



OSSI (Obesity and Metabolic Surgery Society of India) Guidelines for Patient and Procedure Selection for Bariatric and Metabolic Surgery

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Abstract

Background India is the largest hub for bariatric and metabolic surgery in Asia. OSSI is committed to improve the quality of care and set the standards for its practice in India.

Methods The first draft of OSSI guidelines was prepared by the secretary, Dr. Praveen Raj under the guidance of current President, Dr. Arun Prasad. All executive council members were given voting privileges, and the proposed guidelines were circulated on email for approval of the executive council. Guidelines were finalized after 100% agreement from all voting members and were also circulated among all OSSI members for their suggestions.

Results OSSI upholds the BMI criteria for bariatric and metabolic surgery of 2011 IFSO-APC guidelines. In addition to this, we recognize that waist circumference of ≥ 80 cm in females and ≥ 90 cm in males along with obesity related co-morbidities may be considered for surgery. In addition to standard procedures as recommended by IFSO, OSSI acknowledges the additional procedures, and a review of literature for these procedures is presented in the discussion.

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Conclusion The burden of obesity in India is one of the highest in the world and with numbers of bariatric and metabolic procedures rising rapidly; there is a need for country specific guidelines. The Indian population is unique in its phenotype, genotype and nutritional make up. This document enlists guidelines for surgeons and allied health practitioners as also multiple other stake-holders like primary health physicians, policy makers, insurance companies and the Indian government.

Keywords Obesity and Metabolic Surgery Society of India (OSSI) · Guidelines · Bariatric and metabolic surgery · Body mass index (BMI) · Waist circumference · India · Asian Indian phenotype

Introduction

Home to more than 1.37 billion people, India today has the third highest number of people suffering from obesity in the world after USA and China [1]. With rapid increase in levels of obesity in India, bariatric and metabolic surgery has emerged as a valid option for treatment of clinically severe obesity [2]. The Obesity and Metabolic Surgery Society of India (OSSI) was established in the year 2002 with eight founding members. The OSSI had released its first position statement in the year 2013, wherein bariatric/metabolic surgeries were considered as “gastrointestinal surgeries” aimed at improving and/or treating clinically severe obesity and associated co-morbidities. It was also stated that bariatric/metabolic surgery is not a “cosmetic surgery”, but a “life-saving” one.

Today, the society has 450 registered members practicing bariatric/metabolic surgery. In the last two decades, the numbers of bariatric and metabolic surgical procedures have grown more than tenfold in India. As per OSSI data, 20,242 bariatric and metabolic procedures were reportedly performed in India in 2018, and according to the IFSO global registry report 2018, India is the largest hub for bariatric surgery in the Asian continent [3].

A guideline is a systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances [4]. Every country presents a different set of healthcare challenges. Local acceptance of various treatment options varies from region to region, and there are cultural differences that must be taken into account. The burden of obesity in India is one of the highest in the world with numbers of bariatric and metabolic procedures rising rapidly, as the national society, we feel the need for country specific guidelines that will help us to set standards and improve the quality of care for our patients.

In the last three decades, there has been exponential economic growth in India. In addition to the changing environment, Indians also have a genetic preponderance to higher body fat percentage, and that has led to a dual epidemic of obesity and type two diabetes [5]. The Asian Indian phenotype is also characterized with greater central obesity [6]. Studies have shown that in Indian population there is a higher association of central obesity with development of type two diabetes mellitus than that of generalized obesity [7]. Along with this, it is seen that obesity-related metabolic diseases tend

to develop at a much lower body mass index (BMI) in the Asian population [8]. Thus, in the Indian context, not only do we need to have lower BMI criteria as compared to western countries, we also need to take waist circumference into account for classifying obesity.

While on one hand, we have a burgeoning healthcare problem in the form of obesity and type two diabetes mellitus, on the other hand, we are struggling with resources to battle non-communicable diseases. Unlike most western countries, India does not have state sponsored health coverage. Health insurance sector is dominated mainly by private insurance players. Until recently, the Indian insurance sector classified obesity and related disorders as a “cosmetic” issue and any kind of treatment for “obesity”, and related disorders was excluded from insurance coverage. In October 2019, Insurance Regulatory and Development Authority of India (IRDAI) has finally acceded to include bariatric and metabolic surgery as a treatment option for clinically severe obesity and its related diseases. Though this is a welcome change, in absence of country specific guidelines, IRDAI has chosen to follow the archaic NIH guidelines for bariatric and metabolic surgery [2]. As a result of this, many deserving patients will get excluded and will not be able to avail insurance benefit for the treatment of obesity and related metabolic disorders.

