A Sri Lankan experience over a decade in obesity care and understanding future challenges

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Introduction

Obesity; the global health challenge

Obesity is defined as an abnormal or excessive accumulation of body fat which presents a risk to health. Alarmingly, it is becoming an enormous health challenge worldwide.

The global epidemiological data reveal that in 2016, 13% of adults were obese and 39% were overweight worldwide. The mean BMI of women was 25kg/m² and 24.5 kg/m² for men. This falls exactly on the threshold of WHO’s overweight classification. Quite distressingly, the childhood overweight and obesity rates have risen from 4% in 1975 to 18% in 2016. In 2017 alone, 4.7 million died prematurely because of obesity. In comparison to 4.5% of deaths in 1990, 8% died globally as a result of obesity in 2017. Unfortunately, across many middle-income countries in Eastern Europe, Asia, Latin America, and North Africa over 15% of deaths were attributed to obesity. Thus, obesity is one of the largest health problems in today’s world. Interestingly, there is a paradigm shift in obesity trends from being a health problem of rich countries to one that spans all income levels. The greatest number of people with obesity now live in lower and middle-income countries, where the double burden of malnutrition continues, and systems are severely underprepared and ill-equipped to effectively address obesity and its consequences.

Obesity in Sri Lanka; the magnitude of the problem

Sri Lanka is categorized as a lower-middle income country with a population of over 21 million and is equally affected by the disease burden of obesity.

According to a study by Prof. P. Katulanda and colleagues, the community prevalence of overweight and obesity in Sri Lanka was 16.8% and 3.7% respectively, using global body mass index (BMI) cutoffs excluding the war-affected Northern and Eastern provinces. Females were predominantly affected compared to males. The prevalence of obesity was 4.8% (95% CI 4.3-5.3) among females in comparison to 2.8% (95% CI 2.2-2.9) among males. The mean BMI was 22.3 kg/m² and 21.1kg/m² in females and males respectively. Rates of obesity and overweight were high in urban communities as opposed to rural counterparts. Over 50% of the urban population were centrally obese.

In 2014, in a study conducted among adult males less than 40 years in Central Province, the cumulative prevalence of overweight and obesity was 45%. Dr N. Somasundaram and colleagues, in the 2019 “Colombo Urban Study” demonstrated that two-thirds of adults living in the urban population were either overweight or obese indicating that the Sri Lankan population is increasingly being victims of this dreaded disease.

In comparison to global trends, overweight and obesity appears to be an emerging problem among Sri Lankan adolescents and children as well. In a study carried out in the Anuradhapura district, 8.4% of males and 9.6% of females were either overweight or obese highlighting that obesity is an emerging health threat even in rural Sri Lanka.

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Assessment of obesity

Obesity is an “abnormal or excessive accumulation of body fat” which “presents a risk to health”. Body fat accumulation is two folds. “Subcutaneous fat” is located underneath the skin and “visceral fat” is located inside the abdomen and around the abdominal viscera. In fact, visceral fat results in central and abdominal obesity which correlates with a higher risk of obesity-related metabolic complications.

The commonest metric used in the assessment of obesity is BMI. It is calculated by dividing weight in kilograms by the square of height in meters. Using global BMI cutoff values, the World Health Organization (WHO) defines four classes, namely underweight (<18.5 kg/m²), normal range (18.5-24.99 kg/m²), overweight (25-29.99 kg/m²) and obesity (>30 kg/m²). Obesity is further subdivided into 3 classes; class I obesity (30-34.99 kg/m²), class II obesity (35-39.99 kg/m²) and class III obesity (>40 kg/m²). Numerous population studies have demonstrated a J-shaped relationship between BMI and morbidity and mortality risk related to obesity.

However, Asians are at a higher risk of developing obesity-related complications at a lower BMI in comparison to Caucasians. Thus, lower BMI cutoffs are increasingly used in Asian subpopulations to define obesity. In 2015, the Endocrine Society of Sri Lanka published BMI guidelines based on the available epidemiological data, which is particularly important in making management decisions.

Obesity-related health and metabolic consequences

Obesity is a major risk factor for several chronic diseases. Its resultant complications can be due to the metabolic and anatomical effects of obesity.

