Medium to Long-term Outcomes of Bariatric Surgery in Older Adults with Super Obesity

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TABLE OF CONTENTS

ABSTRACT

Background: Indications and outcomes of bariatric surgery in older adults suffering from morbid obesity remain controversial. We aimed to evaluate safety and medium to long-term outcomes of bariatric procedures in this patient population.

Setting: University Hospital, Canada.

Methods: This is a single-center retrospective study of a prospectively-collected database. We included patients aged ≥60years who underwent sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB) or biliopancreatic diversion with duodenal switch (BPD/DS) between January 2006-December 2014 and had at least 2 years of follow-up.

Results: 104 patients underwent 115 bariatric surgeries (11 patients had two procedures). Sixty-six patients were super-obese (BMI>50kg/m^2). Seventy-four percent had SG, 16% RYGB, and 8% underwent BPD/DS. Mean age and BMI were 63.3±2.6years and 51.7±8.1kg/m^2, respectively. Average follow-up time was 42±19months. At baseline, 78% had hypertension (HTN), 60% had type-2 diabetes mellitus (T2D), and 30% had obstructive sleep apnea (OSA). There was no 30-day mortality. Complication rate was 14%(n=16): 2 leaks post-RYGB, 1 leak post-BPD/DS, 1 obstruction post-SG, 1 bleeding requiring transfusion, 1 liver injury with bile leak, 2 port-site hernias, 1 myocardial infarction, 2 gastro-jejunal strictures, 1 wound infection, 1 urinary tract infection, and 3 gastric reflux exacerbations. Mean percent excess weight loss (%EWL) at 2 years was 52.2±23.8. Remission rates of HTN, T2D and OSA were 26%, 44% and 38%, respectively.

Conclusion: Bariatric surgery is safe and effective in improving obesity-related comorbidities in older patients suffering from morbid obesity. Age alone should not preclude older patients from getting the best bariatric procedure for obesity and related comorbidities.

RÉSUMÉ

Contexte : Les indications et les résultats de la chirurgie bariatrique chez les personnes âgées souffrant d'obésité morbide demeurent controversés. Nous visions à évaluer la sécurité et les résultats à moyen et à long terme des procédures bariatriques dans cette population de patients.

Lieu : Hôpital universitaire, Canada.

Méthodes : Il s'agit d'une étude rétrospective monocentrique d'une base de données prospectivement collectée. Nous avons inclus des patients âgés de ≥ 60 ans qui ont subi une gastrectomie verticale (SG), une dérivation gastrique en anse en-Y (RYGB) ou une dérivation biliopancréatique avec un switch duodénal (BPD/DS) entre janvier 2006 et décembre 2014 et qui avaient ai minimum 2 ans de suivi.

Résultats : 104 patients ont subi 115 chirurgies bariatriques (11 patients ont eu deux procédures). Soixante-six patients étaient super-obèses (IMC> 50 kg / m2). Soixante-quatorze pour cent avaient SG, 16% RYGB, et 8% ont subi BPD/DS. L'âge moyen et l'IMC étaient respectivement de 63,3 ± 2,6 ans et de 51,7 ± 8,1 kg / m^2. Le temps moyen de suivi était de 42 ± 19 mois. Au départ, 78% souffraient d'hypertension (HTN), 60% de diabète sucré de type 2 (DT2) et 30% d'apnée obstructive du sommeil (AOS). Il n'y avait pas de mortalité de 30 jours. Le taux de complication était de 14% (n = 16): 2 fuites post-RYGB, 1 fuite post-BPD/DS, 1 obstruction post-SG, 1 saignement nécessitant une transfusion, 1 blessure hépatique avec fuite de bile, 2 hernies, 1 infarctus du myocarde, 2 sténoses gastro-jéjunales, 1 infection de la plaie, 1 infection des voies urinaires et 3 exacerbations du reflux gastrique. Le pourcentage moyen de perte de poids excédentaire à 2 ans était de 52,2 ± 23,8. Les taux de rémission de HTN, DT2 et AOS étaient de 26%, 44% et 38%, respectivement.

Conclusion : La chirurgie bariatrique est sûre et efficace pour améliorer les comorbidités liées à l'obésité chez les patients âgés souffrant d'obésité morbide. L'âge seul ne devrait pas empêcher les patients plus âgés d'obtenir la meilleure procédure bariatrique pour l'obésité et ses comorbidités.

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PREFACE

This thesis consists of a manuscript and an introduction as well as literature review. It is organized in accordance with the McGill University Graduate and Postdoctoral Studies regulations which are as follows:

Manuscript-Based (Article-Based) Theses

As an alternative to the traditional thesis format, the thesis research may be presented as a collection of scholarly papers of which the student is the author or co-author; that is, it can include the text of one or more manuscripts, submitted or to be submitted for publication, and/or published articles reformatted according to the requirements described below. Manuscripts for publication are frequently very concise documents. The thesis is expected to be a more detailed, scholarly work than manuscripts for publication in journals, and must conform to general thesis requirements. A manuscript- (or article-) based thesis will be judged by the examiners as a unified, logically-coherent document in the same way a traditional thesis is judged.

A manuscript-based thesis must:

- be presented with uniform font size, line spacing, and margin sizes (see thesis format);

- conform to all other requirements listed under thesis components above;

- contain additional text that will connect the manuscripts in a logical progression from one chapter to the next, producing a cohesive, unitary focus, and documenting a single program of research;

- the manuscripts alone do not constitute the thesis;

- function as an integrated whole.

There is no specified number of manuscripts or articles required for a Master's or a Doctoral thesis, nor is prior publication or acceptance for publication of the manuscripts a requirement. Publication or acceptance for publication of research results before presentation of the thesis in no way supersedes the University's evaluation and judgment of the work during the thesis examination process (i.e., it does not guarantee that the thesis will be found acceptable for the degree).

In the case of multiple-authored articles, the student must be the primary author. Multiple authored articles cannot be used in more than one thesis. In the case of students who have worked collaboratively on projects, it may be preferable for both students to write a standard format thesis, identifying individual contributions. (See Intellectual Property re: required permissions/waivers.)

