Patient and procedure selection for bariatric and metabolic surgery in Malaysia- The Malaysian Consensus

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ABSTRACT
The rise in obesity has fuelled the current debate of its classification as a disease. Contrary to just being a medical condition or a risk factor for other diseases, obesity is a complex disease with multifaceted aetiology as well as its own disabling capacities, pathophysiology, and comorbidities. The problem of obesity in Malaysia is serious and calls for active intervention by all stakeholders ranging from government agencies to insurers and healthcare providers. To aid efforts to curb obesity, this consensus statement for bariatric surgery provides a basis for inclusion and exclusion criteria as well as the types of procedures accepted as the norm in Malaysia. This consensus statement was initiated by the Society of Endoscopic and Laparoscopic Surgeons of Malaysia and was collaborated with representatives from the Ministry of Health Malaysia.

KEYWORDS:
Bariatric surgery, bariatric policy, obesity, malaysia weight loss

INTRODUCTION
Obesity is fast becoming a global pandemic with over one million affected individuals.¹ Malaysia is not an exception. Approximately 45.3 percent of Malaysians have been identified as either overweight or obese.¹ The fast food culture, the ubiquitous popularity of fast food, increasingly sedentary lifestyles, and the mechanisation of transportation modalities are among the many factors that have led to this health dilemma.² The burgeoning growth of the middle-class has further resulted in higher income that feeds such sedentary lifestyles and access to fatty fast food.³

The growing prevalence of obesity in Malaysia goes hand in hand with the rise in Type 2 Diabetes Mellitus (T2DM), which was found to affect 3.5 million (17.5%) individuals in 2015.¹ Malaysians are from three predominant races, namely Malays, Chinese, and Indians and differences in BMI and medical conditions are observed. For instance, the occurrence of obesity and T2DM has been reported to be higher in Malaysians of Indian women compared with men and Malaysians of other ethnicity.¹ Specifically, the Indians have a higher preponderance of central obesity; the Malays have a genetic tendency for both diabetes and obesity; whilst the Chinese have a lower limit for obesity.⁴ Based on this, a lower BMI standard is recommended for the Malaysian population.⁵

Worldwide obesity as an obvious concern and a major public health challenge and the associated co-morbidities can dampen the productivity of the working class and threaten future economic development in addition to compounding healthcare costs.¹ In 2010 alone, global expenditure on diabetes was estimated at approximately USD$376 billion, forcing member states of the World Health Organisation (WHO) to take immediate notice and introduce plans to combat the rise of obesity and diabetes by 2025.⁶

Malaysia has a dual healthcare system, i.e. public and private. The public system, which is heavily subsidised the Malaysian government, consists of hospitals under the Ministry of Health, Malaysia (MOH), the Ministry of Higher Education, and the Ministry of Defence. The private sector, comprises hospitals under private or equity ownership either by a single conglomerate or a group of conglomerates. This dual system makes it challenging to implement standards for adoption across the board. Another unique aspect of Malaysia’s healthcare is its dependence on insured clients rather than out-of-pocket payees in the private sector.¹

The members of the Society of Endoscopic and Laparoscopic Surgeons of Malaysia (SESLSMA) and the Malaysian Bariatric Society (MyMBS) consist of approximately 62 surgeons who perform open and laparoscopic surgery. Currently, the stance of Malaysian insurance players is that bariatric surgery is a cosmetic procedure. This paper aims to rebut this stance by explaining the importance of bariatric surgery as a necessary metabolic procedure with benefits far beyond cosmetic gains. Advocating that such surgery should be covered by the existing and new policies, this consensus statement advocates the cooperation of the two aforementioned societies to produce a guideline that hopes to serve both the public and private sectors.

