesity-related comorbidities such as hypertension or hyperlipidemia [17]. Careful preoperative and postoperative assessments were performed using suitable guidelines in patients scheduled for intermediate-risk (1–5%) bariatric surgery [18], including history of obesity, clinical evaluation, and health behavior evaluation [18]. However, we did not perform any additional assessment for our patients based on their age alone [10,18]. We retrospectively collected required data at baseline and at follow-up (6 months after performed surgery) from all subjects, including surgery type, sex, age, anthropometric measurements, biochemical measures, comorbidities (e.g., coronary heart disease, other heart diseases, chronic heart failure, hypertension, chronic kidney disease, diabetes mellitus, hyperlipidemia, and obstructive sleep apnea), medications used, smoking status, family medical history, and all data needed to perform risk assessment, described in detail below.

#### Anthropometric assessment

We used the BC 420 S MA by TANITA body composition analyser to measure body weight and its distribution. The analyser has a maximum capacity of 270 kg with a minimum graduation of 0.1 kg and it uses bioelectrical impedance to assess body weight, BMI, fat mass, fat percentage, fat-free mass, and total body water. The obtained results were used to assess the degree of obesity and effectiveness of surgical treatment. Assessed values included baseline excess body weight and weight loss represented by absolute values and the percentage of excess body weight loss (% EWL) and excess BMI loss (% EBMIL).

To assess the distribution of body fat, tape measurements of the waist and hip circumference were used and waist-hip ratio (WHR) was calculated. Waist circumference was measured halfway between the lower rib edge and the upper iliac crest, while hip circumference was assessed at the level of the femoral greater trochanter. All measurements were made by the same team of a doctor and a nurse, always in the same manner.

## **Clinical biochemistry tests**

All patients underwent a full medical examination, and a sample of fasting venous blood was collected. Laboratory tests were used to assess the incidence of comorbidities such as type 2 diabetes and hyperlipidemia and to monitor the course of obesity-related metabolic complications (e.g., hypertension, type 2 diabetes, and hyperlipidaemia). Glucose metabolism was assessed by the value of fasting glucose (mg/dL), HbA<sub>1</sub>C (%), or 2-h (75 g) oral glucose tolerance test, if needed. Lipid metabolism was evaluated by total cholesterol (chol, mg/dL), triglycerides (tri, mg/dL), high-density lipoprotein cholesterol (LDL, mg/dL).

## Surgical technique

Patients were enrolled and prepared for surgery according to the guidelines of the European Association for the Study of Obesity [19]. All patients fulfilled the criteria for bariatric surgery, which means BMI  $\geq$ 40 kg/m<sup>2</sup> or BMI  $\geq$ 35 kg/m<sup>2</sup> with comorbidities such as hypertension and type 2 diabetes. In the following analyses, we excluded the 1 male subject due to the small number of male patients.

#### Metabolic syndrome and risk assessment

In all patients, we assessed the occurrence of the metabolic syndrome according to the International Diabetes Federation's criteria and National Cholesterol Education Program/Adult Treatment Panel III's criteria [20]. Moreover, taking into account the European Guidelines on cardiovascular (CV) disease prevention in clinical practice, systematic CV risk assessment is recommended in individuals at increased CV risk, including family history of premature CV diseases, familial hyperlipidemia, major CV risk factors (such as smoking, high blood pressure, diabetes mellitus, or raised lipid levels), or comorbidities increasing CV risk (IC recommendation) [21]. Therefore, CV risk was evaluated with 3 select, recommended risk scores: the systemic coronary risk evaluation scale (SCORE), the Framingham Risk Score for non-diabetic patients with no prior history of coronary heart disease or intermittent claudication, and the Framingham Offspring Diabetes Risk Score. The SCORE system calculates the 10-year risk of a first fatal atherosclerotic event such as stroke or heart attack. It is calculated based the risk factors of age, sex, total cholesterol, systolic blood pressure, and smoking status [21]. The Framingham Risk Score for non-diabetic patients with no prior history of coronary heart disease or intermittent claudication assesses the 10-year risk of myocardial infarction or coronary death in individuals free of coronary heart disease, intermittent claudication, and diabetes, and 30-79 years of age [22]. It is based on age, HDL cholesterol, total cholesterol, systolic blood pressure, hypertension treatment, and smoking status [23]. The Framingham Offspring Diabetes Risk Score for prediction of 8-year risk of type 2 diabetes is based on age (years), sex, height (cm), weight (kg), fasting glucose (mg/dL), HDL cholesterol (mg/dL), triglycerides (mg/dL), blood pressure (mmHg), and family history of diabetes [24,25]. Patients who did not meet the criteria for risk assessment were excluded from the particular calculations and further analysis; for instance, patients with type 2 diabetes were excluded from the calculation of the Framingham Offspring Diabetes Risk Score. All patients were evaluated twice: once at baseline and then at 6-month follow-up. We assessed the influence of bariatric procedures and the resulting weight loss on cardiovascular risk reduction in the oldest patient group. We deliberately chose these 3 risk scales because they accurately assess the risk of developing cardiovascular diseases and type 2 diabetes during a period of 8-10 years. These scales enabled us to initially assess the effect of major weight loss (about one-third of body weight) in a short period of time as a result of bariatric surgery on the risk of developing these diseases in the future. Our initial verification requires confirmation in a larger group of patients with 8-10 years of follow-up. Due to the anticipated life expectancy of about 20 years it our patients, it was not our intention to investigate the development of the above-mentioned diseases after a long-term observation period.