INTRODUCTION AND LITERATURE REVIEW

BACKGROUND

CLASSIFICATION OF OBESITY

Obesity is a metabolic disorder resulting in excess body fat deposits. It is the result of complex interactions of metabolic, endocrine, genetic, socio-economic, environmental, cultural, psychological and behavioural factors [(1)]. It could be measured by many measurements, though the body mass index (BMI) is the most commonly validated and universally accepted approach. BMI is calculated as a ratio of weight in kg and height in meter [(2)]. According to the International Obesity Task Force, obesity can be divided into three classes: I to III. Morbid obesity refers to Obese Class III, or to Obese Class II if it is associated with other co-morbidity factors [(3)].

- Normal BMI- 19 to 25 kg/m^2
- Underweight BMI- less than 19 kg/m^2
- Overweight- 25 to 29 kg/m^2
- Obesity Class I - 29.1 to 35 kg/m^2
- Obesity Class II - 35.1 to 40 kg/m^2
- Obesity Class III - 40.1 $kg/m^2$and above
    1. Morbid Obesity- 40.1 to 50 kg/m^2
    2. Super Obesity- > 50 kg/m^2

PREVALENCE OF OBESITY

World Health Organization (WHO) as of 1998 started to consider obesity as a major public-health problem and has even been declared a “global epidemic”[(4)]. In Canada, the percentage of obese people (BMI ≥ 30) in the population aged 18 and older in 2011 was estimated to be 18.3%, while

it was 6.1% in 1985. Furthermore, since 1985, the prevalence of obesity in classes I, II and III increased from 5.1% to 13.1%, from 0.8% to 3.6%, and from 0.3% to 1.6%, respectively [5]. In Québec, according to the data from the 1998 Québec social and health survey, 29.0% of the population aged 20 to 64 was overweight (BMI ≥ 27 kg/m^2). This rate rose to 12.7% for a BMI ≥ 30 kg/m^2, and to 3.0% for a BMI ≥ 35 kg/m2 [6, 7].

We are also facing a global ageing given the fact that life expectancy has been steadily increasing in the U.S. and other developed countries [8]. The obesity epidemic has not spared any age group, and as the incidence of obesity continues to rise, so does the number of older adults who are obese and super obese (SO) patients (BMI>50kg/m^2). The prevalence of obesity in the senior population continues to trend upwards, with a proportion of the U.S. population aged 65 or older predicted to rise from 12% since 2000 to 20% in 2030 [9].

According to recent reports from Statistics Canada, the proportion of seniors within the population has been steadily growing since 1960, increasing from 8% at that time to 14% in 2009. According to all population projection scenarios, seniors are expected to comprise around 23% to 25% of the population by 2036, and around 24% to 28% in 2061 [10].

MORTALITY AND HEALTH CONSEQUENCES OF OBESITY

Obesity is a risk factor for many diseases. It is also associated with increased all-cause mortality even after adjustment for potential confounding variables such as smoking. Some studies have demonstrated a linear relationship between BMI and mortality [11]. It causes many deaths each year, owing both to its complications and to its co-morbidities. An early report by researchers from

the Centers for Disease Control and Prevention (CDC) estimated that the number of deaths attributable to overweight and obesity was 365,000 per year [12].

Obesity is an independent risk for non-fatal myocardial infarction and fatal coronary heart disease, as well as predisposing to a number of cardiovascular disease risk factors including hypertension (HTN), dyslipidemia and impaired glucose tolerance [13]. Type II diabetes (T2D) is a serious life shortening condition, which predisposes to hypertension and heart disease and leads to other conditions such as retinopathy, neuropathy and renal disease. The risk of developing diabetes rises with increasing BMI even below the threshold of clinical obesity [13, 14].

An almost positive linear relationship between BMI in obese people and risk of death from cancer has been noted. Obesity is associated with an increased risk of cancer at many sites including breast, colon, prostate, endometrial, kidney and gallbladder cancers [11, 15].

Osteoarthritis or degenerative disease of the knee and other weight bearing joints, and lower back pain are also common. Although these effects are thought to be due to excess weight, there may also be a metabolic effect as an association between obesity and incident symptomatic osteoarthritis in the hands has been demonstrated [11, 14].

Respiratory disorders such as sleep disordered breathing are also associated with obesity. The incidence of obstructive sleep apnea (OSA) in obese and morbidly obese subjects is shown to be greater than 60 % and increases in incidence as the BMI increases. Reproductive disorders are common, occurring in both women and men. Obese women have a higher risk of complications

during pregnancy, such as hypertensive disease, preeclampsia and gestational diabetes, and of neural tube defects in their infants. There is also an increased risk of Caesarean delivery among obese women with or without antenatal complications [14].

Those co-morbidities are even more pronounced in senior obese subjects. Moreover, in older adults, obesity causes a significant decrease in quality of life and independence, and increased functional limitations, and disability [16]. Additionally, obesity has been independently associated with all-cause mortality in older adults [17].

ECONOMIC IMPACTS OF OBESITY

Obesity carries an economic burden representing from 5.5% to 7.0% of total health-care spending [18]; it accounted for 27% of the rise in actual spending per person between 1987 and 2001 [19]. In Canada, for 1997 alone, direct medical costs attributable to obesity in adults were estimated to be $1.8 billion, or 2.4% of total direct medical costs [20]. In 2000 the estimated Québec's obesity direct health-care costs were $700 million, or 5.8% of the province's health-care budget. Costs attributable to productivity losses were evaluated as being in excess of $800 million, and the sum of these two estimates could represent nearly 1% of Québec's gross domestic [21].

The rapid growth of the senior population has had a significant economic impact because of their unique medical requirements and the fact that these individuals consume more than one third of the country's health care resources. In older adults, excess weight is associated with a higher prevalence of many chronic health conditions and reduced quality of life [22].

HELATH BENIFITS OF WEIGHT LOSS

Published estimates of the impact of weight loss on cardiovascular disease and T2D suggest that substantial benefits are produced by modest weight loss. The benefits of 10 kg weight include decrease of 10 mmHg for systolic blood pressure and 20 mmHg for diastolic blood pressure, 91% reduction in angina symptoms and 33% increase in exercise tolerance, 10% fall in total cholesterol, 15% fall in LDL-cholesterol, 30% fall in triglycerides and 8% increase in HDL-cholesterol and more than 50% reduction in the risk of developing diabetes, 30-50% fall in fasting blood glucose and 15% fall in glycated hemoglobin [23, 24].

