

What is the Actual Fate of Super-Morbid-Obese Patients Who Undergo Laparoscopic Sleeve Gastrectomy as the First Step of a Two-Stage Weight-Reduction Operative Strategy?

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Abstract The overall success-rate of the two-stage treatment plan for the treatment of super-morbid obesity has not yet been assessed. We reviewed the long-term results of 41 treated super-morbid-obese patients. Mean initial BMI was 59.5 ± 3.5 kg/m². Twelve patients (29.3 %) achieved after only LSG a BMI <35 kg/m² (mean 31.9 ± 2). They have lost 78.7 ± 11.8 % of excess body weight (EBW). The remaining 28 patients lost 48.1 ± 11.9 % of EBW and achieved a mean BMI of 44.2 ± 4.3 kg/m², thus requiring the second stage. Ten of them (24.4 % of the total or 35.7 % of those in need), were submitted to laparoscopic Roux-en-Y gastric bypass (LRYGBP). They lost 71.9 ± 4.3 % of EBW and have a mean BMI of 33.6 ± 2.7 kg/m². The 18 remaining patients have a BMI of 42 ± 3.6 kg/m² and they still suffer from morbid obesity. They have lost 48.5 ± 8.7 % of EBW. The mean rate of EBW loss for all the available 39 patients after either LSG or both LSG and LRYGBP has been 63.2 ± 16.5 % after a mean follow-up of 42.8 ± 19.5 months. Out of 41 patients, 1 died, 1 was lost to follow-up, 21 (51.2 %) achieved “healthy” BMIs and 18 (44 %) still require LRYGBP. The rate of cure of morbid obesity was 51.2 %. A remaining 44 % of super-morbid obese patients still need the completion LRYGBP but have not undergone it. Half of these patients have lost >50 % of their EBW. The two-stage strategy is an effective treatment plan for super-morbid obesity. A less patient-dependent strategy may be needed for a subset of patients.

Keywords Sleeve gastrectomy · Gastric bypass · Morbid obesity

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Introduction

The ideal surgical treatment of super-morbid obesity has been an issue of debate for more than a decade [1]. Treatment options with reliable and sustainable results have traditionally included combined restrictive-malabsorptive operations, like biliopancreatic diversion with duodenal switch (BPD-DS) or distal Roux-en-Y gastric bypass (RYGBP). The problem with these operations is that they can be extremely difficult to perform on especially heavy patients, thus reducing significantly their safety margins [2].

In order to elaborate a safe and effective treatment plan for this extremely difficult group of patients, the last decade, a two-stage surgical treatment strategy has been popularized by various dedicated bariatric centers of excellence [3–5]. This strategy includes the performance of a lesser but effective restrictive operation as the first step, namely laparoscopic sleeve gastrectomy (LSG), and the addition of a usually more technically complicated malabsorptive procedure at a later time-point, either BPD or distal laparoscopic Roux-en-Y gastric bypass (LRYGBP), when the patient has lost a significant amount of excess body weight thus facilitating the whole process and making it safer.

The main focus of the studies reporting results with this strategy though has always been the success rate of the first step. The perioperative morbidity after initial LSG for these especially heavy patients has been reported at a more than acceptable rate of between 9 and 14 %, equal to recent multi-centric data from nation-wide surveys on LSG [6], while the mortality has been reported to be lower than 1 %, in comparison to a respective 5 % for these patients after LRYGBP. These attractive short-term results have been combined with a rate of excess body weight (EBW) loss that usually has been around 60 % after 1 year, while the average long-term rate of conversion of LSG to LRYGBP has always been approximately 25 % [7]. These results have been

welcomed very positively by the bariatric community and have led to the popularization of LSG even as a stand-alone procedure for the treatment of non-super-morbid obesity [8]. The truth though is that a real assessment of the overall success rate of the staged strategy for the treatment of super-morbid obesity in the long-run has not yet been published. The aim of this study is to assess the actual long-term results of the implementation of a two-stage strategy, comprising of an initial LSG followed by a LRYGBP when weight loss stops, on super-morbidly obese patients, whose initial BMI exceeds 55 kg/m².