#### Statistical analysis

Continuous variables are expressed as mean and standard deviation, and categorical variables are expressed as counts and percentages. Moreover, we compared the distributions of different scores (preoperative and postoperative results) using the Shapiro-Wilk test (all p<0.05). Outcomes of postoperative results (follow-up *vs.* baseline) were analyzed using the *t* test.

# Results

After a detailed selection based on inclusion and exclusion criteria, we enrolled 32 patients.

We excluded the 1 man due to the small number of patients of this sex. All enrolled patients (32 women) met the criteria for further analysis and risk score calculation. Therefore, we included 32 women, ages  $62.3\pm2.7$ , with body mass of  $118.6\pm15.9$  kg and BMI of  $44.2\pm6.3$  kg/m<sup>2</sup>). The following weight loss surgeries were performed: sleeve gastrectomy in 22 patients, vertical banded gastroplasty in 4 patients, and Roux-en-Y gastric bypass in 6 patients. There were no intraoperative or postoperative surgical revisions, significant complications, or deaths. Body mass index was significantly decreased in all patients ( $44.2\pm6.3$  kg/m<sup>2</sup> vs.  $32.25\pm5.11$  kg/m<sup>2</sup>, p<0.001).

# Influence of surgery on occurrence of metabolic syndrome and comorbidities

In all patients at baseline, we screened for metabolic syndrome according to the International Diabetes Federation's criteria and National Cholesterol Education Program/Adult Treatment Panel III's criteria [20]. At the end of the study, metabolic syndrome was found in only 4 (12.5%) subjects. Moreover, before surgery, we diagnosed type 2 diabetes mellitus in 5 patients (15.6%) and complete remission was achieved at 6 months. However, we still observed pre-diabetes in 2 patients. Hypertension was observed in 28 (88%) patients preoperatively and in 13 (40%) patients at follow-up. However, the number of antihypertensive drugs taken in patients remaining in treatment decreased significantly - by up to 2 drugs in 1 patient (ACE inhibitors and a diuretic) and 1 drug in the other patients (ACE inhibitors). Dyslipidemia was diagnosed in 29 (90.6%) patients preoperatively and in 28 (87.5%) patients postoperatively. All of these patients needed treatment with statins. Initially, 8 patients had hyperuricemia treated with allopurinol before complete remission was achieved. The general characteristics and comorbidities of the study group are presented in Table 1.

Table 1. Comorbidities in the study group.

	Preoperative	Postoperative	
Age (years)	62.27±2.70		
Body mass index (kg/m²)	44.63±6.23	32.25±5.11	
Family history of diabetes	16 (50)		
Total cholesterol (mg/dL)	190.23±38.68	163±26.32	
Low-density lipoprotein (mg/dL)	113.00±35.98	104.00±31.98	
High-density lipoprotein (mg/dL)	55.87±18.03	52.87±16.01	
Triglycerides (mg/dL)	130.17±60.55	114.27±22.55	
HbA <sub>1</sub> C (%)	6.37±1.16	6.11±1.03	
Systolic blood pressure (mmHg)	135	131	
Diastolic blood pressure (mmHg)	85	81	
Hypertension: n (%)	28 (88)	13 (40)	
Diabetes: n (%)	5 (15.6)	0 (0)	
Dyslipidemia: n (%)	29 (58)	28 (56)	

Table 2. Cardiometabolic risk preoperatively and at 6 months of follow-up.

	Preoperative	6 months	ARR (%)	P value
SCORE scale	3.48±0.5	2.45±0.5	1.03	p<0.001
Framingham risk score	5.0±1.57	3.25±1.65	1.75	p<0.001
Diabetes risk n=27 (%)	7.4 <u>+</u> 7.22	3.07±0.26	4.33	p<0.001

ARR – absolute risk reduction.