Recent literature showed good outcomes of weight loss in older adults with pronounced improvements in cardiometabolic risk factors and increased muscle mass and bone density which were associated with improved mobility [25].

MANAGEMENT OF OBESITY

The therapeutic approach to obesity is multifaceted and complex. It requires an adapted treatment structure and the availability of a multidisciplinary team. Obesity nonoperative management is based on some key measures: intensive patient education aimed at improving diet and emphasizing the need for regular physical activity; and behavioural approaches designed to help people better regulate the lifestyle habits [26]. Physicians may suggest drug therapy for obese patients unable to meet their target objectives through diet and physical activity. The use of a pharmacological agent requires a doctor–patient discussion before such treatment is initiated. The side effects of the prescribed medication, the lack of long-term safety data and the modest weight loss associated with it, are all points that must be covered [26, 27]. The mean weight loss achieved with the

pharmacological treatment of obesity, after adjustment for the placebo effect, is less than 5 kg after at one year [28].

Inability of nonoperative therapies to achieve and maintain adequate weight loss in morbidly obese patients that reverses direct, weight-related comorbidities has singled out surgical therapy as the most effective treatment for such patients. Bariatric surgery, regardless of the type of procedure used, has proven to be the most effective strategy to reduce weight, improve quality of life and decrease comorbidities such T2D, HTN, hyperlipidemia, and OSA. A recent meta-analysis found that bariatric surgery resulted in higher percentage excess weight loss (%EWL); 75% vs 11% and 16 times the rate of remission T2D compared with conventional weight loss treatment [29]. Significant metabolic impacts of these procedures have led to the understanding that much more than weight loss can be achieved, and many have embraced the term **'metabolic surgery'** to emphasize this [30]. Current indications of bariatric surgery according to the National Institutes of Health (NIH) consensus are a BMI $\geq$ 35kg/m^2 with an obesity-related health problem, such as T2D, HTN and OSA or a BMI $\geq$ 40kg/m^2 regardless the presence or absence of comorbidities [31].

Bariatric surgery encompasses a wide range of techniques, and the effectiveness of each is relatively well established. The choice of one technique over the other is subject to many criteria, such as the patient's clinical and psychological characteristics, the availability of the appropriate infrastructure, the surgeon's preference and the medical team's expertise [32]. The total number of bariatric surgical procedures has dramatically increased since the year 2000 in U.S. and Canada, as well as worldwide [33, 34].

BARIATRIC PROCEDURES

There are currently two major categories of such surgery, grouped according to the predominant mechanism of action: restrictive procedures, such as laparoscopic sleeve gastrectomy (SG), vertical banded gastroplasty (VBG) and laparoscopic adjustable gastric banding (LAGB); and malabsorptive procedures with a restrictive component, such as Roux-en-Y gastric bypass (RYGB), and biliopancreatic diversion with duodenal switch (BPD/DS) [35]. The most commonly performed bariatric procedures nowadays are: laparoscopic sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric banding (LAGB), and biliopancreatic diversion with duodenal switch (BPD/DS) [33]. In general, the more complex the procedure, the better the results in terms of weight loss; but there's evidence that more complex procedures also have higher morbidity and mortality rates [36, 37].

Sleeve Gastrectomy

SG was originally developed as the first stage of the BPD/DS in high risk morbidly obese patients and now been established as a standalone bariatric procedure, it is an irreversible procedure that divides the stomach vertically and removes approximately 80% of it, reducing the remainder to a quarter of its original size. The stomach retains its function, and digestion remains unaltered because the pyloric valve at the distal end is intact [36, 38]. Not only is the appetite reduced, but also consuming very small amounts of food generate early and lasting satiety. Because the small intestine is not shortened nor rerouted, SG does not usually affect the absorption of food, so nutritional deficiencies are less of a problem compared to RYGB or BPD/DS [34]. SG is becoming the most commonly performed bariatric procedure in all age groups in North America and worldwide, given the facts that it is carrying a high safety profile and shorter learning curve for

surgeons [34, 39]. Reported long-term %EWL after SG is 50-65% [40]. Many studies showed somehow comparable outcomes on weight loss and resolution of comorbidities especially T2D and hypertension, when compared to diversionary procedures (RYGB and BPD/DS) on short to medium term [41, 42] but most studies showed more favorable outcomes of diversionary procedures on long term outcome as well as in SO patient [43]. SG early and delayed complications reported rates are 8-21% and includes staple line bleeding, staple line leak and development of an abscess, strictures, nutritional deficiencies and gastresophageal reflux disease (GERD) [44].

Roux-en-Y Gastric Bypass

RYGB is the now second most common type of weight-loss surgery worldwide, used to be the most common and was considered as the gold standard bariatric procedures for decades to which all emergent procedures were compared to [34, 38]. During RYGB a pouch is created in the upper portion of the stomach. A small outlet (gastrojejunostomy) is then created to attach a bypassed small bowel limb to the created pouch. Weight loss from RYGB occurs as a result of food restriction because of the small pouch and stoma as well as the food being rerouted, thus altering the mechanism of digestion and absorption. This affects insulin-regulating hormones in the stomach and intestines. This procedure permanently changes how food is digested resulting in fewer calories and nutrients being absorbed [38]. Weight loss is swift and dramatic; usually 50% of EWL in the first 6 months post-surgery, but may continue for up to 2 years and has a reported long-term sustainable efficacy [45]. Long term reported %EWL after RYGB is 55-70% [40]. As an added benefit of the rapid weight loss, comorbidities such as T2D, HTN, dyslipidemia, arthritis, OSA, GERD, and other conditions often improve quickly and sustainably [45, 46]. Reported rates of RYGB complications vary between 5-23% [47]. Bleeding, staple line leak, gastrojejunal strictures,

stomal ulceration and internal hernias are amongst the most frequently reported complications [48]. RYGB also impairs the body's ability to absorb calories, and increasing the risk for nutrient deficiencies; therefore, RYGB patients should plan to take vitamins and mineral supplements the rest of their lives. RYGB is associated with other side effects such as an increased risk of dumping syndrome in which food is "dumped" from the stomach into the small intestine too quickly before it has been adequately digested. Typically, this occurs when eating too many simple carbohydrates which can lead to diarrhea [24, 34].

