**Title:** Procedure and Patient Selection in Bariatric and Metabolic Surgery

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**Abstract:**

**Introduction:** Sleeve Gastrectomy (SG), Roux-en-Y Gastric Bypass (RYGB), and One Anastomosis Gastric Bypass (OAGB) are the commonest bariatric procedures performed worldwide. The purpose of this review was to analyse comparative data on these three procedures to aid patient and procedure selection for patients seeking Bariatric and Metabolic Surgery (BMS).

**Evidence Acquisition:** We examined published English language scientific literature available on PubMed for data comparing SG, RYGB, and OAGB for various groups of patients.

**Evidence Synthesis:** There are a number of variables that can influence patient and procedure selection for individuals seeking BMS. High-quality data comparing each of these procedures for every patient subgroup, for each possible outcome measure is lacking. It is, therefore, not currently possible to make strict recommendations regarding patient and procedure selection. At the same time, the multidisciplinary teams should understand that risks of surgery may simply be too high for some patients – such as those suffering from end-stage organ disease and those suffering from mega obesity (BMI ≥ 70 $kg/m^2$). Surgery should only be offered to such high-risk groups in dedicated centres with appropriate expertise. For other patients, surgeons should carefully consider the pros and cons of each procedure, their own experience, and patient preferences before deciding the most appropriate BMS procedure for them.

**Conclusion:** This review examines various factors influencing patient and procedure selection in bariatric surgery. Authors feel it is currently not possible to make strict recommendations and surgeons should carefully discuss the pros and cons of bariatric surgery and that of various options available in their practice with the patients before making a final recommendation.

**Key Words:** Bariatric Surgery, Obesity Surgery, Patient Selection, Procedure Selection, Roux-en-Y Gastric Bypass, Sleeve Gastrectomy, One Anastomosis Gastric Bypass, Mini Gastric Bypass, Omega Loop Gastric Bypass, Single Anastomosis Gastric Bypass

**Introduction:**

Practitioners of Bariatric and Metabolic Surgery (BMS) now have more options at their disposal than ever before [1] but the data comparing different procedures for each of a large number of subgroups of patients seeking primary BMS simply does not exist. Studies that do compare different procedures often include all the patients who meet the criteria for BMS [2]. As such they include a very heterogeneous group of patients. Within such groups, subgroups of patients may exist that have very different characteristics from that of the group as a whole.

Patients suffering from more advanced obesity (super obese for example), Type 2 Diabetes Mellitus (T2DM), Gastro-Oesophageal Reflux Disease (GORD), Barrett's Oesophagus (BO), End-Stage Organ Disease, etc. may fall into this category. Scarcity of data makes it extremely difficult for practitioners to choose the most appropriate option for an individual patient from a number of options available.

Furthermore, widely accepted entry criteria for bariatric and metabolic surgery are still based on a consensus achieved some 28 years ago [3]. It is worth emphasising that this was a consensus amongst professionals and as such was not really a data-driven exercise. The Body Mass Index (BMI) cut-offs of 40 $kg/m^2$ without any co-morbidity and of 35 with a co-morbidity $kg/m^2$ as qualifying criteria are not backed up by a thorough statistical evaluation of risks versus benefits of bariatric surgery at various BMI cut-offs.

With the rapid improvement in the safety of BMS, it has now become apparent that some patients with a BMI of between 30 $kg/m^2$ - 35 $kg/m^{2,}$ especially those suffering from T2DM could also benefit from BMS at an acceptable risk. This has led to the inclusion of this group of patients within the qualifying criteria for BMS [4] but once again high-quality data comparing one procedure with the other for patients in this subgroup, and indeed further sub-categories within it, are largely non-existent.

