Acta Scientific Gastrointestinal Disorders (ISSN: 2582-1091)

Volume 7 Issue 1 January 2024

Research Article

The Effectiveness of Endoscopic Argon Plasma Coagulation (APC) of Dilated Gastrojejunostomy in the Treatment of Weight Regain After Omega Loop Gastric Bypass Surgery

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DOI: 10.31080/ASGIS.2024.07.0603

Received: October 30, 2023

Published: December 27, 2023

Abstract

Background: Omega loop gastric bypass bariatric surgery (OLGB) has shown to be an effective measure for treating morbid obesity and metabolic diseases associated with it, however weight regain few years after surgery poses a major problem as it is accompanied by the return of obesity and the associated metabolic disorders. Surgical revision carries a complication rate leading to morbidity and mortality, there is a demand to find a safe and effective treatment for this problem to avoid revision surgery. One of the main causes of weight regain after OLGB is widening of the gastrojejunostomy anastomosis which connects the gastric pouch to the jejunal loop. Endoscopic Argon Plasma Coagulation (APC) can be used potentially to aid narrowing of the anastomosis leading to weight loss.

Objectives: To study the safety and effectiveness of APC in the treatment of widened gastrojejunostomy anastomosis for patients who regained weight after OLGB.

Methods: A prospective observational study was conducted on a group of twenty patients who underwent APC procedure for dilated gastrojejunostomy with 6 months follow up. Outcome measures included weight loss and complication rate. The results were compared to a matched group of patients (n = 31) who underwent revision surgery for the same reason.

Results: In terms of weight loss and complication rate; the APC group showed a mean weight loss of 10 kgs and a drop of 4 BMI units with no reported complications, whereas, the revision surgery group showed similar results with a mean weight loss of 11 kg and a drop of 4 BMI units. There was 10% complication rate which included 2 cases of anastomotic leak and one case of bowel obstruction secondary to internal herniation.

Conclusion: APC can be safe and effective for treating weight regain after OLGB, although an effective innovative idea however more sample number and longer follow up are needed with well-designed randomized trials to validate the findings.

Keywords: Gastrojejunostomy, Endoscopic Argon Plasma Coagulation

Abbreviations

APC: Argon Plasma Coagulation; BS: Bariatric Surgery; GJ: Gastrojejunostomy; GJA: Gastrojejunostomy Anastomosis; RYGB: Ru-en-y Gastric Bypass; OLGB: Omega Loop Gastric Bypass; WR: Weight Regain; WL: Weight Lose; EWL%: Percentage Excess Weight Lose

Introduction

An introduction to the research topic

Obesity and its associated metabolic disorders has been a major public health problem for many decades and is considered as a chronic disorder. It predisposes to several multi-system diseases such as high cholesterol, diabetes, high blood pressure and several more pathologies. Bariatric surgery has proven to offer effective weight-loss and metabolic benefits over the long run [4]. Despite effective weight loss, a large percentage of patients regain a significant portion of their weight after an average of 5 years leading to the return of the obesity and its related diseases [3]. Weight regain has several different causes ranging from patient factors to procedure specific factors, and more than often the causes are multifactorial. In the classical gastric bypass surgery (RYGB) (Appendix 1), dilatation of the outlet from the stomach to small bowel i.e. gastrojejunostomy (GJ) leads to the ability to ingest larger quantity of food resulting in weight regain. Reducing the size of the dilated outlet GJ is routinely done by revision surgery [9] which is proven

to carry significant risks and limited benefits. Non-surgical endoscopic revisions which can reduce the diameter of the gastrojejunal anastomosis may offer a less invasive, effective and safe option as well as being reproducible, less complex to perform and cost effective [14].

Appendix 1: Group 1: Endoscopic APC group.

