Acta Scientific Gastrointestinal Disorders (ISSN: 2582-1091)

Volume 7 Issue 1 January 2024

Research Article

Feasibility, Safety and Operative Outcomes of Omega Loop Bypass Reversal

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DOI: 10.31080/ASGIS.2024.07.0602

Received: December 05, 2023

Published: December 27, 2023

Abstract

Background and Objective: Laparoscopic omega-loop bypass (OLB) is a well-accepted bariatric surgical procedure to combat severe obesity and its related co morbidities. Reversal of OLB (ROLB) to normal anatomy is a potential treatment of rare but severe post OLB complications. This study is the first of its kind to be conducted in the UAE addressing the ROLB experience, strengthening the available literature on indications, technique and outcomes.

Methods: Retrospective chart review of all patients who underwent laparoscopic ROLB from January 2014 to December 2017 at the Al Garhoud Private Hospital in Dubai, UAE was done. Age, gender, weight, body mass index (BMI), biochemical parameters, indications for reversal, and post ROLB complications were reviewed.

Results: A total of 16 patients underwent laparoscopic ROLB to normal anatomy. 62.5% of patients were females, age was 34.38 ± 7.55 years (range, 23-56), and pre-reversal BMI was 24.63 ± 3.74 kg/m2 (range 18-34). The indications for reversal were debilitating nausea and early satiety (n = 11), severe and frequent steatorrhea (n = 3), anastomotic ulcer (n = 2) and Bile reflux with excessive weight lose (n = 1). The mean period of follow-up post ROLB was 27.75 ± 15.31 months (range 6 to 48). The mean BMI recorded at last follow up post reversal was 29.89 ± 2.83 kg/m2 (range, 23.34-34.04) which represented an average cumulative weight gain of 13.81 ± 4.79 kgs from their reversal baseline (63.43 ± 11.09 kgs; p = 0.000), while weight loss of 30.69 ± 13.03 kgs from their index OLB baseline (107.94 ± 15.28 kgs; p = 0.000). Mean length of hospital stay following reversal was 2.0 days (range, 1-3). Of 16 patients, only one patient had persistent nausea post reversal which recovered completely after psychological counseling.

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

Keywords: Body Mass Index; Obesity; Anatomy

Abbreviations

BMI: Body Mass Index; BPL: Biliopancreatic Limb; EWL: Excessive Weight Loss; FPG: Fasting Plasma Glucose; KGS: Kilograms; NIH: National Institute of Health; OLB: Omega Loop Bypass; ROLB: Reversal of Omega Loop Bypass; RYGB: Roux-en-Y Gastric Bypass; UAE: United Arab Emirates; %∇ BMI: Percentage Change in BMI

Introduction

Rational for the study

An epidemic of obesity is sweeping across the Middle East with no good signs of control [24]. It is associated with diabetes, hypertension, hyperlipidemia and high cholesterol levels, as well as, snoring and sleep apnea [6]. A large number of patients undergo bariatric surgeries every year in the United Arab Emirates [1,2]. 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 [6]. Bariatric surgical procedures performed within UAE has increased from 1963 in 2011 to 4143 in 2013 [1,2], with simultaneous increase in postoperative complications. Laparoscopic omega-loop bypass (OLB) is a well-accepted bariatric procedure to combat severe obesity and its related co morbidities [3]. Although similar to traditional Roux-en-Y procedures (RYGB) in terms of weight loss and postoperative quality of life, OLB has advantage of single anastomosis, shorter learning curve for the operating surgeons, fewer

complications and ease of revision [4]. 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.

Omega loop bypass also referred to as the Mini-Gastric Bypass has been performed for more than 20 years and the medical literature is rich with studies and publications declaring the procedure as a successful option in the treatment of morbid obesity. Most studies showed that the procedure is safe, takes shorter time to perform and straightforward in terms of surgical technicality and learning curve. The length of hospital stay and return to daily life activities as well as percentage of excess weight loss is comparable to other bariatric procedures and even more favorable in some studies.

The literature often compares the OLB complications to those of the RYGB procedure and the theoretically suggested indications for reversal rather than scientifically proven include severe and intolerable dumping syndrome, hypoglycemia, bile reflux and marginal ulcers resistant to conservative treatment, malnutrition, excessive weight loss and poor dietary compliance leading to vomiting and other intolerable symptoms [8]. However, it is believed that the occurrence of these complications and their severity depends on how the procedure is done, for example the length of the bypassed biliopancreatic jejunal loop, size of the gastrectomy and even the distance of the gastric transection from the anatomical craws foot of the stomach. The occurrence of severe malnutrition can be due to prolonged biliopancreatic jejunal limb leading to severe malabsorption as well a tight gastrectomy causing inability to eat due to postprandial pain, bloating and discomfort. It is important to bear in mind that at least 3 meters of alimentary limb must be preserved to prevent severe malabsorption resulting in malnutrition. Therefore, it is important to realize that long term complications can depend on how the procedure is done. Omega loop bypass procedure can be tailored to treat patients with morbid obesity to super obesity and even metabolic syndrome in the less obese patients by deciding the length of the jejunal loop to be bypassed and the size of the gastric pouch according to the patient's metabolic and weight loss needs. The procedure is favorable also due to the ease of revision and reversal in case of intolerable and severe complications. Although, malnutrition is the most feared complication of any bypass procedure, we have not seen many patients with this complication in our unit since we started performing OLB in our department 8 years ago. We believe that this is mainly due to the fact that the procedure is tailored according to the individual patient's need and the length of the biliopancreatic limb is always reserved to a maximum of one third of the total small bowel length measured from the ligament of Treitz to the ileocecal valve. For example, if the total small bowel length is 600 cm, the biliopancreatic limb would be measured to a maximum of 200 cm or less in the lower BMI patients with BMI less than 40 kg/m^2.

The goal of reversal is the restoration of pyloric function and duodenal continuity to attain effective available enteric length [5], as the anatomical and physiological changes post-OLB may theoretically lead to complications such as early dumping syndrome, hypoglycemia, macronutrient deficiencies, severe diarrhea, excessive nausea and vomiting, causing a negative impact on patients' health. Individual counseling seems to be the preferred treatment to correct post-OLB problems [6], as patients seem reluctant to undergo any surgical re-intervention for fear of regaining the weight [7]. But, occasionally reversal to normal anatomy helps to resolve intractable complications like eliminating the need for lifelong nutritional interventions.

While several studies have evaluated the outcomes of RYGB reversal due to malnutrition and other complications, only limited global literature is available on the laparoscopic OLB reversal (ROLB) to normal anatomy. Moreover, no similar experience concerning the complications and weight regain post-ROLB has been reported from the UAE till date. Here, we reviewed the first UAE experience with OLB reversal of 16 cases over a 4-year period, to expand the available literature on the indications, technique and expected outcomes.

Hypothesis and aims of the 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 out-

comes of reversal following omega loop bypass surgery worldwide and no such studies have been published reflecting the UAE experience.