Visceral adipose tissue related to obesity is a potent source of inflammatory cytokines [interleukin (IL) - 1, IL - 6, tumour necrosis factor-alpha (TNF-α)]. The resultant chronic inflammation and endothelial dysfunction are the key mediators of metabolic effects of obesity such as type 2 diabetes mellitus, hypertension, dyslipidemia, ischemic heart disease, heart failure, stroke, dementia, non-alcoholic fatty liver disease, biliary complications, subfertility and cancer.

In context, there is a 100-fold increased risk of diabetes with a BMI of 35 kg/m² compared to a BMI of 22 kg/m². A linear relationship was noted in-between BMI and blood pressure among adults. Obesity affects lipid metabolism by raising low-density lipoprotein cholesterol while reducing cardio-protective high-density lipoprotein cholesterol levels.

In addition to the intermediate risk factors such as diabetes, hypertension and dyslipidemia, obesity is an independent risk factor for coronary heart disease. For every 4kg/m² rise in BMI, there is a 26% increment in the odds of ischemic heart disease. Framingham Heart Study found that heart failure risk was doubled in obesity.

Obese individuals are twice as likely to have an ischemic or hemorrhagic stroke than people with BMI <23 kg/m². In addition to the vascular risk factors studies reported an independent association between the risk of dementia and high BMI.

In addition, obesity accounts for nearly 20% of all cancers globally. A comprehensive review by International Agency for Research on Cancer concluded obesity is the cause of 1/3 - ½ of colon, endometrium, breast, oesophagus and renal cell carcinomas.

Non-alcoholic fatty liver disease (NAFLD), the hepatic manifestation of metabolic syndrome demonstrates a strong correlation with BMI. Hepatic steatosis is noted in 56% of people with class I or II obesity and 85% of people with class III obesity.

In males, obesity is associated with oligozoospermia, azoospermia and erectile dysfunction. In females, subfertility, poor outcomes to fertility treatment and pregnancy losses are noted. Polycystic Ovarian Syndrome (PCOS) is the primary cause of subfertility and pregnancy-related complications identified in obesity.

Obesity-related anatomical complications are primarily due to increased adipose tissue resulting in a strain on various body parts. They range from obstructive sleep apnea (OSA), obesity hypoventilation syndrome (OHS), gastro-oesophageal reflux disease (GORD) and osteoarthritis.

Consequently, obesity is associated with a heightened risk of all-cause mortality. Cardiovascular disease and malignancy are the commonest causes of death. Thus, obesity and its consequences are an emerging threat to slow or reverse the improvement seen in life expectancy over the last few decades.

Alarmingly, the global economic burden in managing obesity and related complications is $2 trillion annually. Its 2.8% of the global gross domestic product (GDP). The psychosocial impact of obesity is often a neglected entity. Depression rates are higher.
in obesity, particularly among adolescents and females. The related social stigma and discrimination in employment, healthcare and education are often unaddressed.

Thus, Obesity is an enormous global health and economic burden. Halting the rise of diabetes and obesity was one of WHO’s voluntary global non-communicable disease targets for 2025.

Management of obesity

Management of obesity is of paramount importance in preventing and ameliorating the complications. A minimum of 5-10% weight loss is proven to have a positive impact. The conventional treatment approaches include lifestyle modifications (diet, exercise, behavioural modifications) and pharmacological interventions. Both these methods show variable success rates in achieving initial target weight loss.

The major obstacle in lifestyle modification is weight regain owing to the alteration of neuro-humoral pathway which is a key regulator in appetite regulation and hunger. Although, it is a helpful adjunct it was proven to be less efficacious in achieving weight loss targets in higher degrees of obesity.

Pharmacotherapy has its challenges, from debilitating and limiting side-effect profiles, lack of long-term safety data, cost, weight regain and unavailability. The weight loss achieved with most of the first-generation pharmacotherapeutic agents is not robust. In addition, only a few drugs have received authorization from international regulatory bodies to date. Some agents like lorcaserin, fenfluramine, and dexfenfluramine were requested to be withdrawn from the market after several years of use owing to alarming side effects in post-marketing surveillance.41

In this background, the introduction of metabolic and bariatric surgery (MBS) in 1954 has revolutionized obesity management over the last few decades. The benefits range from long-term and durable weight loss to reversal and remission of most of obesity-related metabolic complications. It has been a life-changing experience for thousands of people suffering from obesity worldwide.