Patients and Methods

Between April 2003 and June 2009, 75 morbidly obese patients underwent LSG in our bariatric unit, out of whom 41 were super-morbid obese with a BMI exceeding 55 kg/m². All these 41 patients were submitted to LSG as the first part of a two-stage weight-reduction surgical strategy. According to the protocol of our Department, patients with BMIs over 55 kg/m² are informed upon their first pre-operative evaluation and sign an informed-consent form, that they are offered only one treatment option: to be submitted first to LSG and then be re-evaluated regularly for a staged LRYGBP. The time-point for the second operation is not set. The necessary conditions for it are that the patients must have stopped losing weight and that their BMI should have fallen below 55 kg/m² but by any means remains still above the threshold of morbid obesity as it has been set by the NIH criteria [9]. During the same period of time 101 patients were submitted to LRYGBP.

The pre-operative evaluation and surgical technique are standard. Intra-operative calibration of the gastric sleeve is performed with the use of the 9 mm endoscope and has been described elsewhere [10]. Post-operatively the patients are re-evaluated in the outpatient clinic after 1, 3, 6 months and in 6-month intervals thereafter. As long as the patients keep on losing weight, no additional operation is scheduled. Any patient, whose excess weight loss reaches a plateau, while his BMI remains between the frames of surgical treatment of morbid obesity, is advised to proceed with the LRYGBP, as it has been planned from the beginning.

All patients' data were retrospectively collected from our prospective obesity patients' database. Any additional information was gathered through phone-call interviews. Statistical processing of the data was performed with PASW Statistics 18. All values are expressed as mean±SD.

Results

Thirteen men and 28 women with a mean age of 39.6±10.2 years comprised the study population. Their mean

body weight was 176.3±25 kg (147–238) and their mean BMI 59.5±3.5 kg/m² (55–65). Mean EBW was 104.9±17.9 kg. The most frequent comorbidities were hypertension in 18 (43.9 %), sleep apnea syndrome in 15 (36.6 %), and diabetes mellitus type 2 in 6 (14.6 %), Table 1.

Mean operative time for the LSG performance for this especially heavy group of patients was 133.1±8.7 min (120–150) and mean time to BMI ratio was 2.3±0.3 min/kg/m². One patient died 3 months post-operatively from sepsis and kidney failure due to rhabdomyolysis with no signs of any leak or any other abdominal source of sepsis. The post-operative morbidity for the rest of the patients was zero. More particularly, no leakage or bleeding from the staple-line was observed in this series of patients. The rate of post-operative excess body weight loss for the remaining 40 patients after initial LSG can be seen in Table 2. One year after the operation, super-morbid-obese patients having undergone LSG in order to lose weight had lost an average of 54.3±16.8 kg (33–84), corresponding to an EBW loss rate of 55.5±16.8 % (27–83).

Twelve out of these patients (26.7 % of the total) achieved after a mean follow-up time of 32±8.7 months to lower their BMI below the threshold of surgical therapy for morbid obesity after only LSG. The current mean BMI of these patients is 31.9±4.9 kg/m². They have lost a mean of 85.3±15.2 kg which corresponds to a mean rate of EBW loss of 78.7±11.8 %.

The remaining 28 patients after a mean follow-up time of 49.1±19.5 months achieved a mean EBW loss of 44.4±8.7 kg (33–57) corresponding to a mean 48.1±11.9 % (27–65.6) rate of EBW loss and reached a mean BMI of 44.2±4.3 kg/m², thus all of them required to proceed with the second stage of the treatment plan, in order to be “cured” from morbid obesity.