Several retrospective studies were conducted to assess the mid-term effects of RYGB reversal to normal anatomy, or revision into sleeve gastrectomy 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 ± 13.7 kg, p = .003), while some weight loss was evident in the Sleeve Gastrectomy group (4.8 ± 15.7 kg) [28]. 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 [9]. The decision to reverse versus revise is often difficult as it is presumed that laparoscopic reversal of OLB will lead to weight regain and return of co-morbid conditions, the literature lacks well conducted clinical studies 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 and Objectives

- To identify potential indications for ROLB
- To report short-term, medium-term and long-term outcomes after ROLB
- To provide technical feasibility and practical steps for performing the reversal procedure.

Criteria for literature review

- **Type of studies**: All published studies in English language from 1997 to 2018
- **Type of participants**: Adult patients who underwent omega loop gastric bypass surgery and reversal to normal anatomy.
- **Type of interventions**: Omega loop gastric bypass.

Type of outcome measures

- Post omega loop surgery complications; short term, intermediate and long term.
- Reversal of Omega loop bypass indications and outcome.

Several search engines were used for literature review; Medline was searched via Pubmed and Ovid, Embase via Ovid SP and Zotero. The search was limited to English language and adult patients. Various combination of words was used, 'mini gastric bypass', 'omega loop', 'single anastomosis gastric bypass', 'one anastomosis gastric bypass', 'technique', 'revision', 'reversal', 'complications' and 'indications for reversal'.

All duplicated publications and those without complete relevant data were excluded and the retrieved references were arranged using Zotero version 4.0.19.

History of bariatric surgery

Bariatric surgery originated in the 1950s, and became a recognized form of treatment for morbid obesity when obesity was addressed as an epidemic disease with serious comorbidities associated with it increasing the risk of premature death, such as Diabetes Mellitus, Dyslipidemia, Hypertension and Sleep Apnea [1]. Bariatric procedures can be Endoscopic or Surgical. Examples of endoscopic procedures are the Bio Enteric Gastric Balloon, Endoscopic Gastroplasty and Endoscopic Gastric Botulinum. Surgical procedures vary depending on the principal effects; Restrictive, Malabsorptive and a combination of Restrictive and Malabsorptive. The most commonly performed restrictive procedures are the Adjustable Gastric Banding and Sleeve Gastrectomy and the most commonly performed malabsorptive procedures are Biliopancreatic Bypass and Duodenal Switch. Combination of restrictive and malabsorptive procedures are the Rue-En-Y Gastric Bypass (RYGB) and Omega Loop Bypass (OLB) also called Mini Gastric Bypass.

It is important to understand the physiological functions of the Gastrointestinal tract to understand how bariatric surgical procedures work. The Gastrointestinal System is responsible for the digestion and absorption of foodstuff and several organs play different roles in this process, for example, the stomach is responsible for the mechanical digestion by breaking down and mixing food in preparation for chemical digestion and mixing with enzymes to fa-

cilitate absorption through the small bowel loops. Bariatric surgical procedures interfere at different stages depending on the technique used either to reduce the caloric intake or reduce absorption [6]. The idea behind restrictive procedures is to reduce the ability to eat and therefore, reduce the calorie intake to cause weight loss, whereas, malabsorptive procedures reduce absorption of calories by bypassing an absorptive segment of the small bowel. The scientific literature proves that more weight loss is achieved with malabsorptive procedures as compared to the restrictive ones. Percentage excess weight loss (EWL%) for gastric banding is reported to be up to 46% compared to 64% for Biliopancreatic bypass and Duodenal switch, whereas combination procedures like RYGB and OLB showed between 60% to 80 % EWL [1].

Literature review - omega loop bypass

The OLB or so called Mini Gastric Bypass was first discovered by Robert Rutledge in the United States of America in 1997. Rutledge was a trauma surgeon and was faced with a case of abdominal gunshot injury where duodenal exclusion and anastomosis was required, this case inspired Rutledge to apply similar technique on bariatric patients with the construction of a long gastric pouch to prevent reflux [10]. This procedure was subject to skepticism and lead to a vast interest in studying the procedure and its outcome worldwide. In 2014 in the International Federation of Surgery for Obesity conference (IFSO) held in Montreal-Canada, 73 experienced bariatric surgeons with an interest in OLB were invited to participate in a survey regarding the OLB. This survey reported almost 25000 cases with an average BMI of 46, mean duration of the procedure was about 60 minutes and average length of hospital stay of 3 days. Complications such as leak and bleeding were reported as less than 0.05%. Percentage of EWL was reported to be 85% of excess weight in two years. The interest in this procedure has grown rapidly worldwide and has become the bariatric procedure of choice in many countries around the world. There are many attractive factors to the OLB procedure such as the technical simplicity, shorter learning curve, less complication rate and reasonable percentage of excess weight loss. Another attractive factor which is being heavily studied in the current literature is modification of the procedure according to the BMI and patients' metabolic needs, as the length of the jejunal limb to be bypassed and the size of the gastric pouch created can vary to suit the individual case. The study of this project focuses on another attraction to the OLB surgery, which is the ease and feasibility of reversing the procedure to normal anatomy in case of complications which fail to respond to conservative treatment measures, like debilitating nausea, steatorrhea and anastomotic ulcers.

Omega loop bypass - surgical technique

As mentioned earlier, it is believed that the occurrence of complications and their severity after the OLB surgery depends on how the procedure is performed, for example the length of the bypassed biliopancreatic jejunal loop, size of the gastrectomy and even the distance of the gastric transection from the anatomical craws foot of the stomach. Therefore, described below is a step-by-step surgical technique of laparoscopic omega-loop gastric bypass surgery adopted by the bariatric surgical department in the center where the study was conducted.

Patient position

The patient is positioned in French Position with the surgeon between the patient's split legs, camera holder on left side of the surgeon and scrub nurse on the right side. The screen is positioned behind the patient's head.

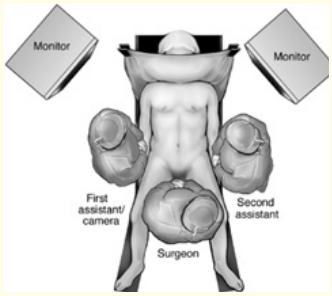


Figure 1: Figure is taken from Research Gate website - Supine split-leg position (French position).

Trocars

One optical trocar size 5mm and two working trocars size 12mm.

Trocars insertion

The optical trocar is inserted at the umbilicus and the two working trocars inserted one at each quadrant as illustrated in the figure below.

Figure 2: Port sites for trocar insertion.

Optical

The telescope used is 30-degree angled telescope size 5mm with a standard length of 37cm or long length of 45cm depending on the individual patient's requirement.

Dissection steps

The procedure begins with the identification of anatomy and adhesiolysis. Atraumatic grasper is used to grasp the lesser omentum upwards to the left of the screen with the left hand. Energy device is handled in the right hand to dissect the lesser omentum and create a window to approach the lesser sac.

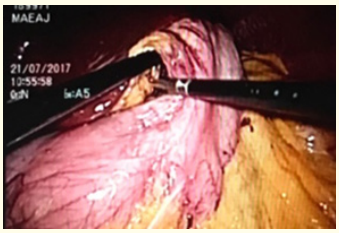


Figure 3

Tips

The grasper can be used as a retractor to the liver while dissecting and retracting the stomach.

Stapling steps

The rotating stapling device Endo GIA stapler is inserted through the surgeon's left 12mm port site trocar into the created window. Transverse stapling below craw's foot is performed using size 60mm purple Endo GIA loading unit. This is then followed by longitudinal stapling.