# Reduction in risk of cardiovascular disease and type 2 diabetes mellitus

Bariatric surgery outcomes and cardiovascular and diabetic risk are presented in Table 2. The 10-year risk of a first fatal atherosclerotic event assessed by the SCORE scale was reduced at 6 months ( $3.48\pm0.5$  vs.  $2.45\pm0.5$ ), with a 1.03% absolute risk reduction (ARR). The 10-year risk of myocardial infarction or coronary death as evaluated by the Framingham Risk Score was also reduced, from  $5.0\pm1.57$  to  $3.25\pm1.65$ . Therefore, an ARR of 1.75% was achieved. Moreover, the 8-year risk prediction of the incidence of type 2 diabetes as assessed by the Framingham Offspring Diabetes Risk Score decreased from 7.4 $\pm$ 7.22 to  $3.07\pm0.26$ , which yields an ARR (%) of 4.33%.

# Discussion

Patients older than age 60 years are reported to have greater risk for mortality after bariatric surgery and they tend to lose

less weight and gain less benefit in comparison to younger patients [26]. Some studies have suggested that, in older people, the risks from bariatric surgery and its accompanying weight loss outweigh the possible benefits [27-29]. A meta-analysis by Giordano et al. reported that the risk of complications after bariatric surgery is higher in older patients than in younger ones. Moreover, younger patients are reported to achieve more weight loss and to have greater reduction of comorbidities compared to older patients [30]. Other studies have confirmed that bariatric procedures have established effects on cardiovascular diseases and type 2 diabetes in morbidly obese patients [31,32], and clearly show long-term remission of cardiovascular diseases such as hypertension and type 2 diabetes mellitus in patients after bariatric surgery [5,6]. However, reports on heart failure are ambiguous; hence, the term "obesity paradox" [33]. However, results of bariatric procedures and their effects on cardiovascular risk in patients aged 60 or over and with morbid obesity are still disputed due to conflicting data on the effect of age on bariatric procedure results [34]. Some researchers reported that bariatric surgery should not

be recommended in older patients, mainly due to sarcopenia (loss of muscle mass and strength). However, some recent research demonstrated that surgical weight loss procedures are as safe and effective for older patients as they are for younger patients [9,34-36]. Vinan-Vega et al. compared the safety, appropriateness, and early results of surgical weight loss procedures in elderly patients and in younger controls (younger than 65 years of age). They presented evidence that bariatric surgery in patients 65 years old or older is safe and is not associated with increased surgical risk, with almost the same effects and nearly identical surgical complication rates as in younger patients, irrespective of the chosen bariatric procedure – laparoscopic sleeve gastrectomy or Roux-en-Y gastric bypass [7,30]. The previously mentioned meta-analysis by Giordano et al. analyzed 7 studies involving 3128 patients. They confirmed an increased risk of death and surgical complications in subjects aged 60 or older in comparison to younger ones (RR, 6.12; 95% CI 1.08-34.83; p=0.04; RR, 1.51; 95% Cl 1.07–2.11; p=0.02), and in older subjects they observed a 1% increased risk of death and 3% increased risk of surgical complications. According to observations by Pereira et al. in a similar group of subjects, patients aged 50 years or older had their 10-year CV risk reduced by 3.41±0.75% in comparison to 0.99±0.18% in a group of patients age 50 years and younger [37]. In the present study we observed very favorable health outcomes. The key finding in our study is that bariatric surgery in severely obese, elderly patients is an effective and safe therapeutic intervention, which is followed by a decrease in risk of developing cardiovascular diseases and type 2 diabetes as early as 6 months after surgery. Moreover, just 6 months after surgery, the risk of developing type 2 diabetes became very close to the ideal risk of developing type 2 diabetes according to the results of the Framingham Offspring Study [23]. Of course, our results need to be confirmed in longer-term research with 8- to 10-year follow-up after bariatric surgery. We recommend using selected, easily used scales in

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routine and very careful evaluations of these patients before bariatric surgery for preoperative assessment, as well as encouraging doctors to refer appropriate patients over 60 years old to bariatric specialists to reduce their 8- to 10-year risk of developing cardiovascular diseases and type 2 diabetes.

#### Limitation of the study

Our study has several limitations. First, more than 1 type of bariatric surgery was performed in our study group. Second, the number of patients included to our group was relatively small. Third, the short period of observation may be considered a limitation, but we emphasize the fact that even within 6 months after bariatric surgery, the decrease in body mass has a positive effect on risk of cardiovascular diseases and type 2 diabetes. However, our short-term study needs confirmation in larger groups of patients with 8- to 10-year follow-up.

# Conclusions

Our study confirmed a significant decrease in the risk of developing of cardiovascular diseases and type 2 diabetes as assessed by 3 selected risk algorithms: the SCORE scale (systematic coronary risk evaluation), the Framingham Risk Score for myocardial infarction or coronary death, and the Framingham Offspring Diabetes Risk Score in bariatric procedures in elderly patients. Further study is necessary to investigate this topic in greater detail and to confirm risk reduction at 8–10 years. Patients aged 60 and over should be very carefully evaluated preoperatively for personalized risk-benefit evaluation.

#### **Conflict of inteerst**

None.

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