No	Age/ gender	Olgb date	Pre olgb wt kg/bmi	Mini wt kg/bmi	Pre-apc weight kg/bmi	Apc date	Follow-up kg/ bmi 1-2 months	Follow-up kg/ bmi 4-6 months	Comp
1	43 F	11.02.20	109 43	62 24	81 32	12.08.22	74 29	69 27	NONE
2	31 F	14.02.17	92 39	56 24	69 29	12.08.22	66 28	61 26	NONE
3	35 M	05.04.20	102 40	65 25	78 30	21.08.22	74 29	68 27	NONE
4	32 F	09.04.20	95 41	70 30	84 36	02.09.22	81 35	77 33	NONE
5	24 F	19.03.19	116 41	63 22	80 28	02.09.22	76 27	71 25	NONE
6	29 F	08.05.19	103 41	68 25	90 36	09.09.22	85 34	79 31	NONE
7	42 F	11.11.18	92 40	64 28	82 36	17.09.22	77 33	72 31	NONE
8	41 M	05.10.19	98 37	65 24	78 29	17.09.22	73 27	64 24	NONE
9	39 F	15.03.20	112 43	75 29	92 35	22.09.22	87 33	82 31	NONE
10	43 F	23.04.18	105 42	77 31	89 36	22.09.22	86 34	81 32	NONE
11	27 F	20.12.19	83 44	60 32	76 40	02.10.22	72 38	67 36	NONE
12	38 F	18.09.18	108 41	68 26	83 31	05.10.22	80 30	77 29	NONE
13	44 M	13.04.20	102 44	67 29	87 37	28.10.22	83 36	77 33	NONE
14	34 F	14.07.17	81 38	56 26	74 35	12.11.22	71 33	65 30	NONE
15	29 M	05.01.20	122 40	69 27	83 33	21.11.22	78 31	71 23	NONE
16	39 M	09.09.20	115 41	73 28	87 35	02.12.22	73 27	71 25	NONE
17	24 F	09.07.19	99 41	63 27	80 33	02.12.22	77 32	73 30	NONE
18	23 M	26.08.19	123 39	64 20	90 29	10.12.22	86 27	79 25	NONE
19	39 F	19.09.20	119 43	77 28	89 32	15.12.22	84 30	80 29	NONE
20	33 M	03.08.18	116 38	71 23	91 30	22.12.22	86 28	81 27	NONE

In 1997, a procedure named Omega Loop Gastric Bypass (OLGB) (Appendix 2) has evolved and its application in increasing worldwide and has proven to be effective and safe, however weight regain was noticed to be an issue in some patients leading to the return of obesity and its related diseases [20]. The writer of this project is a Bariatric Surgeon performing mainly OLGB procedure with more than 15 years' experience of practicing this specific surgery and observing the outcome. Similar to RYGB this procedure showed positive results in terms of weight loss and resolution of metabolic disorders, however weight regain and return of associated diseases were noticed. Revision surgery showed to be associated with complications and high cost burdening patients and the healthcare organization as well as the need for highly skilled and experienced surgeons to perform the revision. The aim of this research is to innovate an idea of a non-surgical procedure that is less invasive, safe and effective. For the innovation to be applicable, it needs to be available, cost effective, accepted by physicians and organizations, less complex to perform and reproducible. The idea is the application of endoscopic Argon Plasma coagulation APC to tighten the dilated GJA in OLGB procedure as a treatment for weight regain will be studies. The hypothesis is "APC can be used safely and effectively as a treatment for weight regain after Omega Loop Gastric Bypass".

Appendix 2: Group 1 Mean data (APC group).

No	Years since olgb	Max weight loss kg/bmi	Weight regain since min wt kg/bmi	Apc weight difference after 1-2 months kg/bmi	Apc weight difference after 4-6 months kg/bmi	Total wt lose 6 months
1	3	47 19	19 8	7 3	5 2	12 5
2	6	36 15	13 5	3 1	5 2	8 3
3	3	37 15	22 5	4 1	6 2	10 3
4	3	25 11	14 6	3 1	5 2	8 3
5	4	53 19	17 6	4 1	5 2	9 3
6	3	35 16	22 11	5 2	6 3	11 5
7	4	28 12	18 8	5 3	4 2	9 5
8	3	33 13	13 5	5 2	9 3	14 5
9	3	37 14	17 6	5 2	5 2	10 4
10	4	28 11	12 5	3 2	5 2	8 4
11	3	23 12	16 8	4 2	5 2	9 4
12	4	40 15	15 5	3 1	3 1	6 2
13	3	35 15	20 8	4 1	6 3	10 4
14	5	25 12	18 9	3 2	6 3	9 5
15	3	53 13	14 6	5 2	7 8	12 10
16	2	42 13	14 7	14 8	2 2	16 10
17	3	36 14	17 6	3 1	4 2	7 3
18	3	59 19	26 9	4 2	7 2	11 4
19	2	42 15	12 4	5 2	4 1	9 3
20	4	55 15	17 7	4 2	5 1	9 3
Mean	4	37 13	17 7	5 2	5 2	10 4

The research topic in the organizational context

From the organizational point of view, weight regain after OLGB imposes negative implications due to overloading the metabolic and bariatric services causing a huge burden on the organization. Several issues are to be considered:

- The need for highly skilled surgeons subspecialized in revision bariatric surgery, most bariatric surgeons are experienced and can efficiently perform the primary surgery however revision surgery requires surgeons who are dedicated and specialised only to deal with highly complex cases and revisions. This calibre surgeons are not readily available and come with a very high cost, making revision surgery highly complex, not easily reproducible, not easily available and highly in cost.
- Since the introduction of the DRG insurance system, weight regain services might not be covered directly by the insurance provider which adds a huge financial burden on the organization. DRG stands for Diagnosis Related Groups, which is based on codes used to classify the severity of the case and accordingly calculate the financial package which is paid to the organization [17]. Admission for the same diagnosis or readmission due to complications might not be reimbursed.
- Redo surgery is associated with unacceptable outcomes, less patients satisfaction, organizational disrepute and lose of public trust.

These issues introduce an opportunity for innovation to avoid revision surgery. The idea of Endoscopic APC as a treatment for weight regain after Omega Loop Gastric Bypass can offer a reasonable option if its safety and efficacy are proven.

The research topic in the wider literature context

Recently OLGB has become a popular bariatric surgical procedure, especially in Europe and the Asia Pacific region. It has proven its metabolic benefits and more than 80% excess weight lose [20]. Like all other bariatric surgeries, weight regain after OLGB is observed worldwide [23]. The writer of this project has observed between 1-2% of patients regain weight over an average of 4-years after the primary surgery requiring intervention, revision surgery was associated with an undesirable complication rate. These observations were similar to what has been reported in the literature, a major Italian study conducted by Musella., *et al*. 2022 showed 12% complication rate after revision of OLGB which included early and late adverse effects.

Although OLGB surgery is being performed more frequently nowadays and weight regain rate is similar to what's reported for other bariatric procedures, there are no studies published to address the treatment options, especially the use of APC has not been studied. Musella., *et al*. 2022 and Kermansaravi., *et al*. 2020 documented the prevalence of weight regain after OLGB and reported that revision surgery was the main treatment adopted. There are no systematic reviews published in the literature to look at other modalities to treat weight regain after OLGB. This causes a major issue for surgeons dealing with this procedure as there is no evidence to guide their preference and they have to treat weight regain after OLGB without evidence based medicine or established guidelines. There is a demand for innovation to provide a safe and effective option other than revision surgery to address the weight regain due to dilated GJA in this type of gastric bypass procedure. In this project, the safety and effectiveness of APC for weight regain after OLGB procedure will be studied by carrying out a pilot study as an observation on a suitable group of patients.

An overview/definition of the innovation

Innovation in healthcare can be defined as the combination of invention, adoption and diffusion put together to introduce a new or any existing idea or method that is new to the field or the organization, and for innovation to be successful it must be desirable and usable [15]. The innovation approach used for this project is derived from the business model of the 4 'P's which is includes paradigm, process, position and product [24].

- Paradigm which makes the driving force of the innovation, and in this case all stakeholders are involved in as the driving force i.e., the patients, physicians, healthcare organizations, insurance providers and even government officials. The writer who is a physician was driven by several factors, mainly the patients' need for a safer and more effective treatment as well as being cost effective and maintain a high quality of care.
- Pprocess innovation is defined as the implementation of a new or improved delivery method including changes in techniques or their use [7]. The application of process innovation in healthcare means optimizing patient care leading to better outcomes. The process innovation for this project is to be able to use APC as a treatment for weight regain after OLGB.
- Position innovation creates a change in the concept of using the technique as positioning it where it's needed. This means a change or shift in perception of the consumer to using the technique differently [24]. The idea of this project is to shift the perception of physicians and patients to using endoscopic APC to tighten the GJA after OLGB.
- Product innovation involves making changes to the product being used to lead to better outcomes, for example improving a clinical procedure or changing it to be used safely and effectively in patient care or treatment [6]. Implementing APC for weight regain after OLGB has several benefits including the non-invasive nature of the technique, availability and ease of application, low complication rate and cost effectiveness.

The research aims and objectives

APC has been used in RYGB surgery and has proven safe and effective, however to date there is no published data in the medical literature assessing its use to treat weight regain due to dilated GJA in OLGB, therefore the project title clearly reflects a specific treatment modality for a specific condition. If APC proves its safety and efficacy to treat weight regain after OLGB, it will be comparable to revision surgery in these terms. The main objectives of this research are to assess the safety and clinical effectiveness of APC as compared to revision surgery. The results will also help to indicate the cost effectiveness, ease of application and reproducibility.

The hypothesis is "APC can be used safely and effectively as a treatment for weight regain after Omega Loop Gastric Bypass".