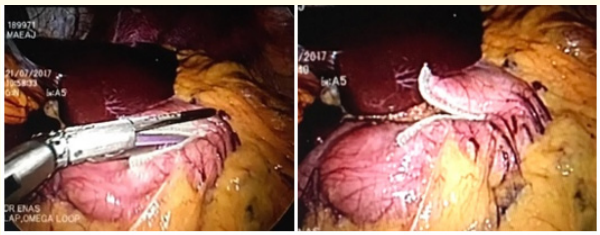


Figure 4

Longitudinal stapling starts by using size 60mm purple Endo GIA loading units.

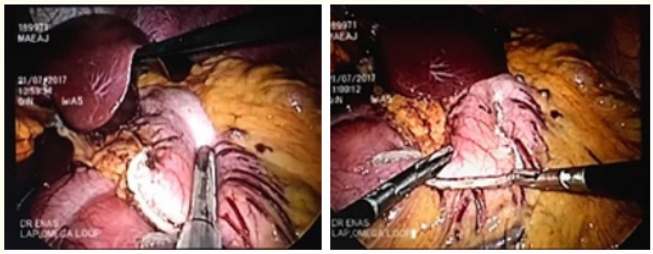


Figure 5

Gastric calibration tube size 40F is then inserted into the created gastric pouch. This is followed by a continuation of longitudinal stapling along the calibration tube until the angle of Hiss.

Figure 6

Counting of Jejunal loop length

With atraumatic graspers, small bowel length measured from the ligament of Treitz to the ileocecal valve. The jejunal loop is then counted to one-third of the total small bowel length e.g. 200cm out of 600cm from the ligament of Treitz. The measured jejunal loop is marked with a temporary stay suture to avoid using extra trocars for this step.

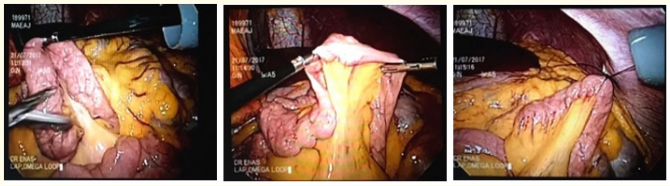


Figure 7

Gastrostomy steps

Gastrostomy of the stump performed with hook diathermy guided by the gastric calibration tube size 40F.

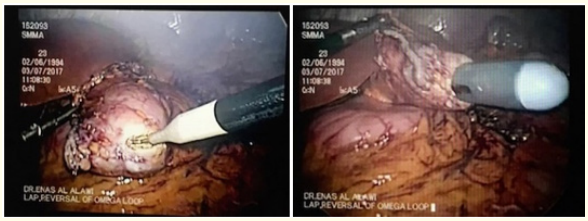


Figure 8

Anastomosis steps

Enterotomy is performed in the counted Jejunal loop using a hook diathermy device.

Figure 9

The thick jaw of the Endo GIA size 45mm length Purple loading unit is inserted through the enterotomy opening. The stapler is then rotated in alignment with the gastric calibration tube and the sharp jaw of the loading unit is guided into the gastric stump to perform the Gastro-Jejunostomy anastomosis.

The calibration tube is then guided through to the jejunal loop and closure with Endo-Stitch using 2-0 Vicryl suture.

Figure 10

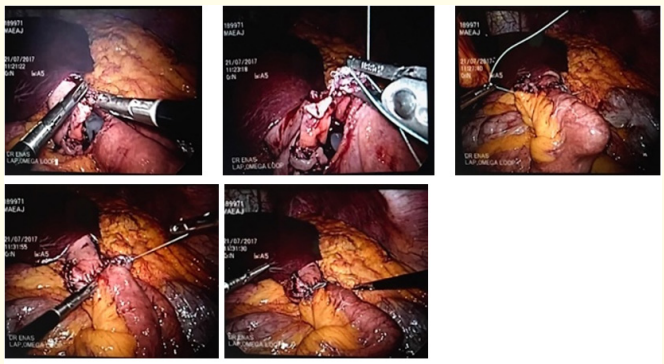


Figure 11

Leak test

At the end of the procedure, Methylene-Blue test performed to assess the anastomosis for leakage. Note the white gauze placed under the anastomosis to ease the visualization of the blue dye leak if present.

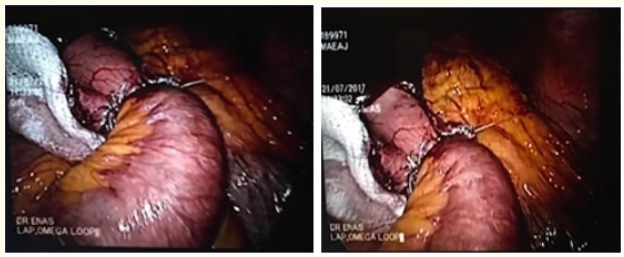


Figure 12

Literature review of omega loop bypass complications

The medical literature supports the fact that OLB surgery is safe with weight loss and complications similar or even more favorable as compared to other forms of gastric bypass procedures. Several studies have reported an average weight loss of up to 80% of excess body weight well maintained over 15 years, with less than 7% of patients having more than 10 kg weight regain [29].

It is also clear from the scientific literature that the long-term complications of the OLB is less frequent than other gastric bypass procedures which makes it more favorable by many surgeons worldwide [30]. The most frequently reported long-term complications are dyspepsia and marginal ulcers, Iron deficiency anemia, gas-cramps, nausea/vomiting, diarrhea/steatorrhea, malnutrition and excessive weight loss. The literature reported frequencies to be up to 5% gastritis and ulceration rate, 2% nausea/vomiting, 1% diarrhea/steatorrhea and 1% malnutrition/excessive weight loss [12,30,31]. Because the OLB procedure is routinely compared to the RYGB which is considered to be the gold standard bariatric procedure, complications like dumping syndrome and bile reflux with bile esophagitis are feared by RYGB surgeons. However, several studies showed that OLB procedure results in less dumping syndrome and hypoglycemic attacks compared to RYGB [31]. In terms of bile reflux with bile esophagitis, the literature suggests that this fear is mainly theoretical and not supported by any published data, and it is thought that bile plays an insignificant role in causing marginal ulcers [30].

Malnutrition after OLB is rare, however if occurs, requires intensive nutritional support and even reversal of the procedure if conservative measures fails [14]. The reported incidence of malnutrition after the Omega loop bypass procedure is between 0.5 and 1% [10,13,32], and it is believed that this incidence is related to the biliopancreatic limb length being bypassed in the procedure. Several studies have shown satisfactory weight loss results with minimal incidence of malnutrition with biliopancreatic limb length of 150 cm and tailoring the loop length according to the severity of obesity and BMI, however other studies suggested loop lengths of up to 200 cm therefore; the issue of loop length remains controversial in the current literature. It is believed that the total small bowel length is associated with height and race as well as other factors such as genetic inheritance, and hence, different population groups might have different requirement of the length to be bypassed to achieve optimal results.