These guidelines recommended in this paper are based on previously published guidelines like NIH, JSSO, APMBSS, OSSANZ, ACMOMS, ADSS, DSS and IFSO-APC [2, 9–12]. IFSO APC guidelines of 2011 are the most recent published guideline for the Asian region; however, these are now almost a decade old [9]. The trends in bariatric/metabolic surgery have changed considerably in the last decade, and there is an influx of new literature. While the OSSI guidelines acknowledge these guidelines and have borrowed from them, there was a need to review the new literature and propose an updated country specific guideline for bariatric/metabolic surgery.

The aim of this document is to enlist the OSSI guidelines for patient and procedure selection for surgeons and allied health practitioners practicing bariatric and metabolic surgery. These guidelines intend to guide IRDAI and multiple other stake-holders such as primary health physicians, specialty doctors, patients, policy makers and the Indian government. We also acknowledge that these guidelines are not rigid recommendations to be enforced in all situations and ultimately clinical discretion is of greatest importance.

Methods

The first draft of the OSSI guidelines was prepared by the OSSI Secretary, Dr. Praveen Raj under the guidance of the current President, Dr. Arun Prasad. All the executive council members were given voting privileges, and the proposed guidelines were circulated on email for suggestions and subsequent approval of the executive council. The OSSI executive council consists of the president, secretary, treasurer, joint secretary, the past presidents of the society and two elected members from the North, South, East, West and Central zones of the country. The elected members serve as the representatives of their respective zones. Table 1 delineates the list of executive council members who served as moderators and voting members for the formulation of these guidelines. These guidelines were finalized after 100% agreement from all voting members. They were also circulated among all OSSI members for their valuable suggestions. This article does not contain any studies with human participants or animals performed by any of the authors, and a statement of informed consent does not apply in this case.

Guidelines

Indications for Bariatric/Metabolic Surgery

1. Bariatric/metabolic surgery should be considered a treatment option for acceptable Indian patients with a BMI ≥ 35 kg/m², with/without presence of any obesity related co-morbidity [9].
2. Bariatric/metabolic surgery should be considered a treatment option for acceptable Indian patients with a BMI ≥ 30 kg/m², in presence of two or more obesity related co-morbidities [9].
3. Bariatric/metabolic surgery should be considered as a non-primary treatment option for acceptable Indian patients with a BMI ≥ 27.5 kg/m², with uncontrolled type 2 diabetes despite optimum medical management [9].
4. Any bariatric/metabolic surgery for an Indian patient with BMI < 27.5 kg/m² should be strictly performed under experimental study protocol with prior ethics committee approval and informed consent from the patient [9].
5. Bariatric/metabolic surgery should be considered as a treatment option for acceptable Indian patients with central obesity with a waist circumference ≥ 80 cm in females and ≥ 90 cm in males along with type two diabetes and other obesity related co-morbidities [10].
6. Bariatric/metabolic surgery may be advised as a treatment option for acceptable Indian patients who qualify for the above BMI criteria if they are ≥ 18 years of age. It may be advised as a treatment option to patients younger than 18 years of age under special circumstances with approval of a multi-disciplinary team constituting a paediatrician, endocrinologist, dietician, psychologist and the bariatric team including a bariatric surgeon. Attainment of puberty and completion of skeletal maturity must be taken into account for this patient population when considering the option of surgery [13, 14].
7. Bariatric/metabolic surgery should be advised as a treatment option for acceptable Indian patients who qualify for