Primary outcome measures are:

- The effectiveness of the procedure in terms of weight lose
- The safety of the procedure in terms of complications

Secondary outcome measures are:

- Cost effectiveness in terms of total cost of the procedure compared to revision surgery

- Availability of the technology and staff needed to perform the procedure
- Ease of application in terms of surgeons training requirement
- Acceptance of the procedure by patients, staff and the organization

Summary and Conclusions

This research project demonstrates effective clinical leadership and academic innovation to help treat a common condition which causes a health hazard and a burden on healthcare organizations worldwide. Leadership is demonstrated by forming the team and gaining their interest and commitment, as well as going through the appropriate channels to obtain ethical approval and funding. The innovation concept is applicable because this non-invasive technique was not studied on this surgical procedure in the past making this project the first of its kind as an observational first exploration study for the innovation suggested.

Literature Review

Introduction

OLGB is recognized as an effective bariatric and metabolic procedure and has many advantages including lower complication rate as compared to other surgical procedures [13]. Weight regain is reported to count for 1%–2% of patients after 4-5 years of surgery [20]. Currently, there is no consensus on the management and no systematic review published in the literature, revision surgery has shown to carry a complication rate which can be reduced and even avoided if less invasive techniques are available [14]. APC has been used endoscopically in other bariatric procedures and has proven its safety and efficacy for its less invasive nature and ease of application [2], however this technique has not been studied on OLGB. A scoping review will be conducted to evaluate the literature on the use of APC as a treatment for weight regain after bariatric surgeries which resulted in GJA dilatation causing weight regain.

The literature review methodology

The purpose of this section is to review and synthesize the existing literature pertaining to safety and effectiveness of APC in the treatment of weight regain after gastric bypass surgery, specifically OLGB. A scoping review conducted and the thematic approach was applied, a comprehensive search for relevant literature using the appropriate keywords joined by operators 'AND' and 'OR' in multiple databases and search engines was carried out. The number of citations for the relevant articles was noted. For the literature search, several databases were used including PubMed, Google web and Scholar, MEDLINE, EMBASE and RCSI library. The keywords used were, RYGB, Omega loop bypass, management of weight regain, dilated gastrojejunostomy anastomosis, argon plasma coagulation. Search period from 2016 to 2023 was chosen to comply with the five-year rule for literature search. Selected studies included patients with weight regain after bariatric surgery, gastric bypass surgery, omega loop bypass, diagnosed dilated gastrojejunostomy, and evaluated the efficacy and safety of APC. The excluded studies were reviews, case reports, animal studies, and studies without full text or sufficient data. Information extracted from each study included the authors names, year of publication, country, study design, number of cases, age, gender, surgery type, widened gastrojejunostomy, follow-up time, APC, short-term and long-term complications. The efficacy of APC therapy was evaluated according to the degree of weight loss, while the safety was assessed based on the incidence of complications, which were categorized as short term (e.g. abdominal pain, bleeding and perforation) and long term (e.g., stenosis, strictures, and anastomotic ulcers). With adherence to the search criteria, fifty-six (56) studies were found. Forty-nine (49) papers were suitable for inclusion and after removing the duplicates and exclusion of irrelevant studies, comments, case reports, and reviews, 26 studies were selected for the review of the full text. Another 14 studies were excluded due to the absence of certain interested outcomes including short term complications, and 12 studies were included in the final review.

Study Title

"THE EFFECTIVENESS OF ENDOSCOPIC ARGON PLASMA COAGULATION (APC) OF DILATED GASTROJEJUNOSTOMY IN THE TREATMENT OF WEIGHT REGAIN AFTER OMEGA LOOP GASTRIC BYPASS SURGERY".

Introduction/Rationale

Following a through scoping literature review, there was no studies published to evaluate the effect of endoscopic APC to treat weight regain after OLGB due to dilated GJA and most of the literature evaluates the use of APC for RYGB surgery. Since OLGB is becoming more popular and increasing worldwide, weight regain is becoming more and more apparent and needs addressing, this introduces an opportunity to start the innovation process and assess the safety and effectiveness of endoscopic APC for OLGB.

Review questions

Research question identified in terms of PICO model.

- **Population** = Patients with weight regain after Gastric bypass surgery RYGB and OLGB
- **Intervention** = Endoscopic APC
- **Follow up period** = minimum of 6 months
- **Comparison** = Patients with weight regain after gastric bypass surgery who underwent revision surgery and APC.
- **Outcome** = Weight loss and complication rate both short and long term.