At the same time, one has to recognise that there are patients amongst those who meet the qualifying criteria for BMS [3-4], whose surgical risks might just be too high. Patients with high anaesthetic risk, End Stage Organ Disease or Organ Failure, or mega obesity (BMI ≥ 70 $kg/m^2$)

might fall into this category. Once again, robust studies comparing risks versus benefits of BMS versus medical management do not exist for these subgroups of patients. Reported data on the results of BMS in most of these subgroups of patients largely comes from small patient series and is as such subject to significant publication bias and Type 2 error when it comes to morbidity and mortality of BMS in these patients.

In the absence of high-quality data, procedure and patient selection for patients seeking primary BMS can be a difficult exercise. The purpose of this review is to provide a comparative analysis of different procedures for different sub-groups of patients seeking BMS and also to find out if there are sub-groups amongst patients who meet agreed qualifying criteria for whom the surgery may not be routinely recommended.

**Evidence Acquisition**

Though there are a large number of BMS procedures currently being practiced, there are only four that accounted for more than 1.0 % of all primary BMS procedures worldwide in 2016 [1]. These are SG (53.6 %), RYGB (30.1 %), OAGB (4.8 %), and AGB (3.0%). Furthermore, given the steep rate of decline of AGB, we suspect AGB accounts for an even lower proportion of primary procedures now than it did in 2016. Hence, we have focused on only SG, RYGB, and OAGB in this review.

An online search of PubMed database was carried out using key-words like, 'bariatric surgery', 'obesity surgery', 'metabolic surgery', 'gastric bypass, 'Roux-en-Y Gastric Bypass (RYGB), 'One Anastomosis Gastric Bypass (OAGB)', 'Mini Gastric Bypass', 'Omega Loop Gastric Bypass', 'Single Anastomosis Gastric Bypass', 'Loop Gastric Bypass', and 'Sleeve Gastrectomy (SG)' to identify all articles on this topic. Articles were also identified from references of relevant articles. Last of these searches were carried out on 15$^{th}$ June' 2019.

Given the relative lack of Level 1 evidence in this area, authors did not think a meta-analysis or a systematic review was feasible for all the various subgroups of patients. We hence felt an evidence-based narrative review, which takes into account the published evidence as well as our own experience would be the best way to achieve the objectives of this paper.

**Evidence Synthesis:** We compare the safety and efficacy of these three commoner BMS procedures - SG, RYGB, and OAGB - for different patient characteristics and patient subgroups in the following paragraphs.

## 1. Comparative Efficacy of Procedures for Weight Loss

Generally, weight loss with OAGB seems to be better than that seen with either RYGB or SG [2, 5-6] but the difference in weight loss between OAGB and RYGB is small and perhaps clinically not meaningful. It should also be noted that marginally superior weight loss seen with OAGB in comparison with RYGB [7] might be due to higher rates of malnutrition [8-9] seen with it and that if surgeons used the recommended safe Bilio-Pancreatic Limb (BPL) length of 150 cm for OAGB [8, 10], the superiority in weight loss might disappear or become clinically irrelevant.

There are studies that have observed superior weight loss with OAGB in comparison with RYGB and/or SG in those with a BMI of ≥ 60 kg/$m^2$ [11-12], and those with a BMI of ≥ 50 kg/$m^2$ [13]. Due to this and the fact that RYGB can be technically demanding to perform in those with a BMI of ≥ 50 kg/$m^2$, authors prefer OAGB in this subgroup.

SG can also be relatively easier to perform in these patients but the weight loss can be disappointing, increasing the need for a second line procedure. Previous authors [14] have found that RYGB offers significantly higher weight loss in comparison to SG at 2 years in patients with a BMI of ≥ 45 kg/$m^2$. In a recent study of 5-year results after SG [15], we also found that patients with BMI ≥ 45 kg/$m^2$ had significantly higher absolute weight loss, percentage Excess weight loss, and higher percentage total weight loss in comparison with those with a BMI < 45 kg/$m^2$ (unpublished data). We, therefore, feel SG should probably be reserved for those with a lesser burden of obesity such as those with a BMI of < 45 kg/$m^2$, in whom the difference in weight loss between SG and a gastric bypass would be clinically irrelevant. It is all the more important because SG also seems to be associated with more weight regain in comparison with RYGB or OAGB [16]. Our current practice is to avoid SG in those with a BMI of ≥ 45 kg/$m^2$ and avoid RYGB in those with a BMI of ≥ 50 kg/$m^2$ unless dictated by other factors or patient preference