Table 1 List of voting members

1	Arun Prasad	President	Moderator
2	Praveen Raj Palanivelu	Secretary	Moderator
3	Randeep Wadhawan	Joint Secretary	Voting
4	Manish Khaitan	Treasurer	Voting
5	Abhay J Agrawal	Executive council member (West Zone)	Voting
6	Aparna Govil Bhasker	Executive council member (West Zone)	Voting
7	Om Tantia	Executive council member (East Zone)	Voting
8	Sarfraz Baig	Executive council member (East Zone)	Voting
9	Rajkumar Palaniappan	Executive council member (South Zone)	Voting
10	H V Shivaram	Executive council member (South Zone)	Voting
11	Sumeet Shah	Executive council member (North Zone)	Voting
12	Vandana Soni	Executive council member (North Zone)	Voting
13	Mohit Bhandari	Executive council member (Central Zone)	Voting
14	Rakesh Shivhare	Executive council member (Central Zone)	Voting
15	Shrihari Dhorepatil	Past President	Voting
16	Pradeep Chowbey	Past President	Voting
17	Mahendra Narwaria	Past President	Voting
18	Shashank Shah	Past President	Voting
19	Rajesh Khullar	Past President	Voting

the above BMI criteria for patients up to 65 years of age. Bariatric/metabolic surgery may also be recommended for patients ≥ 65 years of age if they are medically fit, and the benefits of surgery outweigh the risks [15].

8. All patients who are advised bariatric/metabolic surgery as a treatment option should be motivated to enter a long-term weight management program and should be committed to life-long follow up [16]
9. Long-term weight management programme and follow-up must be provided by all bariatric teams [17].

Contra-Indications for Bariatric/Metabolic Surgery

1. Bariatric/metabolic surgery may not be advised as a treatment option to a patient who is unable to adhere to prolonged follow up programme or express inability to take nutritional supplements [18].
2. Bariatric/metabolic surgery may not be advised as a treatment option to patients who are medically unfit to undergo a surgery [19].
3. Bariatric/metabolic surgery may not be advised as a treatment option to patients with non-stabilized psychiatric disorders [19].
4. Bariatric/metabolic surgery may not be advised as a treatment option to chronic smokers, chronic alcoholics or patients with drug dependencies unless they have been through a deaddiction programme successfully [19].
5. Bariatric/metabolic surgery may not be advised as a treatment option to patients who have a short life expectancy or are suffering from a terminal illness [19].
6. Bariatric/metabolic surgery may not be advised as a treatment option to pregnant women or those who wish to conceive within 1 year after surgery [19].

Standard Procedures

1. Adjustable gastric banding (AGB)
2. Sleeve gastrectomy (SG)
3. Roux en y gastric bypass (RYGB)
4. Biliopancreatic diversion with duodenal switch (BPD-DS)
5. One anastomosis gastric bypass/mini gastric bypass (OAGB/ MGB).

Additional Procedures

1. Sleeve gastrectomy with ileal transposition (SG-IT).
2. Sleeve plus procedures. These procedures involve sleeve gastrectomy with various types of intestinal bypasses. These include but are not limited to sleeve gastrectomy with duodeno-jejunal bypass (SG-DJB), sleeve

gastrectomy with duodeno-ileostomy (SADI), single anastomosis sleeve ileal bypass (SASI), vertical isolated gastroplasty with gastro-ental bypass, sleeve gastrectomy with transit bipartition, etc.

3. Endoluminal therapies. Intra-gastric balloon insertion, endoscopic sleeve gastroplasty and other endoscopic procedures for revision and treatment of complications. These may be performed by a bariatric surgeon, trained in endoscopy or by a gastroenterologist trained in bariatric endoscopy.

There is yet moderate evidence for procedures categorized under “Additional procedures”, and the decision regarding the choice of procedure lies at the clinical discretion of the clinician.

Discussion

With increasing levels of obesity in the population, increasing awareness and acceptance among common people, growing interest of surgeons in the specialty of bariatric and metabolic surgery and the recent inclusion for insurance coverage by the Insurance Regulatory and Development Authority (IRDAI), bariatric and metabolic surgery as a specialty is at a tipping point in India today. We expect the numbers of bariatric and metabolic procedures to increase rapidly in the next 5 years. Hence, it is imperative for us to work towards setting the standard for providing best possible care for patients. These guidelines are a tool to streamline consistency and efficiency of care for but not limited to bariatric surgeons, specialty doctors, allied health practitioners, family physicians, insurance payers and policy makers.