Inclusion criteria

Published systematic reviews, metanalysis, randomised trials, and large cohort studies on adults above 18 years of age, in English language between 2016 and 2023. Full text reviews with abstracts or titles containing the selected terms were included. A total of 49 reviews were included and 12 were finally selected and data was tabulated on an Excel spreadsheet (see appendix).

Search strategy

PRISMA 2020 Flow Diagram

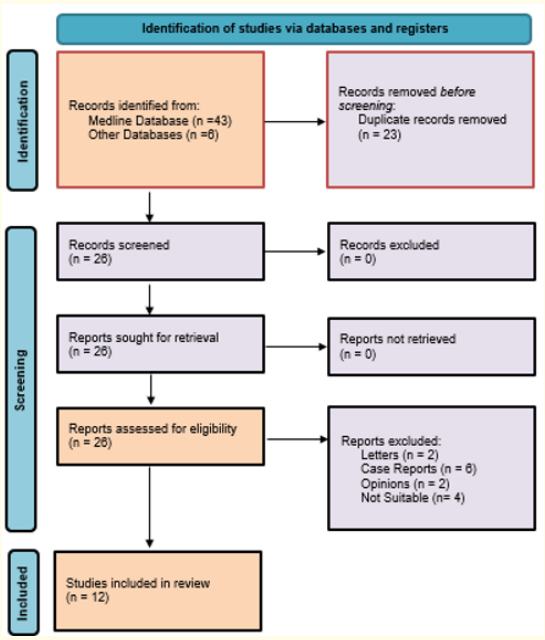

Figure 1

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

Analysis of the evidence

The study by Abidi, Schulman and Thompson published in 'Gastroenterology' journal in 2016, prospectively studied fifty-three patients in a case series on the use of APC for the treatment of weight regain after RYGB. The primary outcome measures were BMI, %EWL, percentage of the regained weight loss and complications. Student paired t-test was used to compare the means. The results showed a significant reduction in BMI with a mean of 4 kg/m^2 at 6-months post APC with a p-value <0.0001. The %EWL was 16 ± 4.7% and regained weight loss of 56 ± 17% at 6 months. The reported complications were 4 out of 53, three patients complained of melena or hematemesis and one had a tight stricture of the GJA. The study concluded that the use of APC on GJA is safe and effective in inducing weight loss in patients experiencing weight regain after RYGB.

Brunaldi., *et al*. 2017 published a systematic review and meta-analysis of the endoscopic treatment for weight regain following RYGB and the role of APC prior to endoscopic suture to systematically assess the efficacy of endoscopic techniques. The search engines included MEDLINE, EMBASE, Scopus, Web of Science, Cochrane, OVID, CINAHL/EBSCo, LILACS/Bireme, and gray literature. The primary outcome measures were total body weight loss, excess weight loss and absolute weight loss. Thirty-two studies were included with a total number of 855 patients. Thirty studies described endoscopic suturing and the results showed 8.0 ± 3.9% total body weight loss, 23.7 ± 12.3% excess weight loss and 8.6 ± 3.5 kg absolute weight loss after 6 months of the procedure. When the endoscopic suturing was combined with APC the results were significantly higher with a p-value of < 0.0001. Two studies described APC alone and the results showed absolute weight loss of 15.4 ± 9.1 kg after 6 months of the procedure. The publication concluded that endoscopic suturing is effective at treating weight regain after RYGB and performing APC prior to suturing results in greater weight loss.

The same group (Brunaldi., *et al*. 2020), published a pilot single-center open-label randomized trial assessing APC alone versus APC combined with endoscopic suturing to treat weight regain after Roux-en-Y gastric bypass. This was a prospective randomized trial published in Gastrointestinal Endoscopy. The primary outcome was % total weight loss at 12 months and secondary outcome was the complication rate. Total of forty illegible patients were recruited, twenty in each group. The results 12 months after the procedure were 8.3% ± 5.5% in the APC alone group and 7.5% ± 7.7% in the

combination group with a P-value = 0.71. Two patients developed stenosis in the combination group and there were no complications reported in the APC alone group. The conclusion of the study was that APC alone and APC combined with endoscopic suturing give similar outcomes at 12 months follow up.

Fittipaldi-Fernandez., *et al*. 2019, is a prospective study including a sham group evaluates the effect of APC as a treatment for weight regain after RYGB, published in the journal of Gastrointestinal Endoscopy. This comparative study between a sham group and APC group aimed to assess the efficacy of APC and the complication rate associated with it. forty-one patients were randomized into the (n = 21) in the APC group and (n = 20) in the sham group. The recruited candidates were similar in minimum weight regain of 10 kg and presented within a minimum of 36 months from the primary surgery. The results showed weight loss of 15 kg in the APC group compared to -0.57 kg in the sham group with a p-value of < 0.0001 concluding the effectiveness of APC for the treatment of weight regain after RYGB.