## 2. Comparative Efficacy of These procedures for patients with T2DM

OAGB appears to be superior to RYGB and SG in terms of diabetes remission rates [2,5,17-18] but many authors [2] have not found RYGB to be significantly superior to SG for diabetes remission. So, for patients whose main objective from surgery is an improvement in T2DM, OAGB would seem to be a better choice than either RYGB or SG. The reason(s) for apparent superiority of OAGB over RYGB is not entirely clear. Whether it is due to an absent Roux limb [19] or longer BPL remains to be adequately studied. Given that with RYGB, even prolonging the length of the BPL does not increase diabetes resolution rates [20], it does appear that an absent Roux limb might be an important factor in improving the anti-diabetic effect of OAGB.

It would be useful to determine if there is a linear dose-response relationship between the length of BP limb and the diabetes resolution rates in the context of OAGB. If not, as is the case with RYGB [20], we need to determine the minimum length of BPL that will yield most of its metabolic effect. That will be particularly relevant for patients with a lesser burden of obesity – like those suffering from class 1 obesity and those who are overweight – who are seeking pure metabolic surgery for remission or improvement of T2DM.

## 3. Comparative Safety of Procedures

RYGB seems to be associated with a 30-day mortality of 0.2 % in comparison with 0.1 % seen with SG and OAGB [21-22]. In a recent survey of surgeons, RYGB was also rated as the most challenging procedure with a mean rating of 3.68+/- 1.16 on a scale of 1-5 compared to SG (2.34+/-0.89) and OAGB (2.34 +/-0.97) [23].

RYGB is also associated with approximately double the rate of unplanned admission to intensive care unit 30-day re-operation, and 30-day readmission in comparison with SG [21]. In a recent RCT comparing RYGB and OAGB [24], OAGB group had half the early complication rate (3.4 % vs 6.8 %) and there were two 30-day reoperations in the RYGB group compared to one in the OAGB group.

In the long-term, major problems seem to be GORD and Weight Regain with SG [15-16]; GORD and malnutrition with OAGB [24]; and Internal Hernia and chronic abdominal pain with RYGB [25] respectively. A recent study [26] found that at 5-year follow up SG was associated with a significantly lower rate of re-intervention compared to RYGB. Alkhalifah et al [6] found the revision rate to be lower (4.0%) with OAGB in comparison to RYGB (5.1%) or SG (5.2%). It is also worth noting here that a number of these revisions in this study, where authors used a tailored algorithm for BPL based on patients' BMI, were for malnutrition. One suspects if authors had used a standard BPL of 150 cm, the rate of revision might have been even lower with OAGB.

Of the three procedures, OAGB appears to carry the highest risk of macro or micronutrient malnutrition [24] but this complication can probably be reduced significantly by avoiding a BPL length of > 150 cm [8, 10]. At the same time, patients should be made aware that this procedure is associated with a definite incidence of protein-calorie malnutrition requiring further surgery. SG appears to carry the lowest risk of malnutrition even though direct comparisons are lacking and may be better suited to patients who want to reduce the burden of micronutrient supplementation medication in the long-term. At the same time, one has to recognise that many SG patients need additional supplementation with Iron, Calcium, and Vitamin B12 over and above a multivitamin tablet [15].

The marginal ulcer is another significant problem with both OAGB and RYGB but it can be reduced by long-term PPI prophylaxis with Lansoprazole 30 mg daily (we currently recommend 5 years). SG obviously does not carry any risk of marginal ulcer and may be particularly suited to patients with lesser severity of obesity (BMI < 45 $kg/m^2$ for example) who smoke, as smoking is known to be a recognised risk factor for marginal ulcers.