WHO defines obesity as a condition of excessive fat accumulation to the extent that health and well-being are affected. Multiple studies have proven that Asians have a higher body fat percentage as compared to their western counterparts [14, 15, 20]. It has also been reported that Asians tend to develop obesity-related health risks even at BMI as low as 22 to 23 kg/m² [8]. In February 2000, WHO revised the BMI cut off for Asians at 23 and 25 kg/m² for overweight and obesity, respectively. The IFSO-APC guidelines in 2011 took note of these cut-offs and suggested lower BMI cut-offs for Asian population [9]. OSSI upholds the IFSO-APC BMI cut-offs for bariatric surgery. In addition to the BMI cut-offs, OSSI has also included waist circumference as additional criteria for bariatric surgery. Waist circumference of more than 80 cm in females and 90 cm in males has shown to be associated with increased risk of metabolic syndrome in Asians [21]. The Asian Indian phenotype characteristically has a higher waist circumference and greater incidence of central obesity. Many Asian patients may not classify as obese by the western criteria, but owing to increased incidence of central obesity are rendered insulin resistant and metabolically obese. Central obesity predisposes them to type two diabetes and other metabolic diseases at a

much lower weight and BMI [6, 22–24]. OSSI also upholds the age criteria of IFSO APC guidelines from 18 to 65 years. However, in special circumstances when the benefits of bariatric and metabolic surgery may outweigh its risks, surgery may be extended as a treatment option for adolescents less than 18 years and patients older than 65 years of age [13–15].

Bariatric and metabolic surgery is an evolving field, and the trends of surgery are ever changing. The 2011 IFSO-APC guidelines recognized gastric banding, sleeve gastrectomy, gastric bypass and BPD-DS as generally recognized procedures. In terms of evidence, level one evidence is now available for all the procedures mentioned in IFSO-APC guidelines, and the grade of recommendation is A [25]. OSSI endorses all the above-mentioned procedures as mentioned in IFSO-APC guidelines [9].

However, over the last 8 years, in addition to the above-mentioned procedures, newer procedures and certain modifications of older procedures have emerged and gained popularity in India. Table 2 depicts the numbers of different types of surgical procedures performed in India in 2018 (Source: OSSI data). As shown in the table, one anastomosis gastric bypass/mini-gastric bypass (OAGB/MGB) has emerged as the second most popular procedure after sleeve gastrectomy in India in recent times. Kular et al. from India have reported a high weight loss and a high satisfaction rate after OAGB/MGB in a 6 years study. They reported a low complication rate and a reversal rate of 0.2% [26]. In another study by GS Jammu et al., OAGB/MGB emerged as an effective procedure out 1107 cases of which there were 473 cases of OAGB/MGB, 339 LSG and 295 RYGB. They attributed the success of the procedure to its ease of performing, efficacy and reversibility [27]. OAGB/MGB has enjoyed a sudden yet sustained popularity among the Indian surgeons. While the literature does not suggest much cause for concern, there have been deliberations about biliary reflux, the future possibility of carcinoma at the gastro-enterostomy site along with optimum limb lengths and nutritional issues, especially for the Indian population which is largely vegetarian. It has now generally been accepted that a bilio-pancreatic limb length of about 150 cm has minimal nutritional deficiencies with adequate results [28–30]. As yet, we have level two evidence for OAGB/MGB, and hence, the grade of recommendation would be B until more robust data comes in.

Table 2 Depicts the numbers of different types of surgical procedures performed in India in 2018 (Source: OSSI data)

Surgery type	Numbers
Adjustable gastric banding	6
Roux-en-Y gastric bypass	3058
One anastomosis/mini gastric bypass	7042
Sleeve gastrectomy	9880
BPD DS	5
Sleeve plus procedures	117
Endoluminal procedures	84
Others	50

Though the numbers are small, ileal transposition with sleeve gastrectomy is also being consistently performed in India, for metabolic improvement and weight loss in select population for over more than 15 years. Ileal transposition with diverted sleeve gastrectomy is another variant of ileal transposition which has been proposed by some authors. These procedures have also been proposed as a treatment option for low BMI type two diabetics [31, 32]. However, there is a need for better evidence with larger trials and longer follow-ups. Grade of recommendation for this procedure would be B in the presence of moderate evidence to support its use.