In our experience the most frequently observed complications requiring reversal of the OLB procedure are debilitating nausea and early satiety, frequent and inconvenient steatorrhea, anastomotic marginal ulceration, and less frequently bile reflux with excessive weight loss. We have not encountered any patient with malnutrition or iron deficiency severe enough to require reversal.

Addressed below is literature review of the most frequently observed long-term complications requiring reversal of OLB in the Bariatric Surgery Department of Algarhoud Private Hospital in Dubai, UAE.

Debilitating nausea and early satiety

Debilitating nausea and early satiety can be related to the wrong eating habits and social eating. Although, several published studies in the literature suggested higher patient acceptance after OLB surgery as compared to the RYGB, and most patients reported an improvement in the quality of daily life style [30], however, it is also reported that depression can be associated with bariatric surgery. Despite the fact that most patients have a positive attitude to surgery and look forward to improved quality of life style and health in general after weight reduction, some patients do experience depression [33], and some literature suggest that over one third of post bariatric surgery patients develop depressive symptoms [34,35]. Food is present in every social ceremony like weddings and funerals or even just going out for a meal with friends and loved ones. Socialization revolves around food. Post bariatric surgery patients may find themselves excluded as they may not be able to participate actively in these social events leading to depression. According to the literature, most patients adapt within 3 to 6 months after surgery. However, we found in our study that removing the emphasis on food can be difficult for some patients and depression takes over to the extent of needing to reverse the surgery. In our experience, most patients requiring the reversal procedure complained of debilitating nausea and early satiety. This is thought to be mainly cultural, and despite continuous counselling and educating patients about the appropriate eating habits post bariatric surgery, it is difficult for patients to adapt and adjust to fit in with the surrounding society. In general, the middle eastern society and social life revolves around food and it is considered rude and unacceptable to reject or refuse offered food. Therefore, many patients find themselves as having to eat when they are not hungry and don't tolerate the eating habits. The options are either to be isolated from society or please the society by accepting what is offered to them. The resultant nausea and early satiety causes frustration and leads to depression. Although, serious counselling and psychological support was offered to our patients, few did not respond and were adamant to reverse the procedure. The decision to reverse the procedure is not taken lightly and involves serious counselling and education as well as psychological assessment and

support however, eventually patients' choice and decision has to be respected. Before the primary bariatric surgery, all patients go for psychological assessment and if depression is diagnosed, surgery is postponed until they are treated and can cope with the stresses of after surgery lifestyle changes. In these cases, timing of surgery is usually guided by the treating psychiatrist unless the procedure needs to be done urgently for health reasons.

There is a protocol in place for patient support in the department where this project was carried out, the counsellor along with the dietician train patients to develop healthier ways to cope with the stress and change in eating habits. Patients are encouraged to take up a hobby and get engaged rather than think about food, they are counselled in a way to help them approach food as a fuel for their activities and try to enjoy them. Since research has shown that regular exercise can help improve depression, those patients who are able to exercise are encouraged to do so regularly. Some patients can benefit from attending regular psychotherapy sessions even if not depressed, therefore; measures like follow up with a therapist and/or attend regular support group sessions are recommended.

Anastomotic ulcers

The literature reports between 0.5% to 5% anastomotic ulcer rate post OLB which is comparable to ulceration rate post RYGB surgery and is shown to be strongly associated with smoking. Treatment of most ulcers is proven to be amenable to conservative treatment [12,31,32]. This is similar to the results found in our study, however two patients required reversal due to anastomotic ulcers being resistant to conservative treatment with acid reducing agents.

Frequent/Inconvenient Steatorrhea

It is thought that OLB is more likely to be associated with diarrhea and steatorrhea due to the higher potential fat malabsorption as compared to RYGB [31,32]. Several studies reported a frequency of two to three fatty diarrheas per day which has settled within one year from the surgery and reduced to one bowel motion per day [31]. This was observed in our experience however very few cases reported this issue to be lasting for more than one year despite low fat diet, and three cases required reversal of the procedure due to frequent steatorrhea of more than 8 motions per day leading to serious inconvenience to the quality daily lifestyle and secondary anal irritation including fissures and hemorrhoids.

Bile reflux

Bile reflux has not proven to be a problem after the OLB surgery and is mainly considered as a theoretical concern by surgeons, however one of our patients required reversal for this matter. Our patient reported frequent spontaneous bilious vomiting not related to eating and almost causing aspiration. On endoscopy, bile was seen in the gastric pouch as well as esophagitis. The patient did not respond to conservative treatment and required reversal after which the symptoms have completely resolved. The same patient had excessive weight loss of almost 100% of the excess body weight and was unhappy with the cosmetic outcome although there was no malnutrition observed in the biochemical parameters. Total protein, albumin and vitamin profile remained within normal limits despite the excessive weight loss.

Nutrients deficiency

There is a concern by many surgeons that the OLB procedure might be more likely to cause micronutrient deficiency due to malabsorption compared to RYGB. However, there is no properly designed published studies in the literature to evaluate hematological and biochemical blood parameter levels in patients after OLB surgery. A study by Madhok et al (2018) compared a group of patients after the OLB procedure to a group after RYGB, and the two groups were matched for age, sex, body mass index and time of surgery. Several parameters were evaluated such as Hemoglobin, Mean Corpuscular Volume, Iron, Ferritin, Vitamin B12 and Folic acid levels. These parameters were studied preoperatively and at 6 monthly intervals post-surgery for a follow up period of 2 years. It was found that at 2 years, both procedures OLB and RYGB were associated with anemia but the post OLB patients were more likely to develop anemia at 2 years, although the difference was not statistically significant. They also found a trend towards lower Iron and Folate levels in the OLB group in comparison with RYGB [36]. In our experience, very few patients developed nutrients deficiency and fully responded to supplementation.

Omega loop bypass reversal - surgical technique

There are no clear guidelines regarding the technique of performing the reversal procedure, some surgeons dismantle the jejunojejunostomy and re-anastomosis the small bowel together and some just dismantle the previous gastrojejunostomy by dividing it at the junction between the gastric pouch and the jejunal loop using cutting stapler loading units. Below is described the technique

used for reversal of OLB in the center where the study project was conducted.

Patient and trocar position

The patient is placed in a split-leg French position with the surgeon standing between the patient's legs, the camera operator on the patient's right side, and the scrub nurse on the patient's left. Gastroscopy is performed immediately before the procedure. The surgery performed under general anesthesia with endotracheal intubation. Three trocars are placed as - one (5-mm) at the umbilicus as a camera port, one (12-mm) at the right quadrant and one (12-mm) at the left quadrant. The surgical steps are shown in Figure 1.

Identification of anatomy and adhesiolysis

The procedure begins with lysis of adhesions using the coagulating hook diathermy device, until clear identification of the gastrojejunostomy and the distal stomach is obtained. The small bowel is then completely inspected in order to identify the alimentary limb, the gastrojejunostomy, and biliopancreatic limbs. The jejunal loop is identified, and the adhesions between the gastrojejunostomy and the left lobe of the liver anteriorly and the remnant stomach posteriorly divided in order to mobilize the gastrojejunostomy. After adhesion around the gastric pouch is cleared, the old gastrojejunostomy is dismantled on the gastric side using Endo GIA linear stapler size 60mm purple loading unit, leaving the small proximal gastric pouch without dismantling the stapled jejunojejunostomy which dropped back down into the abdominal cavity.