Galvao Neto., *et al*. 2021, published a consensus in the journal of in Obesity Surgery titled ' Good Clinical Practices on Argon Plasma Coagulation Treatment for Weight Regain Associated with Dilated Gastrojejunostomy Following Roux-en-Y Gastric Bypass: a Brazilian-Modified Delphi Consensus'. The study involved forty-one experts who answered a questionnaire with short answer questions which were then converted into statements for an online voting webinar. Consensus was defined as 67% or more of positive response. The total number of patients treated by the panel group was 12,349 patients. The study resulted in recommendations include the size definition of the GJA and minimum regain of 20% of the weight lost after the primary surgery for APC to be indicated. The authors concluded that although this consensus highlights a number of recommendations, the level of evidence is low and evidence on the use of APC must be further evaluated.

Goh., *et al*. 2020, published a systematic review on the use of endoluminal techniques in the revision of primary bariatric surgery procedures and the main outcome measures were mean weight loss, excess weight loss, recurrence rate and complications. Twenty-six studies included which described endoscopic plication, APC and combination therapy. Results showed that endoscopic plication resulted in higher weight loss that APC in 12 months follow up however not sustained at 18 months and combination therapy showed the highest sustained excess weight loss at 18 months. There were no major complications reported. The authors concluded that lack of good quality data in the literature limits the efficacy of these techniques and well-designed studies are needed for accurate evaluation.

Gurian., *et al*. 2023, is a study titled 'Efficacy of the argon plasma coagulation in patients with weight regain after gastric bypass: a randomized control trial', published in Endoscopy International journal. The trial recruited 66 patients randomized into two groups, 'APC' study group (n = 38) and 'endoscopy only' control group (n = 28). The outcome measures were total weight loss, excess weight loss and reduction in weight regain. All outcome parameters were higher in the APC group with a p-value of < 0.001 in 6 months follow up, however in the longer follow up of 12 months the difference in parameters did not reach a statistical difference due to the weight regain observed in the 'APC' study group. The authors concluded that although APC is a safe procedure with low complications, weight regain occurs due to the chronic nature of obesity as a disease and the need for a multidisciplinary approach and lifestyle modifications.

Jaruvongvanich., *et al*. 2020, published in the journal of Gastrointestinal Endoscopy and titled ' Endoscopic full-thickness suturing plus argon plasma mucosal coagulation versus argon plasma mucosal coagulation alone for weight regain after gastric bypass: a systematic review and meta-analysis'. The literature review included all relevant publication available until February 2020 and the outcome measures were percentage total body weight loss, complication rate and the diameter of the GJA. The authors used a random-effect model to analyse the pooled effect estimate and they conducted a meta-regression to identify the association between weight loss and GJA diameter. Nine studies with a total number of 737 patients evaluated the combination therapy endoscopic suturing plus APC , and 7 studies with 888 patients evaluated APC alone. The results showed there was no difference between the two groups in 3 and 6 months follow up in terms of weight loss (P > .05), however after 12 moths percentage total weight loss in the APC group was significantly higher at 9.5% as compared to the combination group at 5.8%. In terms of major complications, only one case was observed in the APC group and none in the combination group. The authors conclusion of the study is that both modalities provide a safe options of treatment with comparable outcomes.

Jirapinyo., *et al*. 2020, is a single-centre retrospective study with 217 patients who underwent APC for weight regain after RYGB. The study title is ' Dose response for argon plasma coagulation in the treatment of weight regain after Roux-en-Y gastric bypass' and was

published in Gastrointestinal Endoscopy journal. There were two groups of patients recruited for the comparison between low dose APC and high dose APC, the primary outcome parameters were percentage total body weight loss at 6 and 12 months follow up. Secondary outcome measures were adverse events. The low dose APC group has 116 patients, and the high dose group included 101 patients. At 6 months follow up the weight difference between the two group was not significant however after 12 months the high dose group lost 9.7% excess weight as compared to 5.1% in the low dose group with P = 0.008. the overall complications were similar in both groups at 8%. The conclusion of the study is that APC is effective in the treatment of weight regain after RYGB and a high dose APC is associated with greater weight loss.

