

## A Single-Centre Retrospective Study to Evaluate the Technical Feasibility, Safety and Operative Outcomes of Laparoscopic Reversal of Omega Loop Bypass Surgery

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### Abstract

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An epidemic of obesity is sweeping across the Middle East with no good signs of control [1]. It is associated with diabetes, hypertension, hyperlipidemia and high cholesterol levels, as well as, snoring and sleep apnea [2]. A large number of patients undergo bariatric surgeries every year in United Arab Emirates<sup>3</sup>. This explosion in bariatric surgery, inherently comes with an increase in the number of complications, secondary interventions and even reversal of procedures in about one fourth of the patients [4].

It is now widely acknowledged that laparoscopic Omega Loop Bypass (OLB) is as effective as Roux-en-Y Gastric Bypass (RYGB), for treating obesity and associated comorbidities. OLB takes less time to perform, is technically less demanding and has shorter learning curve for the operating surgeon [5]. Therefore, this procedure is gaining popularity and is rapidly spreading as a preferred choice of bariatric surgery. Despite a proven track record of nearly two decades, the risk of symptomatic bile reflux, marginal ulceration, severe malnutrition, chronic steatorrhea, hypoglycemic attacks and long-term risk of gastro-esophageal cancers are some of the commonly voiced concerns. These conditions usually can be managed conservatively, i.e., by behavioral and medical therapy, but occasionally, a surgical re-intervention may be needed. In extreme cases, a secondary procedure may consist of reversal to normal anatomy.

**Keywords:** Retrospective; Omega Loop Bypass; Laparoscopic Reversal; Roux-en-Y Gastric Bypass; Technical Feasibility; ROLB

### Abbreviations

OLB: Omega Loop Bypass; RYGB: Roux-en-Y Gastric Bypass; BMI: Body Mass Index; POD: Postoperative Days; ROLB

### Introduction and existing knowledge

Introduction should reflect the background, purpose and significant of the study that is carried out.

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### Hypothesis/aim of study

The decision to reverse the primary surgery is challenging and currently, there are no established guidelines or recommendations for reversal. To the best of the literature, limited information is available regarding technical feasibility, safety and operative outcomes of reversal following omega loop bypass surgery.

Arman, et. Al. (2017) conducted a retrospective study on mid-term effects of RYGB reversal to normal anatomy, or into sleeve gastrectomy. They found that reversal corrected early dumping syndrome, malnutrition, diarrhea, and nausea/vomiting. The resolution rate was 75% for hypoglycemic syndrome. However, reversal of the procedure was associated with significant weight regain ( $14.2 \pm 13.7$  kg,  $p = .003$ ), while some weight loss was evident in the Sleeve Gastrectomy group ( $4.8 \pm 15.7$  kg) [6].

A 10-year retrospective analysis from France included 26 OLB cases, who underwent laparoscopic reversal. Genser, et. al. reported a complete clinical and biological regression of the severe and refractory malnutrition syndrome in all the patients, despite a mean 13.9 kg weight regain in 61.5% patients [7].

The decision to reverse versus revise is often difficult. While it is presumed that laparoscopic reversal of OLB will lead to weight regain and return of co-morbid conditions, no well-planned retrospective/prospective clinical study has been published from the UAE. Thus, the indications for this procedure, as well as technique,

complication rate, and success in resolving symptoms are not yet clearly defined. Also, there is very little guidance available for patients and practitioners who are experiencing these *problems*. Therefore, a retrospective study was planned to review the surgical experience with laparoscopic reversals of OLB procedures from Al Garhoud Private Hospital, Dubai, UAE.

### Aims/Objectives

- To identify potential indications of laparoscopic ROLB
- To report short-term, medium-term and long-term outcomes for laparoscopic ROLB
- To provide technical feasibility and practical steps for laparoscopic ROLB.

### Methodology

- **Design:** A retrospective single-Centre, chart review of patients who underwent ROLB
- **Duration:** All the ROLB procedures performed between January 2014 and June 2017
- **Ethics committee:** The study protocol and the proposed informed consent form was reviewed and approved by the institutional review board.
- **Informed consent:** All patients received both written and oral information about risks and consequences of laparoscopic ROLB including immediate perioperative and delayed post-operative complications, and further, weight regain.
- **Surgical technique:** All ROLB surgeries were performed by the same surgeon.

Pre-operative barium meal and endoscopic examination was performed to exclude anastomotic ulcers and other pathologies. The procedure began with a careful adhesiolysis of the left lobe of the liver, gastric pouch, and the omega jejunal loop. Then, the gastro-jejunosomy was divided from the gastric pouch with a 45-mm Endo GIA endo-cutter with purple staples. Gastro-gastric anastomosis performed between the gastric pouch and the excluded stomach. An intraoperative methylene blue dye test performed to rule out anastomotic leak. On table endoscopy done at the end of the procedure to check restoration of anatomy. Post-operative gastrographic meal performed the next day after surgery.

### Primary endpoints

- Clinical evolution was defined by the degree of improvement of the condition that had demanded the reversal: before the reversal, and at 3, 6- and 24-months' post-surgery.
- Weight evolution after the reversal procedure: change of total weight and Body Mass Index (BMI) before reversal, and at 3, 6- and 24-months' post-surgery.