Trends in bariatric/metabolic surgery have changed considerably in the last decade, leading to an influx of new findings. While the Malaysian guidelines acknowledges these new developments and have adopted from them, there remains a need to review the newer findings and propose an updated country-specific consensus for bariatric/metabolic
surgery. Therefore, the consensus statement recommended in this paper are drawn from previously published guidelines, such as those by National Institute of Health (NIH), Japanese Society of Surgery for Obesity and Metabolic Disorders (JSSO), Asia Pacific Metabolic and Bariatric Surgery Society (APMBSS), Obesity Surgical Society of Australia and New Zealand (OSSANZ), Asian Consensus Meeting on Metabolic Surgery (ACMOMS), Asian Diabetic Surgery Summit (ADSS), Diabetes Surgery Summit (DSS), and the IFSO-APC. The aim of this document is to enlist the guidelines developed by a consensus committee comprising bariatric surgeons, endocrinologists, dieticians, pharmacists, intensivists and anaesthetists and is essentially a guide for surgeons and centres that perform Bariatric Surgery as one of their services. Though the initial focus was to provide a guide for Ministry of Health facilities exclusively, the scope was then expanded to encompass the entire health framework of Malaysia.

MATERIALS AND METHODS
The consensus statement were drafted in several meetings held at various points of time beginning in 2014. The meeting committee was initially termed the Bariatric Metabolic Working Committee and eventually evolved to become the Bariatric and Metabolic Framework Committee. The role of this committee was to draft the framework of this policy so that a standard guideline can be adopted by its members.

Meetings were normally conducted as smaller groups with specific assignments. The assignments included discussing the following:
1. Reviewing existing policies and tailoring them for the Malaysian context;
2. Including training protocols and training centres; and
3. Discussing goals and targets to be achieved through this policy.

At the end of the meetings, a drafting committee was elected to write the agreed consensus and subsequently present the report to the MOHM for approval. The drafting committee completed a final meeting in Putrajaya, the administrative capital of Malaysia, on 14th May 2019. To further validate the consensus, the committee also invited several key international surgeons in the field of bariatric and metabolic surgery. The members of the committee were assigned roles and were accepted as voting members. A vote was held to adopt or reject the said policy. The consensus process was done by circulating the document to all members of the committee for recommendations and subsequent approval or corrections. The elected members then act as representatives in their respective fields. These guidelines were finalized after complete agreement from all voting members.

RESULTS
The consensus statements adopted from the meetings are as follows.

Part 1. Indications for Bariatric Surgery
The following patients are indicated for bariatric surgery:
1) Morbid obesity without any comorbidities:
   i. Bariatric surgery should be considered for the treatment of obesity in suitable patients with BMI ≥ 37.5 kg/m² who fulfill the selection criteria.

2) Morbid obesity with metabolic syndrome:
   i. The surgical approach may be considered as a non-primary alternative to treat obesity in suitable patients with BMI ≥ 32.5 kg/m² with metabolic syndrome or cardiovascular risk following inadequate weight loss by virtue of medical therapy and lifestyle modifications.

3) Low BMI with or without comorbidities:
   i. Any surgery for metabolic syndrome or obesity related comorbidity in patients with a BMI ≤ 32.5 kg/m² should not be a routine clinical practice and should be strictly performed only under clinical study protocol with informed consent from the patient and prior approval from an ethics committee.

4) Age restriction:
   i. Bariatric surgery is generally recommended for patients between the ages of 18 and 65 years.

5) Special circumstances:
   i. Upon consultation with a physician, paediatrician, orthopaedic surgeon, clinical psychologist, or a surgeon, bariatric surgery may be performed in morbidly obese adolescent patients provided they have attained the physiological bone maturity consistent with Tanner stage four.

Part 2. Selection Criteria for Bariatric Surgery
Patients who fulfill the indications in Part 1 should satisfy the criteria below:
1) Weight loss history:
   i. Previous nonsurgical attempts at weight reduction for at least six months.

2) Patient commitment:
   Patients are required to comply with the prescribed programme, which includes:
   i. Follow-up visits with healthcare teams, voluntary participation in support groups, and other recommendations made by healthcare teams.
   ii. Recommended medical management, including the use of dietary supplements and exercise routine.
   iii. Compliance with instructions regarding any recommended procedures or tests.
   iv. Smoking cessation for a minimum of four weeks prior to surgery.