Currently, MBS is indicated as the first-line treatment option for patients with class III obesity and patients with class II obesity along with metabolic complications that are expected to improve with weight loss. Also, it is considered in patients with class I obesity and type 2 diabetes and/or arterial hypertension with poor control despite optimal medical therapy based on evidence of randomized controlled trials and subsequent meta-analysis.37

From initial open surgeries, advances in minimally invasive laparoscopic, and endo-bariatric surgical techniques over recent years have contributed to reduced operating times, hospital stays, and complications. The operative mortality is no greater than a laparoscopic cholecystectomy. The new developments in MBS have been exceptional and lead to a dramatic rise in MBS procedures performed worldwide. Currently, common types of MBS performed worldwide are laparoscopic mini-gastric bypass (LMGB), laparoscopic adjustable gastric banding (LAGB), Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG) and biliopancreatic diversion with a duodenal switch (BPD-DS).

The available outcome data of MBS are reassuring. In the short term, it resulted in higher percentages of total weight loss (TWL), achieving targets of estimated weight loss (EWL) and comorbidity control. In the long-term, MBS resulted in substantial and durable weight loss and comorbidity control (diabetes, dyslipidemia, hypertension, NAFLD) in comparison to lifestyle interventions and pharmacotherapy. Consequently, it resulted in a significant reduction in cardiovascular mortality and the first occurrence of fatal and nonfatal cardiovascular events. This is unique to MBS as mortality benefit was not seen in other interventions in obesity care. Initial higher reoperation rates were noted, which reduced markedly with improved surgical and aftercare techniques.

As obesity is a major risk factor for numerous metabolic diseases, MBS has been proven to be a cost-effective management option in comparison to the medical management of obesity-related comorbidities. Thus, it will be beneficial in the long-term in reducing global health expenditure. In addition, research reported improvements in psychosocial status following MBS including employment opportunities, social relations, and improved quality of life making it an attractive treatment approach for obesity.

Justification

Obesity rates are rising at an alarming rate worldwide and Sri Lanka is no exception. As per published data and estimations by the Directorate of Non-Communicable Diseases, Ministry of Health, Sri Lankan obesity rates are rising coupled with a parallel rise in non-communicable diseases. Thus, various interventions to prevent obesity, and promote a healthy lifestyle among Sri Lankans were implemented at the national level. Despite the efforts the prevalence of
obesity was estimated to be 11.2% in 2020 in comparison to 7.58% in 2014.

With this background, the “Obesity Services Unit” was established at the Colombo South Teaching Hospital in 2008 as a joint venture by the diabetes and endocrine unit and professorial surgical unit. The aim was to provide optimum care for patients with obesity. We provide a range of obesity services such as lifestyle interventions, pharmacotherapy, and MBS. Over the last 15 years, 250 patients underwent MBS in the unit. Being the first and largest “Obesity Services Unit” in the country, we are the leading referral center serving patients with obesity across the island. Thus, we follow up a diverse cohort of obese Sri Lankan patients. The scarcity of island-wide new representative studies on obesity is a major obstacle in planning interventions to combat obesity. Studies have demonstrated that Sri Lankans have higher visceral adiposity for a given BMI making them more vulnerable to obesity-related metabolic complications. In this background outcomes of weight loss interventions may be different in Sri Lankans in comparison to others. Unfortunately, there are no large-scale local studies to determine the prevalence of obesity-related metabolic complications and assess efficacy, the short-term and long-term outcome of weight loss in general in the Sri Lankan population.

In addition, there is minimal regional data and no local data on short-term and long-term outcomes of bariatric surgery in obesity. Also, in a time where remission and reversal of metabolic diseases are gaining a great deal of attention globally, there are minimal published data on remission of diabetes and other metabolic diseases in the Sri Lankan population.

In this oration, I intend to describe socio-demographic data and characteristics of patients with obesity followed up at our center. Secondly, I will describe the observations of short-term and long-term outcomes regarding weight loss, maintenance of weight loss, and reversal of metabolic complications. Finally, I will evaluate the cardiovascular risk reduction in our cohort of patients over the last decade.

Methods

This oration is based on seven studies published locally and internationally in peer-reviewed journals and as conference proceedings. Studies were conducted at the “Obesity Services Clinic” at the Colombo South Teaching Hospital from 2011-2022 using follow-up data of patients with obesity which was entered into an electronic database after obtaining written informed consent. Ethical approval was obtained to maintain the database by the Ethics Review Committee of the Faculty of Medicine, University of Colombo.