Ten out of these patients (24.4 % of the total or 35.7 % in need for it) were submitted to the staged LRYGBP. The mean time between the first and the second operation was 18.9±10.5 months (6–29). The mean weight at the time of the completion LRYGBP was 138.2±4.3 kg (135–144), the mean remaining EBW was 69.8±4.9 kg (65–74) and the mean BMI 48.2±1.6 kg/m² (46.7–50.8). The mean rate of

Table 1 Patients' demographics

Male/female (%)	13/28 (31.7/68.3 %)
Mean age (years) ^a	39.6±10.2 (27–59)
BMI (kg/m ²) ^a	59.5±3.5 (55–65)
Diabetes mellitus type 2 (%)	6 (14.6 %)
Hypertension (%)	18 (43.9 %)
Coronary disease (%)	3 (7.3 %)
Sleep apnea (%)	15 (36.6 %)

^a Mean ± SD (min–max)

Table 2 Rates of excess body weight loss after laparoscopic sleeve gastrectomy for patients with BMI > 55 kg/m²

1 month (41 patients)	22.9±7 % (16.1–31.7)
3 months (40 patients)	29.5±8.9 % (19.1–41.4)
6 months (40 patients)	42.4±13.8 % (24.1–66.7)
12 months (39 patients)	55.5±16.8 % (27–83)
Last follow-up (39 patients, 42.8±19.5 months, 3–87)	63.2±16.5 % (36.7–95.2)

Mean±SD (min–max)

EBW loss between the LSG and the LRYGBP had been 27.5±6.7 % (19–35). The mean decline in BMI units was 10.5±2.6 (8.3–14.2), which corresponded to a rate of BMI loss between the two operations of 17.8±3 % (15–22).

Mean operative time for the performance of the LRYGBP was 225.3±22 min (155–310) and this was statistically significantly longer than the initial LSG ($p < 0.001$). One patient was lost to follow-up 3 months after the LRYGBP. The remaining nine patients are alive and have experienced no short- or long-term post-operative complication after a mean follow-up period of 71.7±13.4 months (56–87) after the first and 36.8±16.4 months (24–58.5) after the second operation. Their mean body weight is 96.7±7.8 kg (88–106) and their mean BMI 33.6±2.7 kg/m² (30.5–36.7). These nine patients, who completed the staged LRYGBP after a preliminary LSG, have lost 67.3±6.6 kg (62–76), which corresponds to a cumulative rate of EBW loss of 71.9±4.3 % (67.9–77.5).

Eighteen patients have currently undergone only LSG and after a mean follow-up time of 37.8 months have a mean BMI of 42±3.6 kg/m² (37.9–46.7) and they still suffer from morbid obesity. They have lost a mean of 48.8±8.6 kg (36–60), which corresponds to a 48.5±8.7 % (36.7–60) rate of EBW loss.

The 31 patients, who have been submitted only to the initial LSG, achieved a mean final weight of 113.1±27.5 kg (65–158) and a mean BMI of 37.9±6.5 kg/m² (25.4–46.7), after a mean follow-up period of 34.5±11.1 months (3–54). This group of patients has lost a mean of 63.4±21.5 kg, which corresponds to a 60.6±18 % EBW loss (36.7–95.2). Nine of these patients have achieved to lower their BMI below 35 kg/m² and three below 40 and carry no comorbidity, thus all twelve have been “cured” from morbid obesity only with the LSG, as it has already been mentioned. Twelve patients still have BMIs above 40 kg/m² and six additional patients have BMIs between 35 and 40 kg/m² with comorbidities, thus in total 18 out of the 41 patients are still in need for the staged LRYGBP for further weight loss in order to be “cured” from morbid obesity. Despite our advice, none of them is now convinced to proceed with it and all of them still remain reluctant. A schematic presentation, summarizing the long-term outcome of super-morbid

obese patients intended to be submitted to initial LSG and then to a completion LRYGBP can be seen in Fig. 1. Out of a total of 41 patients, 1 died after LSG, 1 was lost to follow-up after the completion LRYGBP, 21 (51.2 %) are alive with BMIs within “healthy” limits (12 after LSG only and 9 after completion LRYGBP), and 18 (44 %) still require the completion LRYGBP in order to achieve BMIs below the morbid obese spectrum but their operation is still pending for subjective reasons. The mean rate of EBW loss for all the 39 patients who have been fully followed up for 42.8±19.5 (15–87) months after either only LSG or both LSG and LRYGBP has been 63.2±16.5 % (36.7–95.2).