Laparoscopic Adjustable Gastric Banding

LAGB was one of the most performed bariatric procedures in the last decade [34]. An adjustable band is placed around the superior portion of the stomach restricting food intake. The band may be adjusted by accessing a subcutaneous port. Saline can be injected or removed from the port, tightening or widening the gastric pouch opening. Benefits of using LAGB are that recovery is quicker, hospital stays are shorter, and the surgery can be reversed. Because LAGB physically restricts the amount of food consumed, it is a successful method in losing weight [36]. However, weight loss is less dramatic and furthermore, weight is more likely regained over time. Long term reported %EWL after LAGB is 35-45% [40]. A common side effect of LAGB is vomiting, which is often a result of eating too much too quickly. If the band is too tight, GERD can result. Complications with the band itself include slipping out of place, becoming loose, or leaking [48]. Though it might be the least invasive bariatric procedure but due to dismal long-term results and high rate of failure and complications it is falling out of favor [33].

Biliopancreatic Diversion with Duodenal Switch

Lastly, **BPD/DS** mimics a malabsorptive state. A sleeve gastrectomy is performed first to limit food capacity. Then, two distances are measured: the last 100 cm of small bowel which forms the common channel where all digestion occurs and another 150 cm proximal to it which forms the alimentary limb. Then a jejunoileal anastomosis is created between the biliopancreatic limb and the alimentary limb. Afterwards an anastomosis is created between the duodenum, preserving the pyloric muscle and the alimentary limb. The connection directs the food immediately from the stomach to the last 1/3 of the intestines. The first 2/3 of the intestines are now bypassed and are not used anymore for food absorption [49].

The BPD/DS has the most pronounced and sustained effect of weight loss as well as the resolution of obesity related comorbidities especially T2D, HTN and dyslipidemia. Long term reported %EWL after BPD/DS is 65-80% [40]. It also showed to be the most effective bariatric procedure in SO adults in terms of weight loss [50]. The reported complications rate varies between 11% and 26%; slightly higher than the rest of bariatric procedures [37, 51]. It carries almost the same complications as the RYGB but usually dumping syndrome and stomal ulceration are less frequently an issue in BPD/DS because of the preservation of the pyloric sphincter. There is a greater and more serious risk of nutritional deficiencies in BPD/DS, since much of the small intestine is bypassed and digestive enzymes cannot mix with food until it reaches the distal ileum. Patients undergoing BPD/DS require more vitamins and supplements as well as more frequent follow-ups and blood testing than other procedures [51].

BARIATRIC SURGERY IN OLDER ADULTS

As mentioned before, the population ages and older patients will account for increasing numbers of weight-related illnesses, and the bariatric solution might play an increasingly dominant role in improving the health and quality of life of this age group [8, 9]. The overall safety of bariatric procedures has been demonstrated in accredited centers with 30-day mortality rates of 0 to 0.3 % [52]. The geriatric population are considered a high-risk group in terms of postoperative adverse outcomes and remain at a significantly higher risk of mortality. This high mortality rate reflects the decreased physical reserves of the elderly due to the changes of aging, comorbidities, and a lack of understanding of their needs by many healthcare providers [53].

Older reports outlined the risks of bariatric surgery in older adults even at a fairly young age. In 1977, Mason et al. stated that gastric bypass surgery was unsuitable for the treatment of morbid obesity in the patients over 50 years of age due to its higher morbidity and mortality as well as the decreased EWL in this patient population [54], and the NIH soon set the upper age limit for bariatric surgery at 55 years [55]. The detrimental impact of age on tissue healing and the higher comorbidity prevalence in elderly patients may explain the higher complication rates [56].

The argument against those dismal results that the conclusions from these early studies are limited, as they do not differentiate between types of bariatric procedures and have a higher percentage of open compared to laparoscopic procedures than expected today [57]. With the improvement in the safety profile of bariatric surgery, there is a growing evidence that with the advancement in minimally invasive surgical techniques coupled with speedy recovery and multidisciplinary efforts, elderly patients are benefiting from bariatric surgery [58]. Over the past decade, metabolic

surgery in older adults has increased by 3-fold and comprises 10% of the total bariatric procedures performed annually [59].

There are few other concerns about bariatric surgery in older adults. Since weight loss post-surgery is initially rapid, losing muscle and fat mass is a valid concern in older patients. As one ages, the loss of muscle mass, known as sarcopenia, usually happens as part of the aging process. But losing additional muscle mass through rapid weight loss has the potential to result in more mobility issues for older adults [59], though it is a legitimate concern but good dietary habits and enough protein intake post-operatively abolish this concern.

Recent literature advocates that age alone should not be an absolute contraindication for bariatric surgery. Indications should be carefully evaluated in the light of routine preoperative tests and discussed with the patients knowing that there are some risks, and that the results might not be as good as they might expect. The American Society for Metabolic and Bariatric Surgery (ASMBS) stresses the importance of multidisciplinary teams that in addition to surgeons, trained registered nurses, dietitians, mental health professionals, and physical therapists should have a role in managing those high-risk patients [60].

DEFINITION OF OLDER ADULTS IN BARIATRIC POPULATION

The term elderly as defined by the Medicare in U.S. is 65 years and older. The cut-off age of older adults in bariatric surgery remains arbitrary, variable and controversial. In reporting the outcomes of bariatric procedures in older morbidly obese adults there is no consensus in the literature about the definition of older adults. Some studies set the older age cut-off at 65 years [61, 62], many others

have considered ≥60 as elderly [48, 63, 64]. Some large single-center studies have considered patients older than 55 to be old enough to have poorer outcomes than younger patients [65, 66] and few studies reported outcomes in patients older than 70 [67-69]. Although different age cut-offs are used, there is a trend in the recent literature to build an evidence to demonstrate good outcomes of bariatric surgery in older adults especially in the U.S. to support insurance coverage policies for those procedures in this frail population [52, 70].