Results

Efficacy of weight loss interventions among Sri Lankans with obesity – The first Sri Lanka experience on laparoscopic bariatric surgery

Weight loss

From 2011 to 2019 a total of 127 patients underwent laparoscopic bariatric surgery. Out of them 85% (n=108) were females. The mean age was 38.9 (+/- 10.3) years. The mean pre-operative BMI was 44.7 +/- 7.3 kg/m². The mean pre-operative body weight was 109.6 +/- 21.7 kg overall.

Males weighed 130.0kg +/- 23.5kg pre-operatively, while their waist circumference (WC) and body fat percentage (BFP) were 129.0cm +/- 14.9cm and 40.6% +/- 6.1% respectively. Whereas females had a pre-op weight of 106.0 +/- 19.4 kg and a comparatively high BFP of 45.4% +/- 4.8%. Their mean WC was 119.0cm +/- 11cm.

At 1 month, 3 months, 6 months, 9 months and 12 months after bariatric surgery patients lost 11.3 +/- 5kg (female: 10.0 +/- 3.9kg, male: 14.8 +/- 6.0kg), 19.3 +/- 6.4kg (female: 17.8 +/- 4.4kg, male 25.5 +/- 9.2kg), 26.0 +/- 8.6kg (female: 24.7 +/- 6.8kg, male: 30.1 +/- 13.2kg), 28.7 +/- 7.6kg (female: 28.5 +/- 7.8kg, male: 29.6 +/- 8.2kg) and 30.1 +/- 8.1kg (female: 30.0 +/- 8.2kg, male: 30.8 +/- 8.4kg) of body weight respectively.

On average, bariatric surgery patients lost weight more rapidly than females in the first 6 months after BS, but at the end of 12 months, there was no difference in weight loss among the two genders.44
Improvement in visceral adiposity indicators – waist circumference and body fat percentage

A marked reduction of WC and BFP was also noted post-bariatric surgery. At 1 month, 3 months, 6 months, 9 months, and 12 months after BS the reduction of WC from baseline was 6.1 +/- 7.4cm, 13.7 +/- 8.4cm, 19.1 +/- 9cm, 20.4 +/- 7.8cm and 21.1 +/- 8.2cm respectively. The reduction of BFP from baseline at 1month, 3 months, 6 months, 12 months were 1.6 +/- 4.6%, 4.6 +/- 6.6%, 7.5 +/- 5.6%, 9.3 +/- 9.9%, and 9.1 +/- 6.5%) respectively. There was no significant difference in the reduction of WC and BFP among males and females. Similarly, both WC and BFP demonstrated a rapid improvement in the first 6-9 months and the effect was noted to be plateauing afterwards.45

Does the type of intervention matter?

As we were a specialized center for MBS majority of patients referred to our unit underwent MBS. The commonest type of surgery performed was LSG in 67.7%, followed by LMGB in 21% and laparoscopic RYGB in 9.7%. Patients who underwent LMGB lost more weight compared to LSG at 3 months (22.5 +/- 8.9kg vs 18.3 +/- 5.2kg, p=0.07), 6 months (32.6 +/- 14.7kg vs 24.7 +/- 7.1kg, p=0.13), 12 months (34.6 +/- 8.4kg vs 30.0 +/- 8.4kg, p=0.13). However, the noted differences did not reach a statistical significance.44,45

Prevalence and impact of weight loss on reversal of obesity-related metabolic complications

Non-alcoholic fatty liver disease (NAFLD)

NAFLD was detected in 88.7% of the patients preoperatively. According to ultrasound scan (USS) imaging 29.8% had grade I fatty liver while 58.9% had grade II fatty liver. The pre-operative mean ALT and AST values were 39.1 +/- 28.3 U/L and 30.4 +/- 18.6 U/L respectively.

On the USS imaging at 6 months after MBS, the prevalence of fatty liver reduced to 29.4% (grade I fatty liver 19.6%, grade II fatty liver 9.8%). The pre-operative mean ALT and AST values were 39.1 +/- 28.3 U/L and 30.4 +/- 18.6 U/L respectively.