Gastric stapling

Gastrostomy of the stump and remnant stomach is performed with the hook diathermy device guided by the 40-French gastric calibration tube. The gastric continuity is then restored through a linear stapled side-to-side anastomosis (gastrogastrostomy) between the posterolateral wall of the gastric pouch and the anteromedial wall of remnant stomach using Endo GIA 60 mm purple loading units. The gastro-gastrostomy is closed using a 2.0 Vicryl suture.

Leak testing

Gastric anastomotic site is assessed for leakage using a methylene blue saline solution injected via the orogastric calibration tube. The jejunal loop is then checked to exclude stenosis and assure a comfortable continuity. Gastroscopy was performed immediately after the procedure. No Intra-abdominal drains or nasogastric tubes are used unless surgically indicated.

Video 1. Laparoscopic Reversal of Omega Loop Bypass Surgery Published in Youtube by author - URL address: https://youtu.be/UssFW-Lx9iE

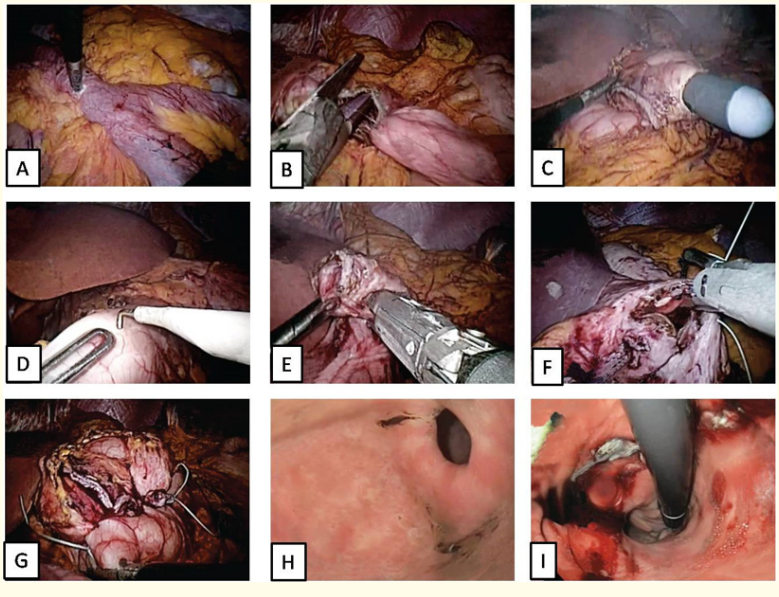


Figure 13: Details of Laparoscopic Reversal of Omega Loop Bypass Surgery - Surgical technique.
(A) Demarcating line of the gastrojejunostomy (B) Transection of gastrojejunostomy with Endo GIA stapler (C) Gastrostomy of stump with hook diathermy (D) Gastrostomy of remnant stomach with hook diathermy (E) Side to side anastomosis between the two parts of the stomach (F) Closure with 2-0 Vicryl suture (G) Methylene blue test to assess newly established gastrogastrostomy (H) Endoscopic visualization of pyloric sphincter (I) Endoscopic J-view of the cardiac sphincter and staple line.

Methodology

This is a retrospective chart review of a prospectively collected data of 16 patients who underwent ROLB between January 2014 to December 2017. All the procedures were performed in accordance with the ethical standards at Al Garhoud Private Hospital Dubai, UAE after Institutional Review Board approval. Primary laparoscopic OLB and laparoscopic ROLB were performed by one surgeon according to the NIH criteria for the management of morbid obesity.

Study design and endpoints

- **Design:** A retrospective single-center, chart review of patients who underwent ROLB
- **Duration:** All the ROLB procedures performed between January 2014 and June 2017 and follow up continued to December 2017.
- **Centre:** Department of Bariatric Surgery, Al Garhoud Private Hospital, Dubai, UAE
- **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 postoperative complications, and further, weight regain.

Primary endpoints

- Clinical evaluation was defined by the degree of improvement of the condition that had demanded the reversal: before the reversal, and at 3, 6, 12, 24, 36 and 48 months' post-surgery.
- Weight evaluation after the reversal procedure: change of total weight and Body Mass Index (BMI) before reversal, and at 3, 6 ,12, 24, 36 and 48 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) [29], 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.

Achievability

From October 2012 to December 2017 there were 920 cases of OLB performed in the department of bariatric surgery where this study was conducted. Reversal procedures started in January 2014 and therefore the study period between January 2014 to December 2017. In the study period of 4 years 17 ROLB procedures were performed in Al Garhoud Private Hospital and 16 patients were included in the study.

Novelty

To the best of our knowledge, this is the first report from the UAE describing the technical feasibility, safety and operative outcomes of laparoscopic ROLB surgery. The reversal procedure appears feasible and safe to resolve the post-operative complications in patients who have undergone OLB. 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.

Preoperative preparation

Before reversal surgery, all patients underwent extensive face-to-face preoperative counseling on diet and lifestyle modification for 6 months with a multidisciplinary team consisting of a nutritionist, psychologist, endocrinologist, and surgeon. Each visit included an extensive discussion about the proposed procedure, the surgeon's decision to offer surgery, weight regain and other complications and necessity of close follow-up after the reversal. Emotional and behavioral causes for failure of primary surgery were ruled out. Patients were then evaluated to exclude causes for technical failure. The pros and cons of the reversal procedure were explained to all patients in detail, and all provided informed consent for the procedure. Upper GI contrast radiology and endoscopy performed to check for ulcers and other pathologies. Supplementation with albumin, vitamins and minerals were administered according to laboratory investigation results in case of deficiencies. On admission to hospital, compression stockings and pneumatic compression devices were used before and after surgery, for prevention of deep venous thrombosis.

Postoperative care

Patients were kept nil by mouth for 6 hours postoperatively after which sips of water was started at 60 mls per hour and full am-

bulation commenced as part of our ERAS protocol (Early Recovery After Surgery). Immediate postoperative endoscopy performed on all patients and oral contrast study using a water-soluble dye was performed on postoperative day 1 to check for a leak. After this, patients were started on liquids orally for 15 days followed by semi-solids for 15 days and subsequently solids.

Data collection

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 multidisciplinary assessment, blood tests, barium meal and gastroscopy to rule out complications.

Pre-OLB demographic information including age, sex, weight and body mass index (BMI) were at first captured for patient identification. All additional relevant information evaluated during an in-office consultation including details of index OLB, ROLB, gastrointestinal status, postoperative course, development of complications, eating and exercise habits, use of medications, and complete biochemical reports were then extracted from records archival. Clinical follow up data was collected at 3, 6, 12, 18, 24, 36 and 48 months' post ROLB.

Laboratory analysis

Routine biochemical investigation records, such as full blood count (CBC), electrolytes, fasting plasma glucose (FPG), calcium and potassium levels were noted for all patients at baseline and at last visit post-operatively. In addition, nutritional parameters including serum iron, serum vitamin B12, serum albumin, and total protein were also evaluated.