BARIATRIC SURGERY IN SUPER-OBSESE OLDER ADULTS

SO patients (BMI >50kg/m^2) are considered to have increased operative morbidity and mortality compared to morbidly obese patients with BMI <50 kg/m^2. Moreover, reported weight loss after bariatric surgery in SO is inferior to that reported in non-SO [71, 72]. There is very scant literature about the outcomes of operative management of obesity in SO older adults. Recent studies have showed that both BMI and age are strong risk predictors for 30-day mortality in RYGB patients, demonstrating even a linear relationship between increasing BMI and increasing age with mortality risk [73]. To our best knowledge only two studies tackled this issue, and both have a small sample size, as well as only reporting short to medium-term outcomes (<3 years). Daigle et al. reported short term outcomes of laparoscopic bariatric procedures (LAGB, SG and RYGB) in a small cohort of 30 SO elderly patients which were well tolerated by patients and had an overall early morbidity rate of 16.7% (early major complication rate of 10% with no deaths in this series) [74]. McGlone et al. retrospectively compared the outcome of 26 SO older adults to 24 morbidly obese older adults (BMI 35-50 kg/m^2), who underwent either LAGB, SG or RYGB and showed a non-significant difference in weight loss or resolution of comorbidities between both groups [75].

CHOICE OF BARIATRIC PROCEDURES IN OLDER ADULTS

As SG is currently the most common bariatric/metabolic procedure performed worldwide for all age groups [33], it is not surprisingly that recently, most published studies of bariatric surgery in older adults report the results of SG [61, 76, 77]. Moreover, many studies report other restrictive procedures such as LAGB [69, 78, 79]. This is well understood since restrictive only procedures (SG and LAGB) carry lower perioperative risk profile, making them safer choice for the high risk older patients and most of this population is either offered or advised to get the least invasive procedure. Fewer studies evaluated RYGB [80, 81], and even fewer assessed BPD/DS outcomes in older obese and SO adults [74, 82].

RATIONALE AND RESEARCH OBJECTIVES

Despite the abundance of studies in the field of bariatric surgery in older adults, yet, there is no consensus about the indications/contraindications, age cut-off, BMI cut-off, best/safest bariatric procedure in older adults and as mentioned before there is a scarcity in literature on outcomes of bariatric surgery in SO older adults. Moreover, there is rarity in reporting the outcomes of BPD/DS in this patient population. Lastly, most studies report short to medium term outcomes in older patients, with very few studies reporting outcomes beyond 3 years.

In our study, we aimed to assess perioperative morbidity and mortality, and to report medium to long-term (more than 2 years) weight loss and metabolic outcomes of various bariatric surgical approaches including SG, RYGB and BPD/DS of a cohort of morbidly obese or SO older patients (aged ≥60 years), who had bariatric surgery at McGill University Health Center from January 2006 until December 2014.

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MANUSCRIPT

INTRODUCTION

Obesity is an epidemic that has spared no age groups [1, 2]. By 2050, it is projected that older adults will represent 22% of the population in the US. The rapid growth of the senior population has had a significant economic impact because of their unique medical requirements [3]. Obesity is known to decrease the quality of life as well as life expectancy [4]. Bariatric surgery is the most effective treatment for weight loss and obesity-related comorbidities such as type-2 diabetes mellitus (T2D), hypertension (HTN), dyslipidemia, and obstructive sleep apnea (OSA) in morbidly obese individuals [5].

The geriatric population is considered a high-risk group and shown to have higher postoperative adverse outcomes including mortality as well as decreased percentage excess weight loss (%EWL) following bariatric surgery compared to younger adults [6]. Moreover, super-obese (SO) patients (Body Mass Index [BMI] >50kg/m^2) are considered to have increased operative morbidity and mortality compared to morbidly obese patients with BMI <50 kg/m^2 [7]. However, as minimally invasive techniques and multidisciplinary care evolve, there is growing evidence that older adults are benefiting from bariatric surgery with acceptable safety. Over the past decade, metabolic surgery in older adults has increased by 3-fold and comprises 10% of the total bariatric procedures performed annually [8]. As a result, more older SO patients have undergone bariatric surgery to attenuate the burden of their metabolic disease [9].

However, controversy still remains regarding the indications, age cut-off, outcomes and type of bariatric surgery offered to older patients especially those suffering from super obesity. This is in part due to limited literature on the safety and long-term outcomes of various bariatric procedures in this population. Most published studies report the results of restrictive procedures only, such as adjustable gastric banding [10] and sleeve gastrectomy (SG) [11, 12]. Only a few studies evaluate Roux-en-Y gastric bypass (RYGB), and even fewer assess biliopancreatic diversion with duodenal switch (BPD/DS) outcomes in obese and older SO adults [13, 14]. Thus, we aimed to evaluate the medium to long-term safety and outcomes of a cohort of morbidly obese or older SO patients (aged ≥60 years), who underwent various bariatric procedures including SG, RYGB or BPD/DS at our institution.

METHODS

After approval from the institutional Ethics Review Board, we carried out a retrospective study of a prospectively-collected database from a single academic tertiary institution. We included patients aged 60 years and older, who underwent SG, RYGB, BPD/DS or revisional bariatric procedure from January 2006 until December 2014 to have at least two years of follow-up. All data were inputted in the database by a member of the multidisciplinary team (surgeon, nurse, or the nutritionist) at each follow-up appointment. To improve follow-up, patients who either missed their appointments or had no follow-up in the last six months of the study period, were contacted and scheduled for a clinic visit. However, not all such patients were successfully reached or were able to present to their respective appointments.

The information on patients' age, sex, weight, BMI, procedure type, postoperative complications, re-admission, re-operations/re-intervention, %EWL, and percentage total body weight loss (%TBWL) were obtained. Postoperative complications were reported as early/late, minor/major according to the established standardized reporting recommendations for bariatric surgery [15].

The obesity-related comorbidities assessed preoperatively and at last follow-up were T2D, HTN and OSA. We did not report postoperative outcomes on dyslipidemia due to significant missing data during the follow-up. Remission of T2D was defined as cessation of anti-diabetic medication along with a fasting blood glucose ≤125mg/dL (7mmol/L) and HbA1c <6.4%. Remission of HTN was defined as a blood pressure ≤120/80mmHg without any anti-hypertensive medication. Improvements in both HTN and T2D were defined as either remission or improved parameters using less number of medications or at a lower dosage which was clearly documented in the physician consultation notes. Remission of OSA was defined as a normal sleep pattern reported by the patient without the use of continuous positive airway pressure device. Routine postoperative polysomnography was not performed.