Part 3. Types of Bariatric Procedures
The committee also deliberated on several established studies comparing the effectiveness of various treatments, in particular sleeve gastrectomy and the gastric band. The consensus recommends the four procedures listed below, in line with recommendations from international guidelines for bariatric surgery:

- Restrictive
  1) Gastric band
  2) Sleeve gastrectomy (Refer to Figure 1)

- Malabsorption
  3) Biliopancreatic diversion / Duodenal switch (BPD/DS)
  4) Roux-en-Y gastric bypass (Refer to Figure 2)
Although novel bariatric surgical procedures (outside the scope of the four mentioned) have shown promising results for Asians, such procedures should only be carried out by surgeons with experience. Examples of these new procedures include the One Anastomoses Gastric Bypass (OAGB) and the Single Anastomoses Duodenal Ileal Bypass with Sleeve Gastrectomy (SADI-S).

Part 4. Contraindications to Bariatric Surgery
It was agreed upon that the following patients are contraindicated for this procedure:
1. Pregnant patients.
2. Patients who are unable to comply to continuous medical follow-ups as required.
3. Patients with non-stabilised psychotic disorders, severe depression, or personality and eating disorders, unless specifically advised by a psychiatrist/psychologist.
4. Patients with reversible endocrine disorders that can cause obesity.
5. Patients with alcohol abuse and/or drug dependencies.
6. Patients with diseases threatening their life in the short term (ASA-4).
7. Patients who are unable to care for themselves and have no long-term family or social support to provide such care.

Part 5. Audit and Governance
All bariatric surgery procedures must be documented using a standard notification document. All forms of patient data should be kept by the bariatric nurse or case manager and dispatched for audit on a yearly basis upon request. Mortality from bariatric surgery should be reported with adequately filled and submitted Post Operative Mortality Report forms.

DISCUSSION AND CONCLUSION
Bariatric and metabolic surgery continues to gain acceptance around the world due to its popularity of the technique and outcome. In Malaysia, the introduction of bariatric and metabolic surgery remains at a moderate level with several hospitals offering surgical services and establishing dedicated weight loss units. Existing information suggests that the sleeve gastrectomy remains the popular procedure of choice in Malaysia. In a study conducted at the Taiping Hospital, Malaysia and published in 2019, the sleeve gastrectomy was performed on more than half of the patients while the other patients underwent bypasses. A survey among surgeons also showed the same outcome reflecting their preference for the sleeve gastrectomy.

Facts on obesity stipulates that Malaysia has the highest number of overweight and obese patients among Asians at 64 percent of males and 65 percent of females. Reports also reveal that the prevalence of diabetes among adults aged 18 and above increased from 11.6 percent to 17.5 percent over the nine-year period from 2006 to 2015. The presence of hypertension remains high as well at around 30 percent. Notably, more than half of cases of diabetes or hypertension are undiagnosed. Throughout the world, newer and more amended policies have been developed to combat diabetes, which include algorithms for the treatment of diabetes with bariatric surgery. The worrying figures mentioned above warrant a review of the current strategies, particularly in relation to combating this problem in Malaysia. Better policies are required not just to guide practising surgeons and physicians on referral policies but also to streamline and standardise the existing practices of bariatric and metabolic surgery in Malaysia.
In Malaysia, two issues need to be addressed pertaining the progression of bariatric and metabolic surgery. First, there is a lack of policies and training programmes for surgeons and this may be resolved through this consensus statement, as well as through efficient top-down direction from the MOHM. The second issue is the lack of support and coverage from insurance providers for this procedure, and consequently cost needs to be borne by patients to undergo the procedure in public facilities. Though the operative fees and hospital administrative charges are minimal, patients still have to pay for consumables such as staplers, energy devices, and trocars. In Malaysia, patients can fund their bariatric and metabolic surgery via withdrawals from their Employers Provident Fund, reimbursement from the Federal Government (JPA), or a soft loan from a local financial P2P portal with low interest and flexible payment schemes.11

The existing evidence points towards a dire need for a standardised policy to allow all stakeholders to be on the same page. The field of bariatric science evolves continuously and as such it is essential that this change is effectively embraced to offer the best service to patients. Hence, the rapid changes in this field demands that policy be revisited every three years to adapt to latest developments. It is also hoped that better research goes into the phenotyping and genotyping of the Malaysian population to determine the cause of growing obesity rates. While this consensus paper serves as a guide for surgeons undertaking bariatric surgery, it should be noted that it does not constitute a strict guideline that restricts further changes in the future.

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