Statistical analysis

Continuous quantitative variables are presented as mean ± SD and range. Categorical variables are expressed as number and frequencies (%). Differences between OLB, laparoscopic ROLB, and last follow-up time points were investigated using paired nonparametric tests ($\chi 2$ test for categorical variables pair-t-test for continuous variables). Statistical significance was defined as a two-tailed p values less than or equal to 0.05. All analyses were performed using statistical software SPSS version 17.

Results

Patient demographics and operative data

A total of 920 patients underwent OLB at Al Garhoud Private Hospital in Dubai, UAE between October 2012 and December 2017. The reversal procedure started in January 2014 and the study period was restricted to 4 years between January 2014 to December 2017. The percentage of the reversed cases was found to be 1.85% of the total number of performed OLB surgeries. Total of 17 cases out of 920 required reversal and the elapsed time between the primary OLB and laparoscopic ROLB was approximately 33 months (range, 18-48).

This retrospective chart review was restricted to 16 patients who underwent elective reversal procedure during the period between January 2014 to June 2017 and follow up continued to December 2017. One patient was excluded from the study because reversal was done as an emergency procedure following ingestion of detergent solution by the patient. This case will be studies separately and will be published as a case report. The remaining 16 cases were done electively under controlled circumstances.

The mean age was 34.38 ± 7.55 years (range, 23-56), 10 females (62.5%) and 6 male (37.5%), mean BMI prior to index OLB was 41.56 ± 2.61 kg/m^2 (range 38-47). Average BMI immediately prior to reversal was 24.63 ± 3.74 kg/m^2 (range 18-34).

Mean length of hospital stay of 2.0 ± 3.0 days (range, 1-3). Operative time for reversal surgeries ranged from 86 to 150 minutes (average 118 minutes). There were no major postoperative complications, no anastomotic leak and no additional interventions were

required.

Indications for omega loop reversal

The most frequent indications for reversal in our series were debilitating nausea and early satiety after OLB surgery. This was observed in 11 patients (68.75%) and out of these 11 patients, one also had inconvenient steatorrhea. Two more patients were reversed because of frequent and inconvenient steatorrhea. Anastomotic ulcer was the reason for reversal in 2 patients and one patient suffered from bile reflux along with excessive weight loss. Those with anastomotic ulcers and bile reflux requiring ROLB were amongst few patients who did not respond to conservative treatment measures. Indications for reversal and outcomes are summarized in Table 1.

Case	Reason for reversal	BMI PRE OLB kg/m^2	BMI PRE ROLB kg/m^2	BMI POST ROLB kg/m^2
1 M	Nausea/Early satiety	47	18	23
2 F	Nausea/Early satiety	39	24	30
3 F	Bile Reflux/EWL	41	28	32
4 F	Nausea/Early satiety	38	19	25
5 F	Nausea/Early satiety	40	26	29
6 M	Anastomotic Ulcer	45	25	30
7 M	Nausea/Early satiety	39	24	28
8 M	Nausea/Early satiety	43	24	30
9 F	Steatorrhea	41	23	32
10 F	Anastomotic Ulcer	40	21	28
11 M	Nausea/Early satiety	40	23	30
12 F	Steatorrhea	42	25	32
13 F	Nausea/Early satiety	43	27	32
14 M	Nausea/Early satiety	40	26	31
15 F	Nausea/Early satiety	46	27	33
16 F	Nausea/Early satiety/Steatorrhea	41	34	34

Table 1: Individual patients: Reason for reversal and BMI change summary.

OLB-Omega loop bypass; ROLB- Reversal of Omega loop bypass; BMI- Body mass index.

Post-reversal weight outcomes

The post reversal follow up protocol was set at 3,6,12,24 and 48 months' period. Average BMI reported at 6 months follow up was 26.79 ± 2.99 kg/m^2. The difference between BMI before and after bypass reversal was not statistically significant at 6 months follow up. For the studied 16 patients, last follow up date ranged between 6 to 48 months. Units of BMI loss from the primary OLB to reversal and units of BMI gain from the ROLB to last follow up are shown in Table 2. Weight and BMI changes before and after reversal are demonstrated on Graph 1, and the average BMI changes before and after reversal shown in Table 3 below.

Patient follow up information was available for an average of 27.75 ± 15.31 months (range 6-48) post ROLB. The average BMI at last documented follow-up appointment was 29.89 ± 2.83 kg/m^2 (ROLB baseline; 24.52 ± 3.74; p = 0.000); this represented an average cumulative weight gain of 13.81 ± 4.79 kgs (23.02% increase) from their reversal baseline (63.43 ± 11.09 kgs; p = 0.000), while weight loss of 30.69 ± 13.03 kgs (27.85% decrease) from their index OLB baseline (107.94 ± 15.28 kgs; p = 0.000). One patient maintained the same weight till the last follow up. Another patient had lost about 62% of weight (from 147.0 to 56.0 kgs) over 2 years following primary OLB. However, he regained weight point of 73.0 kg in 2 years after ROLB, but did not gain all the weight back to pre-OLB weight (147.0 kgs). Patient's weight and BMI changes are summarized in Table 4.

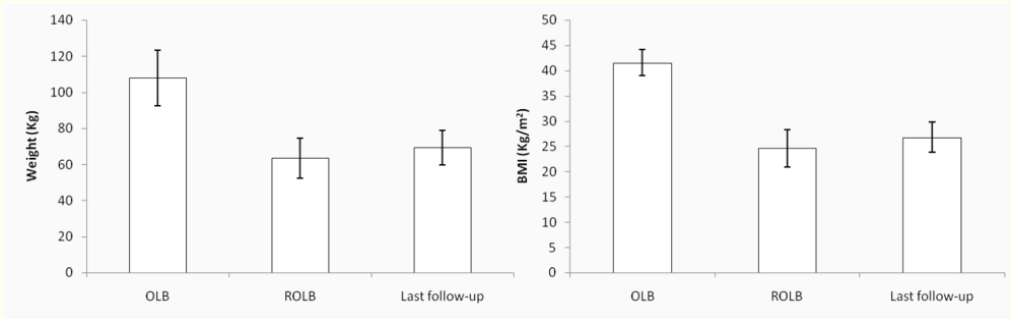
Biochemical analysis before and after reversal

Biochemical analyses remained stable and within the normal

Case	BMI LOSS PRE ROLB kg/m²	BMI GAIN POST ROLB kg/m²	%∇ BMI PRE ROLB	%∇ BMI POST ROLB
1 M	-29	+5	61.7	27.78
2 F	-15	+6	38.46	25.00
3 F	-13	+4	31.71	14.29
4 F	-19	+6	50.00	31.58
5 F	-14	+3	35.00	11.54
6 M	-20	+5	44.44	20.00
7 M	-15	+4	38.46	16.67
8 M	-19	+6	44.19	25.00
9 F	-18	+9	43.90	39.13
10 F	-19	+7	47.50	33.33
11 M	-17	+7	42.50	30.43
12 F	-17	+7	40.48	28.00
13 F	-16	+5	37.21	18.52
14 M	-14	+5	35.00	19.23
15 F	-19	+6	41.30	22.22
16 F	-7	00.00	17.07	00.00

Table 2: BMI changes before and after reversal.

OLB-Omega loop bypass; ROLB- Reversal of Omega loop bypass; BMI- Body mass index; %∇ BMI**-** Percentage change in BMI.



Graph 1: Weight and BMI changes before and after reversal.