Other long-term problems with RYGB seem to be Internal hernia and chronic unexplained abdominal pain after RYGB [25], which can be very difficult to treat. An internal hernia can lead to disastrous consequences but its incidence can be reduced significantly if surgeons close the mesenteric defects at the time of surgery [27]. Patients undergoing RYGB should be made aware of these complications, particularly chronic abdominal pain which can be very difficult to treat with consequent influence on patients' quality of life.

Our impression is that although all procedures have a definite long-term complication rate; long-term problems seen with OAGB (performed with a 150 cm BPL) and SG are easier to prevent and manage in comparison to those associated with RYGB but this needs to be examined in randomised studies comparing all these procedures over a period of time. RYGB is also more difficult to reverse if needed in comparison with OAGB, because of its technical configuration.

## 4. Comparative Safety of These procedures for patients with GORD

RYGB seems to be associated with lower incidence and prevalence of GORD and may also lead to resolution of Barrett's Oesophagus (BO) [28]. On the other hand, a number of patients undergoing either SG or OAGB suffer from GORD requiring medications and some may even need conversion to RYGB [20-30]. This has led to many surgeons recommending RYGB for patients with GORD and/or Hiatus Hernia [31].

However, in a recent consensus statement on OAGB [32], experts agreed with consensus that OAGB was a suitable procedure for patients with mild to moderate GORD and HH, but there was no consensus on it being suitable for patients with severe GORD requiring daily medication, large HH (≥4 cm), or BO. In our opinion, it can be an option for these patients where other factors dictate it to be a safer/better choice (BMI ≥ 50 $kg/m^2$ for example) as long as the patient is aware of a higher risk of conversion to RYGB. We further feel it can even be an option for patients with BO if the patient understands that need for lifelong surveillance or conversion to RYGB if dysplasia develops. Similarly, SG experts [33] also do not rule it out as being an option or patients with GORD or HH.

In patients with hiatus hernia undergoing SG, the concurrent crural approximation is known to improve GORD outcomes [34]. Our personal preference with any bariatric procedure is to only carry out anterior crural approximation (with non-absorbable sutures) when there is an obvious hiatal opening seen on laparoscopy. We feel routine dissection of hiatus for posterior crural approximation is unnecessary and may even destroy natural anti-reflux mechanisms.

## 5. Safety of BMS for patients with End Stage Organ Disease

It is clear from several case series that some, carefully selected patients with heart failure [35], Renal Failure on Dialysis [36], and Cirrhosis of the liver [37] can safely undergo bariatric surgery. However, these studies almost universally have small numbers and are therefore prone to publication bias and type 2 errors. Moreover, they only examine short term outcomes and do not report longer-term safety. This is especially important in the case of Cirrhosis of the Liver with liver failure emerging as one of the commonest causes of long-term mortality after bariatric surgery [38]. Randomised controlled trials that can show benefits of bariatric surgery in terms of reduced mortality or improved quality or duration of life for these high-risk cohorts are lacking.

Furthermore, these patients are referred for bariatric surgery at a stage when organ function cannot be expected to improve. The main driver for bariatric surgery in these patients is not an improvement in organ function but eligibility for transplants because many transplant programmes use arbitrary weight criteria for patients to go on the waiting list. For these patients, once again, there is no evidence that bariatric surgery followed by organ transplant is safer than organ transplant at patients' current weight. If at all these complex patients are offered BMS, it should probably only be in dedicated centres in close collaboration with respective medical specialities and provision for lifelong follow up in specialist centres.

## 6. Safety of BMS for patients with BMI ≥ 70 kg/m$^2$

Though there are case series [39-40] that show BMS can be safely performed in patients with a BMI ≥ 70 kg/m$^2$, these patients cannot be expected to have the same risk versus benefit profile as those with a lesser burden of obesity. They can be extremely challenging technically and may need several weeks of a supervised very low-calorie diet and/or gastric balloon first to get their weight down to a safe operable range.