### Secondary endpoints

- Proportion of patients with various indications
- Mortality, minor and major postoperative complications.

Postoperative complications were considered major when Clavien-Dindo type III or more (modified classification) [8], requiring surgical, endoscopic, or radiological intervention. Early and late mortality/morbidity was defined as death or adverse outcomes occurring within and after the first 30 postoperative days (POD), respectively.

### Data collection process

Both paper and electronic documentation was used for data abstraction. Data collection points were organized in a logical order to parallel the flow of the information in the health record at Al Garhoud Private Hospital, Dubai, UAE. Internal validity and reproducibility of data abstraction instrument was checked through pilot data collection. A clear set of protocols and guidelines were created for collection and review of data. Missing data was left blank and was not imputed. Data abstractor chosen was familiar with the Al Garhoud Private Hospital, health records and was provided training in the data abstraction instrument and protocols.

Data included preoperative demographic information, time to reversal from the initial surgery, clinical and biological parameters collected during the follow-up, intraoperative findings, and postoperative outcomes. Before reversal, all patients underwent a multi-disciplinary assessment, blood tests, barium meal and gastroscopy to rule out complications.

### Achievability

#### Weight and BMI change

Between January 2014 to June 2017, 437 OLB procedures were performed in Al Garhoud Private Hospital and 16 patients under-

went laparoscopic ROLB. Of these patients, 10 (62.5%) were females. At the time of primary OLB, mean age and BMI was  $34.38 \pm 7.55$  years and  $41.56 \pm 2.61$  kg/m<sup>2</sup>, respectively. The mean BMI was reduced to  $24.63 \pm 3.74$  kg/m<sup>2</sup> at the time of the laparoscopic ROLB. The elapsed time between the primary OLB and laparoscopic ROLB was approximately 33 months (range, 18-48).

Average BMI reported at last-documented follow up (at 6 months) was  $26.79 \pm 2.99$  kg/m<sup>2</sup>. The difference between BMI before and after bypass reversal was not statistically significant.

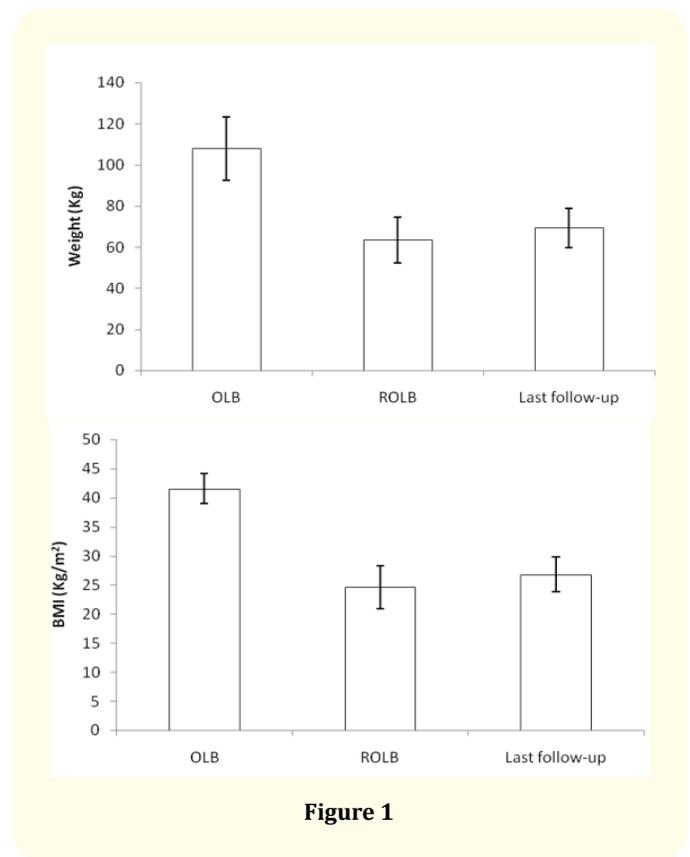


Figure 1

### Indications for reversal

The most frequent indication for reversal in this study was nausea and early satiety, as observed in 11 patients (69%). Although there was no malnutrition observed in these patients, they opted for reversal mainly for psychosocial reasons and to fit in with society. The remaining five patients underwent laparoscopic reversal for one or more of the following conditions: steatorrhea with or

without nausea (3 patients), anastomotic ulcer (one patient), and bile reflux (one patient).

### **ROLB outcome**

Operative time for reversal surgeries ranged from 86 to 150 minutes. There were no intraoperative complications. The length of stay in the hospital ranged from one to three days. There were no major postoperative complications, no anastomotic leak was seen and no additional interventions were required.

### **Novelty**

To the best of our knowledge, this is the first report from UAE describing the technical feasibility, safety and operative outcomes of laparoscopic ROLB surgery. This laparoscopic reversal appears feasible and safe to resolve the post-operative complications in patients who have undergone OLB. Our findings suggest that a majority of patients will be able to maintain their weight following reversal. With such small numbers in the study group, resolute conclusions are difficult to make. However, this initial evidence is persuasive and has encouraged us to continue this approach. Additional research with larger study groups is needed to enable definitive recommendations for ROLB procedures.

### **Conclusion**

Laparoscopic ROLB to normal anatomy is feasible and safe therapeutic option for patients with intractable complications post OLB.

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### **Conflict of Interest**

None.

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