Average BMI pre OLB kg/m²	Average BMI Pre ROLB kg/m²	Average BMI post rolb kg/m²	Average BMI loss pre rolb kg/m²	Average BMI gain post rolb kg/m²
41.5	24.6	29.9	16.9	5.3

Table 3: Average BMI changes before and after reversal.

OLB-Omega loop bypass; ROLB- Reversal of Omega loop bypass; BMI- Body mass index.

Parameters	Baseline Index OLB	Baseline ROLB	At time of most recent follow-up
Weight kgs, mean ± SD	107.94 ± 15.28	63.44 ± 11.09	75.69 ± 8.61
BMI kg/m^2, mean ± SD	41.56 ± 2.61	24.52 ± 3.74	29.89 ± 2.83
Cumulative weight change, kgs ± SD		Loss from index OLB 44.50 ± 15.23 (p = 0.000)	Gain from ROLB 13.8 1 ± 4.79 (p = 0.000) Loss from index OLB 30.69 ± 13.03 (p = 0.000)

Table 4: Patients weight change summary.

SD- Standard deviation; OLB-Omega loop bypass; ROLB- Reversal of omega loop bypass.

ranges following reversal surgery. There were no significant differences between pre- and postoperative levels of Hemoglobin, Iron, vitamin B12, calcium, potassium and total protein levels. However, slightly significant increase in albumin levels was observed post-reversal. Fasting blood glucose level was within normal range, and there was no evidence of hypoglycemia (Table 5).

Variables	Normal values	PRE ROLB	POST ROLB	p value
Hemoglobin (g/dL)	12.0 - 16.2	12.44 ± 0.87	12.69 ± 0.81	0.008
Iron (µg/dl)	41 - 141	38.25 ± 5.01	41.19 ± 4.72	0.003
Vitamin B12 (pg/ml)	279 - 996	586.63 ± 128.26	560.75 ± 111.57	0.070
Albumin (g/dL)	3.5 - 5.5	3.81 ± 0.20	3.98 ± 0.23	0.001
Total protein (g/dl)	6.7 - 8.6	6.51 ± 0.46	6.60 ± 0.41	0.219
Total calcium (mg/dL)	8.7 - 10.2	8.89 ± 0.20	8.91 ± 0.24	0.423
Potassium (mmol/L)	3.5 - 5.0	3.83 ± 0.20	3.83 ± 0.20	1.00
FBG (mg/dl)	75 - 100	87.81 ± 4.69	89.63 ± 5.16	0.124

Table 5: Comparison of laboratory investigations.

ROLB- Reversal of omega loop bypass; FBG- Fasting blood glucose.

Reversal outcomes

Mean length of hospital stay following ROLB was 2.0 ± 3.0 days (range, 1-3). One patient stayed in hospital as a day case as has made a remarkable recovery with minimal postoperative pain and discomfort and his residence was only 2 miles away from the hospital. This patient returned to hospital the next day for water soluble contrast study and follow up.

Reversal completely resolved the post-OLB complications of all patients except one that required psychological counseling and support for persistent nausea. During the mean follow-up of 27.75 ± 15.31 months (range 6 to 48) post reversal, no postoperative morbidity or mortality was encountered and none of the feared potential complications occurred such as GERD, temporary food intolerance/gastroparesis, liver dysfunction, strictures, hernia, diarrhea, syncope, peritonitis, abdominal abscess, or anastomotic leak. Post reversal complications studied are demonstrated in Table 6.

Discussion

Following a thorough review of the literature to evaluate the reported indications for reversal of OLB, it was noticed that the OLB surgery was routinely compared to the traditional RYGB as it has shown similar or even better results in terms of percentage of excess weight loss and improvement of quality of life. Most of the literature regarding the indications for reversal of OLB addresses malnutrition and other potential complications like bile reflux and anastomosis ulcers which are mainly associated with the RYGB procedure. Minimal data are available on the indications, technique

Post-operative Complication after ROLB	Total out of 16 n (%)
Morbidity	0
Anastomotic Leak	0
Post-operative Bleeding	0
Abdominal Abscess	0
Stenosis	0
Strictures	0
Hernia	0
Diarrhea	0
Temporary Food Intolerance/Gastroparesis	0
Liver Dysfunction	0
Syncope	0
Peritonitis	0
Persistent Nausea	1 (6.25)

Table 6: Post reversal complications.

and outcomes of Omega loop bypass reversal to normal anatomy. The present study reports our experience with ROLB in terms of indications of reversal, post reversal outcomes and the surgical technique adopted.

This is the first clinical experience from the UAE which evaluated the outcome of laparoscopic ROLB and confirmed that this procedure is effective and durable with low complication rate. In our experience, the primary indication for reversal was nausea and early satiety in 68.75% of patients while the literature suggested more severe potential complications mainly due to the routine comparison of OLB with RYGB. Dapri et al. reported a variety of indications for reversal of the OLB to normal anatomy, including food intolerance, dumping syndrome, excessive weight loss, and dissatisfaction with the bypass [8] while Campos et al. reported endocrine complications as an indication for reversal [5].

In this retrospective review, the reversal rate of the OLB was found to be 1.85% of all OLB surgeries performed in our center over 5 years' period, and was associated with low incidence of overall postoperative complications. Our results are not only comparable to those published by Genser et al. and Rutledge and Walsh reporting 0.89% and 1.41% of revision surgery after OLB [9,10] but also discordant from Himpens et al. publication in which 9.2% reversal post laparoscopic RYGB was recorded [11].

In contrast to other studies reporting 0.4-1.3% of OLB patients needed surgical revision due to malnutrition [10,12,13], none of the patients in our experience underwent ROLB because of nutrient deficiency. This can be theoretically attributed to the 40 French calibration tube size for the gastrectomy and mean BPL length of at least 180-200 cm (one third of the small intestine length ranging between 560 to 600cm) used in this study.

A questionnaire-based survey conducted among surgeons performing OLB found 0.6% revision surgery rate with BPL length of >250 cm and lowest rates of 0% with BPL of 150 cm or lower [14]. Previous studies have also reported 1.75% complication rate with 170 cm and 1.28% rate with 180-200 cm [15]. This can be explained by variations in patient characteristics or a lack of precision in techniques used for measurement of small bowel length.

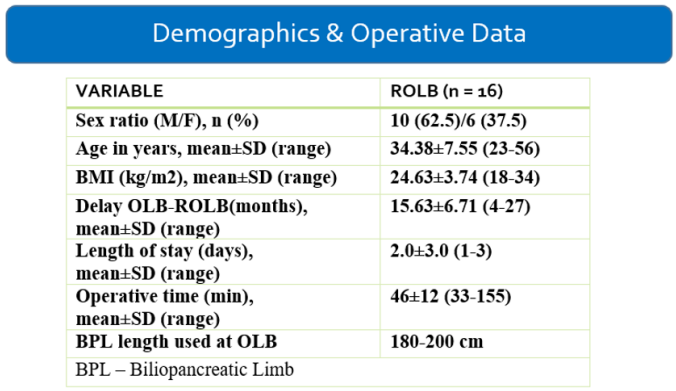
Our patients underwent a reversal surgery at an average 33 months (range 18-48) post-OLB. Genser et al. 2017 in 10-year retrospective chart review of OLB reversal in 26 patients reported a mean delay of 20 months' post OLB [9]. In 2016, Reche et al. published a case report on reversal of OLB to normal anatomy indicating a delay of 2 years for reversal post OLB [16].