The same group of authors followed up on the previous study and published a personalized algorithm for the management of weight regain after RYGB (Jirapinyo and Thompson, 2020). Their aims were to assess the relationship between the outcomes and the anatomical size of the GJA, and to formulate an algorithm for treatment. The study design is a retrospective analysis on prospective data collection. The hospital registry was searched for all patients who underwent APC, endoscopic suturing and endoscopic plication for weight regain after RYGB. The primary measure was percentage total body weight loss in 12 months follow up. Number of recruited patients was 751 for the three groups. At 12 months follow up the percentage total weight loss was 5.2% for the APC group, 7.5% for the suturing group and 8.2% for the plication group. Taking into account the gastric pouch size and the GJA diameter. An Anova test was used for the comparison between the three groups and student t-test for sensitivity analysis. The study concluded that for pouch size >5 cm and GJA diameter is <30 mm endoscopic plication should be considered. For pouch size less than 5 cm and GJA lass than 30mm endoscopic is suturing is to be considered. For GJA less than 18 mm APC is preferred.

Moon., *et al*. 2018, conducted a multi-center study titled 'Efficacy of Utilizing Argon Plasma Coagulation for Weight Regain in Roux-en-Y Gastric Bypass Patients', and was published in Obesity Surgery journal. The objectives were to study the effectiveness of APC for weight regain after RYGB from eight bariatric centers in terms of weight loss and complications. A retrospective chart review included 558 patients from two countries USA and Brazil with 24 months follow up period. The mean weight loss was 6.5 kg at 6-months follow-up, 7.7 kg at 12-months and 8.3 kg at 24 months and the changed of weight over time was statistically significant with a p-value of < 0.0001. complications data was available for 333 out of 558 patients and accounted for 5%. The study conclusion was that APC is a useful modality however randomized trials are needed to validate the findings.

Sander, 2020, published an study in the Academic Journal of Gastroenterology & Hepatology titled ' Weight Regain after Bariatric Surgery - Argon Plasma Coagulation for Gastrojejunal Anastomosis Decrease'. This study evaluated the effectiveness of APC for weight regain after RYGB due to widened GJA. Sample number was 554 patients who presented with weight regain at least 2 years after RYGB and had APC as a treatment for a minimum of 18 mm and maximum 40 mm diameter of the GJA. Data pertaining to weight loss and complications was collected and analysed with descriptive statistics, student t-test and Spearman correlation. The demographic data included 80% females and 20% males, average months after primary surgery of 96 and average weight regain of 22 kg. the mean diameter of GJA was 24 mm. Average weight loss after APC was 13 kg and BMI drop of 4.5 kg/m^2 at 6 months follow up. The final average reduction in GJA diameter was 12 mm. Out of the 554 candidates, 122 did not achieve the target GJA diameter, 5 patients did not lose weight despite achieving the target diameter. 146 subjects followed up to 12 months showed a 20% weight regain. The study concluded that APC is safe and effective technique for treating weight regain due to dilated GJA after RYGB.

Presentation of results

The results of the literature review in terms of the outcomes of interests will be presented for the evaluation of the effectiveness of APC in terms of weight loss and the safety of the procedure in terms of complications. All the selected papers suggested that APC is safe and effective option for treating weight regain after RYGB, however there were also unified in the conclusion that the data is limited and randomized trials are needed to validate the findings. Thorough review of the literature gave an insight into the magnification of this problem worldwide, and the burden on patients and healthcare organizations, yet the research level as an evidence is weak. Although the selected articles include systematic reviews and meta-analysis, the impact factor ranged between 1 and 77. It is understandable that citation count measures the research impact and not necessarily the quality of the work [22], the maximum citations of 77 for high quality studies going back to 2016, reflects the level of interest in this research topic worldwide. The least cited article was by Gurian., *et al*. 2023 due to being a recent publication less than 6 months old which can justify the low impact. The systematic review by Goh., *et al*. 2020, polled more than a 1800 patients and 26 publications, the citation count was 9. This observation reflects

obstacles to sound research, including low level of interest, limited number of experts dealing with this problem, funding, ethics, and most importantly is the complexity and chronicity of Obesity causing pessimistic feelings of the experts in tackling this issue.

The following table shows the citation count of each article.

- Abidi, Schulman and Thompson, 2016 cited by 6
- Brunaldi., *et al*. 2017a cited by 77
- Brunaldi., *et al*. 2020 cited by 12
- Fittipaldi-Fernandez., *et al*. 2019 cited by 2
- Galvao Neto., *et al*. 2021 cited by 3
- Goh., *et al*. 2020 cited by 9
- Gurian., *et al*. 2023 cited by 1
- Jaruvongvanich., *et al*. 2020 cited by 22
- Jirapinyo., *et al*. 2020 cited by 5
- Jirapinyo and Thompson, 2020 cited by 27
- Moon., *et al*. 2018 cited by 40
- Sander, 2020 cited by 18

The secondary outcome questions were only partially answered after concluding the review. Cost effectiveness in terms of total cost of the procedure compared to revision surgery briefly discussed in some articles without accurate analysis implying that endoscopic APC is affordable and cost effective as compared to revision surgery.