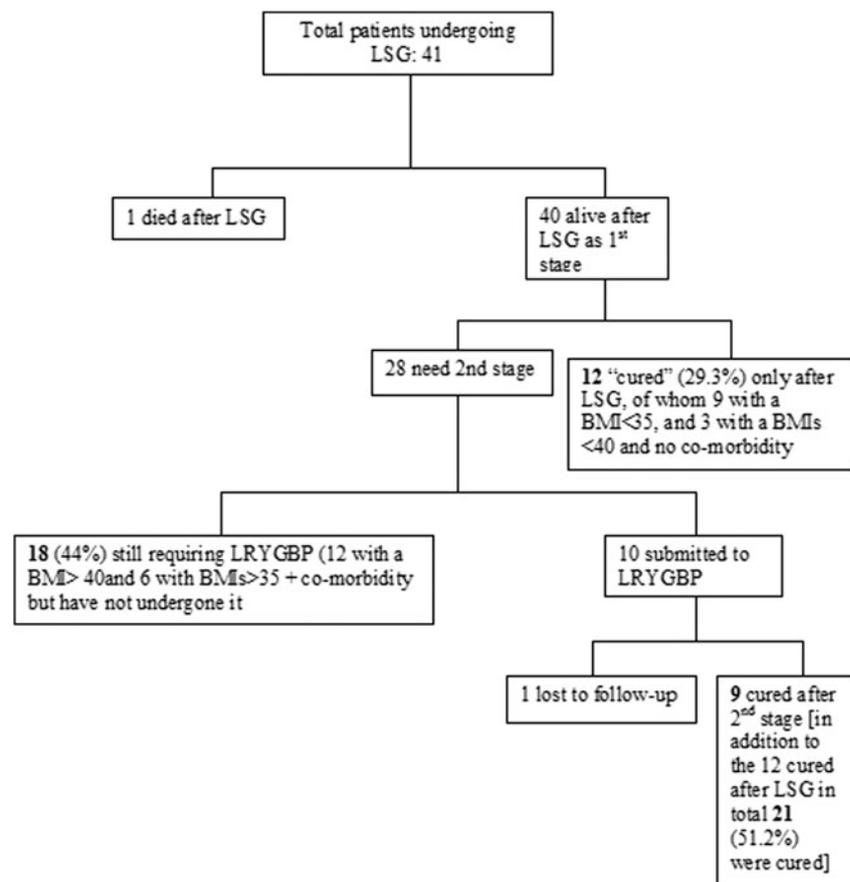
Discussion

Super-morbid-obese patients with BMIs exceeding 55 kg/m² have by far the greatest compromise in their quantity and quality of life in comparison to lesser morbidly obese patients thus can benefit most from bariatric surgery. However, high BMI patients, particularly men, comprise a unique group of patients, for whom the complex bariatric procedures, which are known to achieve the most sustainable EBW loss results, such as LRYGBP or BPD-DS, are very challenging, take longer and carry a significantly higher perioperative morbidity and mortality [2, 5].

In an effort to reduce this increased morbidity and mortality various authors have advocated a staged approach for super-obese patients, consisting of an initial LSG and the addition of a malabsorptive operation at a later time-point [3, 4, 11]. The rationale behind the evolution of this two-stage strategy is that LSG is a rather simple and not very time-consuming operation with minimal surgical and medical morbidity. Indeed, with the two-stage weight-reduction plan, everybody is happy. The patients are happy because they are offered a good chance to find a promising way out of their problem without an accompanying discouraging hazard. The surgeons are happy because they can deal with this extremely difficult group of patients with a treatment plan which does not carry a prohibitive risk. The first part of the plan consists of a rather short and easy operation with a good chance of achieving a curative result. In case this is not achieved, one can always fight another day under better circumstances.