On average MBS fully reversed NAFLD in 68.1% (p<0.001) and reduced the grade of NAFLD in 87.2% (p<0.001) on USS imaging. It significantly reduced baseline AST and ALT values by 27.3% and 49.3% respectively post procedure.46

NAFLD reversal according to the type of intervention

The baseline pre-op AST and ALT values did not show a statistically significant difference among patients undergoing LSG vs LMGB (AST 31.8 +/- 21.1 vs 26.8 +/- 11.6 U/L, p>0.05 and ALT 41.1 +/- 30.3 VS 35.8 +/- 25.7 U/L, p>0.05). At 6 months post-BS AST and ALT levels were lower in patients with LSG in comparison to LMGB. Thus, LSG showed a greater reduction of AST (32.1% vs 6.7%, p<0.05) and ALT (53.5% vs 24.9%, p<0.001) in comparison to LMGB.

Overall, LSG showed a higher rate of complete reversal of NAFLD (75.0% vs 44.4%) and improvement in the grade of NAFLD (91.7% vs 66.7%) on USS imaging compared to LMGB.47

Prevalence of Type 2 Diabetes Mellitus and efficacy of weight loss in diabetes remission

The type 2 diabetes mellitus (T2DM) remission study included 245 patients who underwent BS at our unit. Among 245 patients 44.4% (n=109) had pre-operative T2DM while 17.9% (n=44) had pre-diabetes. Interestingly, 37.7% (n=92) had normoglycemia.

The mean age of the group of patients who had T2DM pre-operatively was 40.0 +/- 10 years. The majority (71.6%) were females. The mean pre-op weight and BMI were 115.8 +/- 24.4kg and 45.4 +/- 7.4 kg/m2 respectively. The mean HbA1c was 8.5 +/- 1.6% while the average duration of diabetes was around 3.5 years. Approximately 45% of the patients were taking metformin only as pharmacotherapy, while the rest were taking variable combinations of oral hypoglycemic agent (OHA), OHA and insulin and insulin only.

At 1 year follow-up, 87.1% (n = 94) achieved T2DM remission (males: 90.3%, females: 84.6%). A separate analysis was performed to determine the long-term T2DM remission at 5 years. This included 57 patients from the initial sample of 109. At the 5-year follow-up 74.5% had diabetes remission. While 14 patients (25.5%) were having diabetes at 5-year follow-up with the persistence of pre-op diabetes in 13 patients and new occurrence of T2DM in 1 patient.48

Predictors of Type 2 Diabetes Mellitus Remission among Sri Lankans

Patients who were diagnosed with T2DM before 40 years of age had significantly higher remission rates in comparison to a diagnosis made after 40 years (p<0.05). A 100% long-term diabetes remission rate was noted among those who were <30 years at the time of surgery. The pre-operative BMI did not have a

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significant impact on diabetes remission in our study \((p=0.35)\). RYGB had a better reversal of diabetes (71.4\%) whereas LSG and LMGB had similar outcomes (62.8\% vs 59.3\%).48

Cardiovascular risk reduction in weight loss

A separate analysis was performed to assess the improvement of Framingham 10-year risk score in post-BS patients. The study included 240 patients while the Framingham risk score (FRS) was calculated in 180 patients to whom it was applicable.

75.2\% (n=79) were females, while the mean age was 37.1 years (range: 22-53). 85\% (n=88) were non-smokers. LSG was performed in 65.6\% while LMBG was performed in 25.8\%. Pre-operative BMI of 45.9 kg/m\(^2\) came down to 32 kg/m\(^2\) with consequent remission of diabetes, hypertension and improvement of lipid parameters as mentioned above.

Pre-operatively 88\% were in the low-risk category of FRS. The initial FRS was higher in males compared to females \((p<0.001)\). The 10-year cardiovascular disease risk reduced significantly at 12 months after surgery \((p<0.0001)\) with a greater effect seen in LMGB than LSG.49

Discussion

Over a decade of obesity research, we were able to identify obesity-related metabolic complications, the impact of weight loss in reversing aforementioned complications such as diabetes remission and NAFLD reversal and to do a rather comprehensive analysis of short-term and long-term outcomes of metabolic and bariatric surgery in Sri Lankan population.