The estimates on the study parameters are expressed as mean ± standard deviation (SD) and number (%). Descriptive statistics were carried out using the STATA software (Stata Corp, Texas, USA) version 12.

RESULTS

The study cohort included 104 patients, who underwent 115 bariatric procedures during the study period. Mean age and BMI were 63.3±2.6 years and 51.7±8.1kg/m^2, respectively. Thirty-two patients (31%) were ≥65 years old and the age of the study cohort ranged between 60-70 years old. There were 66 SO patients (63%) with a mean BMI of 56.4±6.4kg/m^2. At baseline, 81 (78%) patients in the study cohort and 54 (82%) of the SO sub-group had at least two obesity-related comorbidities. Table 1 shows baseline characteristics of both study cohort and the SO sub-group.

Twelve patients (11%) had 2 bariatric procedures: 2 patients underwent unplanned conversion to RYGB for weight loss failure after 30 and 34 months from initial SG, both had <35%EWL at time of revision; one underwent repeat SG for weight loss failure along with a hiatal hernia repair 25 months post initial SG (40%EWL prior to revision); one patient had a conversion to RYGB 3 months after sleeve obstruction due to twisting; and 8 patients had a planned second-stage BPD/DS after an initial SG, but one had the SG at age 58 that was not included in the total procedure count. The interval time between the SG and the second-stage BPD/DS was 21.7±15.4 months. All procedures were performed laparoscopically except for one conversion to laparotomy due to adhesions while converting a twisted SG to RYGB. Mean follow-up time was 42±19 months and ranged between 2-10 years. The retention rate was 79% at 2 years for both study cohort and the SO sub-group. As the follow-up time increased, the retention rate decreased to 48% at 3 years and 37% at 4 years. The 8 patients who underwent BPD/DS had a relatively high follow-up rate (63% and 38% at 4 and 7 year, respectively), which is likely due to the need for frequent blood work.

There was no 30 day mortality, but 16 patients suffered from postoperative complications (14%). Seven (44%) were early and 9 were late complications beyond postoperative day 30. There were also 9 major complications. Eleven of 16 postoperative complications and 7 of the 9 major ones occurred in the SO sub-group. The detailed list of major/minor, early/late postoperative complications as well as their respective implications and managements is provided in Table 2.

Mean %TBWL for both study cohort and the SO sub-group were 25.5±11.7 and 26.9±11.7, respectively. Fifty-two patients (50%) of the study cohort and 32 patients from the SO sub-group (48%) achieved and maintained a successful weight loss (>50%EWL) on their last follow-up, respectively. Table 3 reports the detailed overall and procedure-specific weight loss outcomes for both study cohort and the SO sub-group. Finally, both overall and procedure-specific frequencies of the changes in the status of T2D, HTN, and OSA after surgery are reported in Table 4.

DISCUSSION

Choosing an age cut-off to define elderly population is controversial. In the field of bariatric surgery, while some studies set the older age cut-off at 65 years [12, 14], many others have considered ≥60 as elderly [16, 17]. There has also been conflicting data regarding the effect of age on safety and outcomes of bariatric surgery. Previously, some large single-center studies have reported higher operative mortality in patients older than 55 [18, 19]. On the other hand, some recent studies have shown that bariatric surgery in older patients is safe and effective for

treatment of obesity and related conditions [10, 12, 20]. Hence, many older patients are not referred for bariatric/metabolic procedures due to misplaced safety concerns.

Moreover, the literature on medium to long-term outcomes of bariatric surgery in older adult population is scant and even less studies exist evaluating outcomes in the SO sub-group [14]. The mean baseline BMI of our cohort was 52kg/m^2 and more than half of our study cohort (66 subjects) suffered from super obesity, making it one of the largest reported cohorts of the SO elderly patients. Our study cohort also includes a substantial number of patients who underwent diversionary-type procedures including RYGB and BPD/DS. To our best knowledge, no other study has reported medium to long-term outcomes on various bariatric procedures especially BPD/DS in older patients particularly the SO sub-group.

We observed a 14% overall morbidity rate, where only 8% were considered to be major complications, an estimate which is comparable to bariatric surgical outcomes in other high-risk populations such as dialysis-dependent patients or those on immunosuppressants [21, 22]. While most complications occurred in the SO sub-group, the occurrence of early and late major complications was only 9% for this sub-group with an overall rate of 14%. Our observed complication rate in the SO sub-group is within the acceptable morbidity profile for adult SO patients from all age categories in whom major complications are reported to range between 2.5%–32.2% [7, 23]. Moreover, contrary to the study by Livingston et al. that reported a threefold higher mortality rate for patients >55 years in a series of 137 patients after RYGB [18], we observed no 30-day mortality in our cohort where a quarter of patients underwent RYGB or BPD/DS. Furthermore, we detected only 3 leaks out of 115 procedures: 2 after RYGB and 1

post-BPD/DS (2.6%; Table 3), which is comparable to those of other reported cohorts including SO elderly and two-stage BPD/DS patients (2.2%–3.3%) [14, 24, 25]. In addition, in a recent case-control study of 210 patients who underwent open BPD/DS, Michaud et al. reported that while those aged ≥60 had more major complications compared to those <55 years (16.2% vs. 8.6%), there were no differences in mortality and both groups benefited from similar long-term outcomes [13]. Therefore, while major complications for older adults maybe more frequent after BPD/DS, old age alone should not deny the SO elderly patients who are heavily burdened by metabolic syndrome from the optimal metabolic procedure. Our findings further demonstrate that diversionary-type procedures including BPD/DS can be performed with acceptable morbidity in older patients.

We report an abdominal re-operations rate of 14% (n=15) throughout the study period, where 11% (n=11) were second weight loss procedures and the remainder addressed complications of the original operation. Ten of 11 repeat weight loss procedures were done in SO patients and 8 were planned second-stage BPD/DS operations. We chose a two-stage surgical approach for patients that underwent BPD/DS due to their higher-risk profile and since all were SO at baseline. A two-stage BPD/DS for the SO patients has been advocated irrespective of the patient's age [24]. Our unplanned revisional surgery rate was 4% and is lower than that reported for the general bariatric population, which depending on the original bariatric procedure, ranges between 10%–25% [26].