The use of LSG for super-morbid obese patients though has two drawbacks. The first is a well documented in the literature more moderate EBW loss after LSG for patients with BMIs exceeding 50 kg/m², compared to lighter patients [12, 13]. The delayed addition of a malabsorptive procedure for these patients when they stop losing weight has been identified as the best solution. Within the frame of a planned two-stage weight-reduction strategy this drawback has already been recognized and incorporated in the overall

Fig. 1 Schematic presentation of the long-term outcome of super-morbid obese patients undergoing a two-stage weight-reduction operative strategy including laparoscopic sleeve gastrectomy and a staged LRYGBP



treatment plan, so it does not look like a real problem. The problem though with any two-stage approach is that the patient has to stay co-operative for a long period of time and this is not always possible. Super-morbid-obese patients are notorious for their non-compliance with any treatment plan, so there really is a question what is the actual overall long-term outcome of this two-stage operative strategy, in terms of rate of “cure” of morbid obesity. The aim of this study was to calculate this actual outcome after a very reasonable follow-up period that has always been longer than 2 years. The findings of this retrospective review were rather encouraging. The current overall “success” rate of the whole treatment plan was 51.2 %, including a 29.3 % of the total who were cured only with LSG and an additional 24.4 % that were later submitted to LRYGBP. All of these patients achieved to lower their BMI below 35 kg/m².

On the other hand a considerable 44 % of the super-morbid obese patients who were submitted to initial LSG still need to undergo LRYGBP in order to lower their BMIs below 35 kg/m², but to the time-point of this review they are not willing for it. The question is, can we call all these cases as “failure” of the treatment plan? The first issue concerning the answer to this question is the definition of “success” and “failure” after any bariatric operation, in terms of EBW loss, in pure medical terms. All five patients who suffered from

diabetes mellitus and were under treatment with per os antidiabetic drugs were either cured or much improved after the LSG (one patient with diabetes mellitus under insulin treatment underwent the sequential LRYGBP and was then lost to follow-up). Nine out of these 18 patients with BMIs still within the frame of surgical treatment of obesity have lost more than 50 % of their initial EBW (data not shown) and this has also arbitrarily been proposed as a cutoff point for the definition of “success” or “failure” after bariatric surgery [14, 15]. If we sum up these patients as “successes” in our series, the final rate of success would approach the much more persuading 80 %.

The second issue is that the perception of “failure” or “success” can differ between bariatric surgeons and patients themselves. If a patient has lost 30–40 kg of weight, has lowered his BMI from over 55 kg/m² to the low forties or even less and has improved his general medical status through this weight loss, may feel already satisfied thus unwilling to seek a further reduction in his weight through a second and more complex operation. In this case, a subjective over-evaluation of the outcome on behalf of the patient diverts him from completing the overall treatment plan. On the contrary, it can very well be that a considerable, but not sufficient in order to cure morbid obesity, weight loss after LSG can create a nihilism concerning the efficacy

of bariatric surgery as a whole and discourage in this way the patient from completing the original treatment plan. In this case, an untimely under-evaluation of the initial post-operative results from the side of the patient precludes him from completing the whole treatment plan. So there is an issue that despite the fact that all patients are thoroughly informed from the very beginning about the almost unavoidable necessity for a second operation at some point after the initial surgical treatment and despite the moderate results of the LSG in terms of EBW loss for almost half of the patients, a considerable percentage of them still remain skeptical. The problem is that these are the patients that more often miss their appointments at the outpatient clinic and the information about their course has to be collected by phone. Judging by their ultimate non-compliance with a treatment plan which had been very clearly explained to them from the very beginning, one can assume that they have also been non-compliant with the orders about their eating habits after the LSG thus compromising its effectiveness in terms of weight loss. Other groups have also reported a similar 28 % rate of completion LRYGBP for super-morbid-obese patients, with a 46 % rate of one year follow-up with a lot of patients having been lost [7]. The EBW loss in that study was a moderate 45 % and the feeling of the authors was that LSG did not address efficiently the associated medical problems of the patients. It seems that if we want to improve our long-term results, we have to identify from the beginning the non-compliant subset of patients, for whom it can be anticipated that they will have less than optimal results after LSG, less than optimal follow-up and finally will not show up for the staged LRYGBP, wasting somehow in this way the medical resources which have been invested on them at the time of the initial operation. It looks reasonable that once we can identify these patients, we have to offer them a safe but more reliable treatment plan, less dependent on the patient's long-term compliance.