Over the last couple of years, the concept of sleeve plus procedures has emerged in Asia and India. In the last decade, sleeve gastrectomy enjoyed immense popularity, and even today it is one of the most commonly performed bariatric/metabolic procedure. We are aware that obesity is a chronic progressive disease, and almost all bariatric procedures are plagued with the issue of weight regain in the long term. This is more so with restrictive procedures like the sleeve gastrectomy [33]. The idea of sleeve plus procedures emerged from the success of BPD DS but with an effort to decrease the related nutritional and metabolic complications and increase the technical ease of performing them. These procedures involve sleeve gastrectomy with various types of intestinal bypasses. These include but are not limited to sleeve gastrectomy with duodeno-jejunal bypass (SG-DJB), sleeve gastrectomy with duodeno-ileostomy (SADI), single anastomosis sleeve ileal bypass (SASI), vertical isolated gastroplasty with gastro-enteral bypass, sleeve gastrectomy with transit bipartition, etc. [34]. Though the rationale is to reduce the morbidity and increase the effectivity of existing procedures, at the moment, we only have level three evidence for these procedures, and the current grade of recommendation would be C.

Endoscopic sleeve gastroplasty (ESG) is a technique to reduce gastric volume using full thickness sutures. It is performed trans-orally, and the sutures extend from incisura – upwards along the greater curvature of the stomach. ESG is of value for those patients who desire greater efficacy and better results than currently available conventional conservative medical methods for weight loss and has been positioned as an efficacious bridge procedure for such patients [35–39]. Though ESG is less invasive, safer and has less complication, it leads to lesser weight loss and long-term results are yet lacking. As yet we have level two evidence for ESG, and grade of recommendation would range between B and C in the absence of long-term data. Same holds true for other endoscopic interventions that are currently being used for revisions and management of complications.

Bariatric science is evolving at a fast pace, and there is an influx of newer devices, endoscopic procedures as well as multiple modifications of existing operations. The quest for procedures with better outcomes along with lower morbidity and mortality continues, and it is a constant endeavour from bariatric surgical community to improve upon the existing surgical options.

The purpose of these guidelines is not to be rigid but to better define the checks and balances for patient care. IFSO recognizes, gastric banding, sleeve gastrectomy, Roux-en y gastric bypass, one anastomosis gastric bypass and BPD-DS as standard bariatric procedures. We have presented an overview of the evidence and current status of other procedures and advise a careful scrutiny of results before tailoring treatment options for patients. Having said that, today the world is staring at an epidemic of obesity, and currently, less than 1% eligible patients are able to avail bariatric surgery. There is a need to be more inclusive and also recognize that something is better than nothing. However, the onus is on bariatric community to be able to offer all options after using their clinical discretion for the best interest of their patients. Practitioners must be cognizant of the available literature and data and must refrain from advising ineffective, harmful and wasteful interventions.

These guidelines will also serve as a reference point for insurance payers in India. In a recent positive development, the IRDAI does not consider bariatric and metabolic surgery as an exclusion anymore, and patients will be eligible to avail insurance. However, the IRDAI has chosen the age-old NIH criteria for patient selection. This will deny the benefit of bariatric and metabolic surgery to many suitable patients. In the presence of strong data and pre-existing guidelines with lower BMI cut-offs, in the future, OSSI guidelines will serve to reinforce the need for insurance coverage for the rightfully eligible patient population.

Bariatric science is growing at a rapid rate, and the dynamics of treatment options are ever changing. There is a constant influx of new data, and hence, there is a need for regular re-evaluation of recommendations and guidelines. Hence, at OSSI, we recommend that these guidelines may be re-evaluated every 3 years, and appropriate modifications and updates may be made. We also acknowledge that the Indian population is unique in its phenotype, genotype and nutritional make up. We in India need to focus more on research related to obesity and its associated diseases as well as long-term studies to evaluate the outcomes of various bariatric/metabolic procedures. While the quest for the ideal bariatric procedure goes on, we must together focus on breaking barriers that prevent patients from getting an access towards treatment of obesity.

Compliance with Ethical Standards

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

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