We were able to achieve a relatively good follow-up rate of 79% at 2 years, which is hard to obtain especially in older adult population. We observed a 52%EWL for the study cohort at 2

years and 50% at the last follow-up (mean follow-up of 42 months). The mean EWL was 49% for the SO sub-group at 2 years, which is superior to the study by Daigle et al. that reported 45%EWL at one year and beyond for a cohort of 30 SO elderly patients [14]. For the patients that underwent a planned second-stage BPD/DS, this resulted in an added 31%EWL and an overall 64%EWL.

As expected, we observed major improvements in the obesity-related comorbidities. Eighty-two percent of diabetics and more than half of hypertensive patients had either improvement or resolution of their T2D and HTN, respectively. Furthermore, improvements in all reported comorbidities were more pronounced after diversionary-type procedures (RYGB and BPD/DS). However, sample size especially in the BPD/DS group was not enough to carry out a meaningful subgroup analysis. These findings corroborate with what is expected after bariatric surgery irrespective of age [27-29]. Our results further underscore the efficacy of bariatric/metabolic surgery in improving the cardiometabolic risk profile of elderly patients especially those suffering from super obesity.

Our study is limited by its retrospective nature and sample size. Another limitation may be the choice of the age cut-off to define older patients. We included older adults ≥60 years, while subjects ≥65 years are considered by Medicare to define older patients. However, the defining age cut-offs for older subjects especially in the surgical literature are arbitrary, variable and controversial [12, 14, 16, 17]. Furthermore, the information on some obesity-related comorbidities e.g. dyslipidemia and reflux disorder were not uniformly recorded in our database. We also lacked complete data on other important but under-appreciated issues in older adults e.g. changes in quality of life and functional capacity. Despite a decent medium-term follow-up rate of 79% at

2 years, our long-term retention rate was lower. Achieving high long-term follow-up rates after bariatric surgery is challenging especially for older adults whose compliance with regular and long-term follow-up can be limited by their lower functional capacity. Another limitation, is the lack of a younger comparison group to compare the perioperative, medium, and long-term outcomes. Finally, while we report outcomes from two major diversionary-type procedures (RYGB and BPD/DS), the respective sample sizes were too small to carry out a meaningful sub-group analysis. However, our study is one of the largest of such cohorts of older SO patients reporting on outcomes of RYGB and BPD/DS in addition to SG.

CONCLUSION

Bariatric surgery including diversionary-type procedures (RYGB and BPD/DS) is safe and effective in improving obesity-related comorbidities in older patients especially those suffering from super obesity. While we acknowledge the absence of a matched younger comparison cohort, further studies comparing long-term outcomes of older adults with those who are clearly younger can further elucidate the safety of bariatric procedures specifically diversionary-type such as BPD/DS in this patient population. Although outcomes of bariatric surgery in older adults warrant further long-term and larger studies, the emerging literature continues to suggest the efficacy of such interventions in these patients. Age alone should not preclude older patients especially those suffering from super obesity from getting the best bariatric/metabolic procedure.

DISCLOSURES

The authors have no commercial associations that might be a conflict of interest relevant to this article.

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TABLES

Table 1. Baseline characteristics of the study cohort

Variable	Study Cohort n=104	SO Sub-group n=66
Age (year) − mean ± SD	63.3 ± 2.6	63.3 ± 2.6
Sex (male) − n (%)	38 (37)	22 (33)
Weight (kg) − mean ± SD	138.8 ± 24.2	149.1 ± 22.5
BMI (kg/m^2) − mean ± SD	51.7 ± 8.1	56.4 ± 6.4
Obesity-related comorbidity		
T2D − n (%)	62 (60)	39 (59)
HTN − n (%)	81 (78)	48 (73)
DLP − n (%)	37 (36)	24 (36)
OSA − n (%)	31 (30)	18 (27)
Procedure type* − (n=115)		
SG – n (%)	85 (74)	52 (68)
RYGB − n (%)	18 (16)	13 (17)
BPD/DS† − n (%)	8 (7)	8 (11)
Revision‡ − n (%)	4 (3)	3 (4)

SO = Super-obese; SD = Standard Deviation; BMI = Body Mass Index; T2D = Type-2 Diabetes Mellitus; HTN = Hypertension; DLP = Dyslipidemia; OSA = Obstructive Sleep Apnea; SG = Sleeve Gastrectomy; RYGB = Roux-en-Y Gastric Bypass; BPD/DS = Biliopancreatic Diversion with Duodenal Switch.

* The study cohort (n=104) underwent a total of 115 bariatric procedures during the study period. The extra 11 procedures consisted of: 8 patients who underwent a planned second-stage BPD/DS after an initial SG, one of whom had the first-stage SG at age of 58 and was not included in our cohort (7 procedures); and 4 revisional bariatric surgeries during the study period after an initial SG.

† All the BPD/DS procedures in our study cohort were planned two-stage operations.

‡ All revisions during the study period were performed after an initial SG. 2 patients underwent RYGB for weight loss failure; 1 patient had a conversion to RYGB after twisting/corckscrewing of the initial SG; another patient underwent repeat SG with a hiatal hernia repair.

Table 2. Postoperative complications of the study cohort*

Complication†	n (%)	Implications and Management
Any morbidity	16 (14)	-----
Major morbidity	9 (8)	-----
Early	5 (4)	-----
Leak	3 (3)	-----
GJ anastomosis post-RYGB	2 (2)	Both drained by IR; prolonged hospitalization.
DI anastomosis post-BPD/DS	1 (1)	Laparoscopic exploration, repair and drainage.
Bleeding post-SG	1 (1)	Blood transfusion.
Liver injury post-SG	1 (1)	Bile leak; laparoscopic exploration, suture repair of liver injury and drainage.
Late		-----
Obstruction post-SG due to twisting	1 (1)	Laparoscopic converted to open conversion to RYGB.
Port-site hernia post-SG	2 (2)	Laparoscopic hernia repair with mesh.
Acute MI post-SG	1 (1)	Admission to CCU (occurred 6 weeks after surgery); prolonged hospitalization.
Minor morbidity	7 (6)	-----
Early	2 (2)	-----
Superficial SSI post-SG	1 (1)	Incision and drainage with outpatient wound-packing
UTI post-SG	1 (1)	Re-admission to rule out a leak which was negative; antibiotic therapy.
Late	5 (4)	-----
GJ stricture post-RYGB	2 (2)	Outpatient endoscopic balloon dilations.
De novo GERD post-SG	3 (3)	All required PPI, two needed log-term therapy; one had laparoscopic HH repair not addressed at original surgery which was deemed to be too small.