Moreover, there is currently a lack of data showing that weight loss with BMS improves quality of life in these patients as many of them will probably never get to their expected BMI. This can even lead to mental health problems which are further exacerbated by loose skin and restriction placed by surgery on their eating habits. Ideally, BMS should only be offered to mega obese

patients in dedicated centres in close consultation with dieticians experienced in Very Low-Calorie Diet, psychologists, and plastic surgeons.

**Discussion:**

**Procedure Selection:**

There are potentially a large number of variables that can influence the choice of a procedure for a particular patient. To name a few, these are the anaesthetic fitness of the patient, abdominal conditions (like large ventral hernia, adhesions, Crohn's Disease etc.), short and long-term effectiveness of surgery with regards to weight loss, short and long-term metabolic effectiveness of surgery for patients with T2DM, early morbidity and mortality, late morbidity and mortality, ease of managing complications, reversibility, surgeon experience and preference, patient preference, impact on quality of life, impact on GORD, impact on eating behaviour, need for micronutrient supplementation, effect on bowel habits, etc. The list is potentially endless.

The sheer number of variables means no fixed rule can be made with regards to procedure selection for a particular patient seeking BMS. Surgeons should obviously work within their comfort zones and that of their teams and patients should understand various options and if possible, discuss them with other patients, before making a choice.

In our experience, we find we are performing fewer RYGBs than we did 10 years ago and in comparison, we are performing more OAGB and SG procedures. Authors generally feel that the vast majority of patients seeking BMS can safely undergo either SG or OAGB as experience with these procedures builds up globally. Undoubtedly, some of these patients will need conversion to RYGB at a later date but this will mean that most patients can have procedures that seem to carry half the 30-day mortality of RYGB and fewer long-term life-changing complications.

**Patient Selection:**

While it is generally agreed that there are patients with BMI <35 $kg/m^2$, especially those suffering from early T2DM and South Asians, who would also benefit from BMS, what is less

understood is that there are patients with a BMI ≥ 35 kg/$m^2$, who may not benefit significantly from BMS and whose risks may be higher than the potential benefits.

Patients with End Stage Organ Disease and mega obesity (BMI ≥ 70 kg/$m^2$) might fall in this category. Data specifically examining these cohorts of patients in the randomised setting are lacking and offering BMS to these patients in the absence of such data perpetuates the lax attitude amongst many healthcare professionals towards BMS. Just like any other disease, patients undergoing BMS can expect best short and long-term outcomes when they are referred early for surgery and not when the disease is so far advanced that even surgery will not bring any meaningful benefits and would be associated with significantly higher risks.

There is a need to educate our medical colleagues that patient suffering from morbid obesity and organ dysfunction need to be referred at an earlier stage when bariatric surgery can prevent or delay the need for organ transplants and not at a later stage when the risks are higher and benefits become somewhat questionable.

**Conclusion:**

This review examines various factors influencing patient and procedure selection. Authors discuss the implications of these factors on the final choice that patients and surgeons have to make. We also discuss our own preferences and encourage surgeons to adopt local protocols that deliver safety with a willingness to audit and alter them as appropriate.

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**Abbreviations:**

**BMS:** Bariatric and Metabolic Surgery

**T2DM:** Type 2 Diabetes Mellitus

**GORD:** Gastro-Oesophageal Reflux Disease

**BO:** Barrett's Oesophagus

**BMI:** Body Mass Index

**RYGB:** Roux-en-Y Gastric Bypass

**OAGB:** One Anastomosis Gastric Bypass

**SG:** Sleeve Gastrectomy

**BPL:** Bilio-Pancreatic Limb

**BO:** Barrett's Oesophagus

**HH:** Hiatus Hernia