Revision surgery has been associated with higher complication

rates of 3%-33%, than index bariatric procedure [17]. However, it can be successfully performed laparoscopically without any major complication as reported in previously published series [5,7,8,18-22]. Similarly, in our experience, laparoscopic reversal eliminated most of the chronic complications related to OLB, with only one re-admission for persistent nausea. This was completely resolved after psychological counseling and support. The remaining patients had a satisfactory post-operative phase with no complications and improved quality of life.

The American Association of Clinical Endocrinologist (AACE), the Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS) recommends appropriate nutritional evaluation before and after any bariatric surgical procedure (Category of Recommendation: Grade C) [23]. Reversal of OLB to normal anatomy for severe malnutrition may correct the malabsorption problem [7] but might prevent adequate weight loss by also eliminating the restrictive component of the primary surgery. In our experience, laparoscopic ROLB slightly significantly increased the level of albumin however all other studied parameters remained the same and within the normal range. As per other published reports [20], our patients also showed a significant increase in BMI after 27.75 months of reversal; though overall it was significant loss from the index OLB baseline. One patient was even able to maintain the same weight till the last follow up post reversal. On the contrary, Moon et al. and Dapri et al. reported that more than 70% and 50% of patients regained all or some of their lost weight following reversal to normal anatomy, respectively [8,20]. Although revision surgery could have been considered rather than reversal to prevent weight regain, however, we opted for reversal to avoid burdening them with more complications and taking into consideration patient choice and decision after intense counseling.

This retrospective review is limited due to small sample size and no comparator group. It also misses those patients who have been operated on by surgeons other than the primary surgeon. In view of these limitations, we have shown that laparoscopic ROLB to normal anatomy is feasible and may successfully reduce post OLB complications. However, OLB reversal should be performed only by sufficiently experienced bariatric surgeons to prevent occurrence of post-operative complications. More research is needed with well conducted multicenter trials, larger sample numbers and longer period of follow up to evaluate the outcome of Omega Loop Bypass Reversal surgery.



VARIABLE	ROLB (n = 16)
Sex ratio (M/F), n (%)	10 (62.5)/6 (37.5)
Age in years, mean±SD (range)	34.38±7.55 (23-56)
BMI (kg/m2), mean±SD (range)	24.63±3.74 (18-34)
Delay OLB-ROLB(months), mean±SD (range)	15.63±6.71 (4-27)
Length of stay (days), mean±SD (range)	2.0±3.0 (1-3)
Operative time (min), mean±SD (range)	46±12 (33-155)
BPL length used at OLB	180-200 cm

BPL – Biliopancreatic Limb

Figure 1: Demographics and Operative Data.

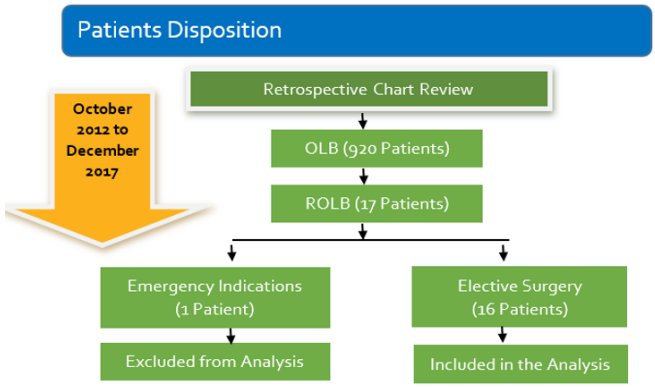


Figure 2: Patients Disposition.

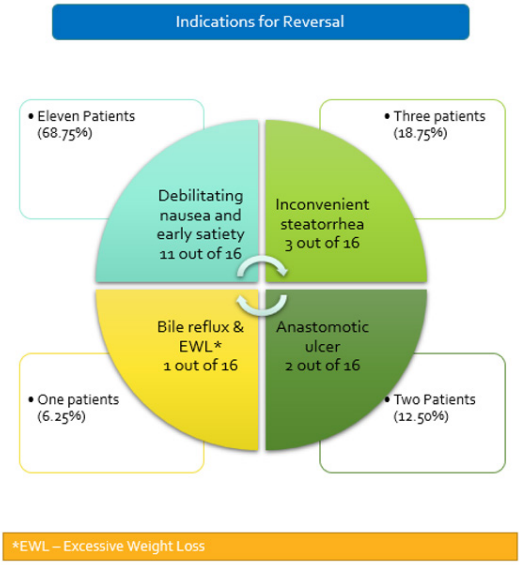


Figure 3: Indications for Omega Loop Bypass Reversal.

Post ROLB Complications

Post-operative Complication after ROLB	Total patients' n (%)
Morbidity	0
Anastomotic Leak	0
Post-operative Bleeding	0
Abdominal Abscess	0
Stenosis	0
Strictures	0
Hernia	0
Diarrhea	0
Temporary Food Intolerance / Gastroparesis	0
Liver Dysfunction	0
Syncope	0
Peritonitis	0
Persistent Nausea	1 (6.25)

Figure 4: Complications post Reversal.

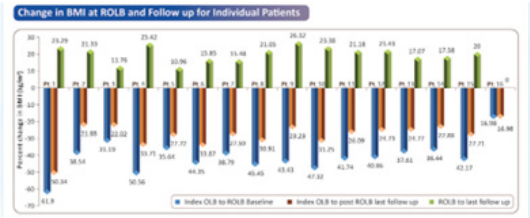


Figure 5: Changes of BMI at the time of Reversal and at Follow Up.

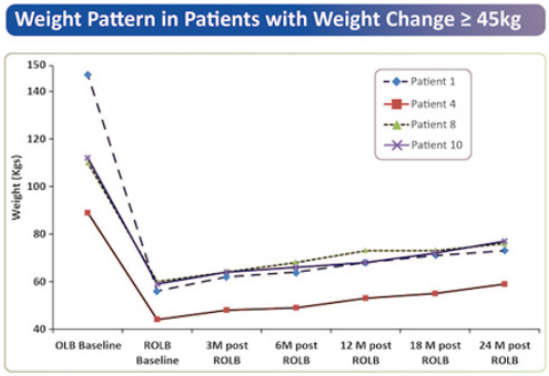


Figure 6: Weight pattern in patients with a weight change of more than 45 Kgs.

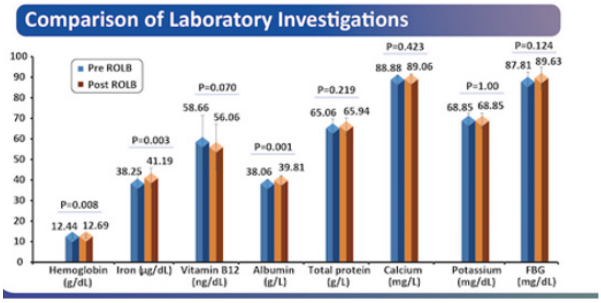


Figure 7: Comparison of Biochemical Parameters.

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