One solution could be the performance of LRYGBP for super-morbid obese patients as a single-stage operation exactly as for lighter morbidly obese patients. There are accumulated data in the bariatric literature that the perioperative morbidity and mortality for patients with BMIs exceeding 60 kg/m² are not necessarily prohibitively high and they simply depend on the surgical experience and the available expertise [16–18]. A more careful analysis of this reported data reveals though that single-stage LRYGBP for super-morbid-obese patients may be a good option basically for a subgroup of patients comprising of young women with no comorbidities. Performing LRYGBP on older, male super-obese patients with concomitant diseases like sleep apnea syndrome or diabetes mellitus type 2 still does not look unanimously like a good bet [7].

Another option for the surgical treatment of super-morbid obesity would be the performance of an open instead of a

laparoscopic RYGBP. A direct comparison of the two techniques for super-morbid-obese patients has not yet been performed, but the experience of open RYGBP for morbid obese patients has shown an increased incidence of pulmonary and incisional complications [19, 20]. Under these circumstances, the performance of an open gastric bypass on an extra-heavy patient with central obesity and sleep apnea syndrome or chronic obstructive pulmonary disease does not really look like a safe option to be offered indiscriminately.

A variation of LRYGBP, the so called laparoscopic mini-gastric bypass has also been reported for this group of patients. This consists of the construction of a more elongated gastric pouch thus requiring an easier to suture, more distal gastrojejunal anastomosis, than for the standard LRYGBP [21, 22]. A variation of this technique could be the fashioning of the bypass exactly like a distal gastrectomy, with the preservation of the excluded part of the stomach. In case of a long-term less than optimal EBW loss a staged laparoscopic sleeve gastrectomy of the gastric pouch can be performed, in order to enhance the restrictive potential of the technique. The results have so far been reported as being promising but they lack strong long-term verification. We have recently tried this technique once, on a male super-morbid-obese patient and he did really well immediately post-operatively but we still wait for the long-term results.

The disadvantages of this study are that it is retrospective and that the number of patients is not so big in order to draw solid conclusions. Despite this, the fact that we were able to follow almost all the involved patients for a long enough period of time, permits us at least to make an initial evaluation of the “success” rate of the two-stage strategy for the treatment of super-morbid obesity and in addition to raise the question if the two-stage weight-reduction strategy represents a treatment plan that fits all the super-morbid obese patients.

In conclusion, the two-stage weight-reduction strategy for the super-morbid obese patients consisting of an initial LSG and a staged LRYGBP remains a very popular treatment option and it is indeed a very safe and efficient therapeutic plan. Its overall effectiveness in terms of rate of cure of morbid obesity has not yet been accurately assessed. It seems that the actual overall long-term outcome, in terms of rate of “cure” of morbid obesity, is partly compromised due to patients' non-compliance. Our results have shown a 44 % rate of “failure” when “success” is defined as achieving a BMI below 40 kg/m² or below 35 kg/m² when any comorbidity exists. This rate of failure is further pushed down to 22 % when “success” is defined as losing 50 % of the initial excess weight. These “failures” comprise of patients who still need but are unwilling to undergo the staged LRYGBP, after a long enough follow-up period of time. This observation might be alarming enough to lead the bariatric community to try to identify the subset of patients who are at greater risk for “failure” of the overall plan from the beginning and

offer them a less patient-dependent operative strategy. Whether this would be a single-stage LRYGBP for lesser-risk surgical candidates or mini LRYGBP for high-risk surgical candidates remains to be found.

Conflict of Interest All the authors (Alexandrou A, Felekouras E, Giannopoulos A, Tsigris C, and Diamantis T) declare that they have no conflict of interest.

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