SO = Super-obese; GJ = Gastro-jejunal; DI = Duodeno-ileal; RYGB = Roux-en-Y Gastric Bypass; BPD/DS = Biliopancreatic Diversion with Duodenal Switch; IR = Interventional Radiology; SG = Sleeve Gastrectomy; MI = Myocardial Infarction; CCU = Cardiac Care Unit; SSI = Superficial Surgical Site Infection; UTI = Urinary Tract Infection; GERD = Gastro-esophageal Reflux Disorder.

* The study cohort included 104 patients, who underwent 115 bariatric procedures during the study period.

† Eleven of 16 postoperative complications and 7 of the 9 major ones occurred in the SO sub-group.

Table 3. Weight loss progress after surgery for the study cohort

	Weight (kg)	BMI (kg/m^2)	%EWL	%TBWL
Patient cohort				
Study cohort (n=104)				
Baseline	137.8±21.2	51.7±8.1	-----	-----
2-yr follow-up	98.0±24.5	38.0±8.4	52.2±23.8	29.1±14.7
Last follow-up	102.1±21.0	38.3±8.2	50.2±23.0	25.5±11.7
SO sub-group (n=66)				
Baseline	149.1±22.5	56.4±6.4	-----	-----
2-yr follow-up	103.2±23.1	41.0±8.3	48.8±20.8	29.8±14.3
Last follow-up	107.3±20.1	41.2±8.4	48.1±21.0	26.9±11.7
Procedure type[*]				
SG (n=78)				
Baseline	138.0±22.4	51.1±8.6	-----	-----
2-yr follow-up	98.3±25.6	37.8±8.9	51.6±24.7	28.4±15.4
Last follow-up	104.9±21.6	38.9±8.8	46.9±23.3	23.4±11.5
RYGB (n=18)				
Baseline	130.6±14.6	51.6±5.9	-----	-----
2-yr follow-up	91.2±15.7	36.8±7.9	59.1±23.5	30.3±11.0
Last follow-up	92.0±15.6	36.4±6.0	58.2±20.1	29.4±9.9
BPD/DS[†] (n=8)				
Baseline (Prior to SG)	168.6±40.1	58.0±5.7	-----	-----
Prior to BPD/DS	125.7±13.5	47.3±5.5	32.4±7.3	18.6±3.4
2-yr follow-up	106.4±15.4	39.4±5.1	55.5±11.4	31.8±6.7
Last follow-up	98.7±19.9	36.9±6.5	63.7±18.2	36.2±9.6
Revisional (n=4)				
Baseline	124.8±36.2	47.9±8.7	-----	-----
Prior to revision	101.9±25.7	39.3±6.2	39.5±10.5	17.6±4.2
Last follow-up	98.6±29.2	37.8±5.6	46.3±12.2	20.4±6.3

BMI = Body Mass Index; %EWL = Percent Excess Weight Loss; %TBWL = Percent Total Body Weight Loss; SO = Super-obese; SG = Sleeve Gastrectomy; RYGB = Roux-en-Y Gastric Bypass; BPD/DS = Biliopancreatic Diversion with Duodenal Switch.

* The study cohort included 104 patients, who underwent 115 bariatric procedures during the study period.

† All the BPD/DS procedures in our study cohort were planned two-stage operations. All initial SG operations were performed during the study period, except for 1 patient who had the first-stage SG at the age of 58 and was not included in the total procedure count.

Table 4. Postoperative outcomes of the obesity-related comorbidities*

	Study Cohort (n=104)			SO sub-group (n=66)		
Comorbidity	**Baseline n**	**Remission n (%)**	**Improvement n (%)**	**Baseline n**	**Remission n (%)**	**Improvement n (%)**
T2D†	62	27 (44)	51 (82)	39	17 (44)	31 (79)
SG	45	16(36)	35(78)	24	8(33)	17(71)
RYGB	12	7(58)	11 (92)	10	5(50)	9(90)
BPD/DS	5	4(80)	5 (100)	5	4(80)	5(100)
HTN‡	81	21 (26)	47 (58)	48	11 (23)	31 (65)
SG	62	12(19)	32(52)	32	5(16)	19(59)
RYGB	13	6(46)	10(77)	10	3(30)	7(70)
BPD/DS	6	3(50)	5(83)	6	3(50)	5(83)
OSA§	31	12 (38)	12 (38)	18	6 (33)	6 (33)
SG	18	6(33)	6(33)	9	2(22)	2(22)
RYGB	8	3(38)	3(38)	4	1(25)	1(25)
BPD/DS	5	3(60)	3(60)	5	3(60)	3(60)

SO = Super-obese; T2D = Type-2 Diabetes Mellitus; SG = Sleeve Gastrectomy; RYGB = Roux-en-Y Gastric Bypass; BPD/DS = Biliopancreatic Diversion with Duodenal Switch; HTN = Hypertension; OSA = Obstructive Sleep Apnea.

* Remission rates of dyslipidemia are not reported due to significant missing data and inconsistent documentation during follow-up.

† Remission of T2D was defined as cessation of anti-diabetic medications along with a fasting blood glucose ≤125mg/dL (7mmol/L) and HbA1c <6.4%. Improvement in T2D was defined as either remission or improved parameters using less number of medications or at a lower dosage.

‡ Remission of HTN was defined as a blood pressure ≤120/80 mmHg without any anti-hypertensive medication. Improvement of HTN was defined as either remission or improved parameters using less number of medications or at a lower dosage.

§ Remission of OSA was defined as a subjective reporting of a normal sleep pattern by the patient without the use of continuous positive airway pressure. No repeat sleep study was carried out.