As obesity is increasingly becoming common among Sri Lankans it is imperative to actively look for effective weight loss interventions in our population. In this context, our study demonstrates a rapid and clinically meaningful weight loss in short term. In addition, our data are compatible with regional and global experience of successful short-term outcomes. As the country's leading centre for MBS, we provide care for people with obesity across the nation. Therefore, it increases the generalizability of our data. Thus, we can conclude that MBS is an effective weight loss intervention in the Sri Lankan population when indications exist.50,51

Thirdly, obesity is the root cause of many downstream metabolic diseases. Thus, the focus of any obesity treatment is the reversal or prevention of aforementioned diseases rather than mere weight loss. In this regard, our data from short-term and long-term outcomes of MBS in our population is highly encouraging. We noticed satisfactory remission of diabetes, and reversal of NAFLD.

The prevalence of NAFLD among our cohort of patients was slightly higher than the estimated global prevalence of NAFLD in the obese population (75.27\% vs 88.7\%).52 Importantly, MBS showed impressive levels of complete reversal and downgrading of NAFLD both biochemically and ultrasonically in Sri Lankan patients with comparable efficacy to studies done in Caucasian populations.53,54 Thus, BS can be considered a potential therapeutic option in obese South Asian patients with NAFLD, especially when it is of an advanced grade.

Interestingly, our data reveal that LSG has a more favourable impact on complete reversal and improvement of NAFLD when compared to LMBG which is independent of the weight loss. This contrasts with published data from systematic reviews and meta-analysis where no difference was found between SG and gastric bypass regarding histopathological outcomes.55 The observed difference could be due to chance or an inherent difference in Sri Lankan population. In the context of the latter LSG should be considered ahead of LMBG when MBS is planned for obese patients with NAFLD in our setting. However, further long-term data is needed to make conclusions.

Among comorbidity reversal outcomes, the diabetes remission data is a landmark in our study. This is the first published Sri Lankan study on short-term and long-term diabetes remission. Globally, studies on the efficacy of MBS on diabetes remission demonstrate a rate of 80\% which is similar to our data.56 A >70\% remission rate of diabetes was noted in all types of surgeries performed. However, the highest rates of improvement were seen in the RYGB group in keeping with global data, where RYGB resulted in improvement of glycemic status even before achieving a significant weight loss compared to other surgical procedures.57

In addition, we were able to identify several predictors of diabetes remission in our setting. Our study identified younger age at diagnosis as a positive predictor of diabetes remission in Sri Lankans. The higher diabetes remission rates in males observed in our study could be due to the lower number of male participants. Even though, some suggest pre-operative BMI as a marker of diabetes remission, our study did not demonstrate such an association.
Finally, the ultimate desired effect of reversal or remission of metabolic diseases with weight loss is an improvement in cardiovascular risk and mortality. In our study, MBS had a significantly positive impact on cardiovascular risk reduction among the local population. However, further long-term follow-up data is needed to ascertain how this translates into cardiovascular and all-cause mortality benefits.

In addition, the successful follow-up rate and good-quality data are other positive aspects of our published studies.

Conclusions and recommendations

The community prevalence of obesity and overweight is rising in Sri Lanka. Younger age groups in the urban population are predominantly affected. Thus, urgent community-based interventions are needed to combat this epidemic.

MBS resulted in effective, sustained, and progressive weight loss along with a reduction in waist circumference and body fat percentage among obese patients in the short term. Thus, MBS should be considered an effective treatment option in Sri Lankans with obesity when indicated.

Weight loss and MBS shows impressive levels of complete reversal and downgrading of NAFLD biochemically and ultrasonically in Sri Lankan patients. Bariatric surgery should be considered as a potential therapeutic option in obese South Asian patients with NAFLD, especially when it is of a higher grade.

LSG has a more favourable effect on complete reversal and improvement of NAFLD when compared with LMBG independent of weight loss. Thus LSG should be considered ahead of LMBG when MBS is planned for obese Sri Lankan patients with NAFLD.

Weight loss and MBS is associated with both short- and long-term diabetes remission in Sri Lankan population. Thus, it should be considered a potential treatment option for diabetes reversal and improvement of obesity after MBS has a significant positive impact on cardiometabolic risk reduction among people with obesity in Sri Lanka. Further long-term follow-up data is needed to ascertain how this translates into cardiovascular and all-cause mortality benefits.

Author declaration

Ethics approval and consent to participate

Ethical approval was obtained to maintain the database by the Ethics Review Committee of the Faculty of Medicine, University of Colombo and Institutional Ethics Review Committee approval was obtained for individual research.

Competing interests

None.

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