Availability of the technology and staff needed to perform the procedure were not directly addressed in any of the articles however it could be extrapolated from the methods and discussions that the service is readily available. The issue regarding simplicity and ease of application in terms of surgeons training requirement was also indirectly suggested by the publications rather than being based on studies and data. Acceptance of the procedure by patients, staff and the organization was an overall observation without reference to any qualitative studies or data.

Review questions

Primary outcome measures are:

- The effectiveness of APC in terms of weight lose
- The safety of the procedure in terms of complications

Secondary outcome measures are:

- Cost effectiveness in terms of total cost of the procedure compared to revision surgery
- Availability of the technology and staff needed to perform the procedure
- Ease of application in terms of surgeons training requirement
- Acceptance of the procedure by patients, staff and the organization

Table of Characteristics

Presentation of themes

As the thematic approach, will be used for the literature review,

	First author (Year, area)	Study design	Studies Number	Patients Number	Mean Age (yrs)	Duration from RYGB (yrs)	Weight regain (%)	EWL % after APC in Final FU	Complication rate	Follow up
1	Abidi (2016, USA)	Large Case Series		53	42	4.5	21	16 +/- 4.7	No major complications reported	6 months
2	Brunaldi (2020, Brazil)	Prospective RCT		40	48	5.5	29	21	5% 2 Stenosis	12 months
3	Brunaldi (2017, Brazil)	Systematic Review/ Meta-analysis	32	855	43	4.4	39.4 +/- 15.8	16.9 +/- 11.1	No major complications reported	12 months
4	Fernandez (2019, Brazil)	Prospective		96	44	9 +/- 3.5	42.3 +/- 21.3	18.7	No major complications reported	12 months
5	Galvao Neto (2021, Brazil)	Prospective/ Good clinical practice	13	150	45 +/ - 6.6	5.5	33	23.1	1.4% 1% Stricture 0.3% Bleeding 0.08% Perforation 0.01% Ulcer 0.00008% Death	12 months
6	Goh (2020, UK)	Systematic Review	26	1835	38	7.6	41	19.3	No major complications reported	18 months
7	Gurain (2023, Brazil)	RCT		66	40	10 +/- 5.2	37.1 +/- 16.8	16.6	No major complications reported	12 months

8	Jaru-vongvanich (2020, Italy)	Systematic Review/ Meta-analysis	16	1625	42	4.5	28	21.3	No major complications reported	12 months
9	Jirapinyo (2020, USA/ Brazil)	Prospective		217	37	10.8 +/- 5.4	41.4 +/- 29.8	19	No major complications reported	12 months
10	Jirapinyo (2020, USA/ Brazil)	Prospective		57	52	9 +/- 4	26	17	8% 1 Bleeding 1 Esophageal tear 1 Melena 1 Stenosis	12 months
11	Moon(2018, USA/Brazil)	Retrospective		558	39	7.5	40.3 +/- 31.7	17.6	2.5% 1.5% Stenosis 0.6 % Vomiting 0.3% Leak 0.1% Malena	36 months
12	Sander (2020,Brazil)	Systematic Review		554	42	5	36	18.3	No major complications reported	12 months

Table 1

the following themes were identified; APC as a stand-alone treatment, APC compared to revision surgery, APC compared to other endoscopic modalities, APC in combination with other modalities and complication rate.

Theme 1: APC as a stand-alone treatment

Most of the data from systematic reviews and meta-analysis suggested that the use of argon plasma coagulation alone is as safe and effective as the surgical revision and other endoscopic modalities like suturing and clipping procedures [10,12,23].

Theme 2: APC compared to revision surgery

A study by Moon., *et al*. 2018 suggested that APC is as effective as revision surgery in reducing the weight regained after gastric bypass, as well as being more economic and feasible with less side effects. APC can be repeated several times safely if needed.

Theme 3: APC compared to other endoscopic modalities

Dilated GJA can be successfully treated with revision surgery, however, this can be technically challenging with higher risk and complication rate. Galvao Neto., *et al*. 2021 [9] discussed a systematic review and meta-analysis to examine the efficacy and safety of full-thickness suturing plus APC and APC alone. Both techniques showed similar safety and effectiveness, however APC was more cost effective and can be repeated.

Theme 4: APC combined with other endoscopic modalities

In terms of gastrojejunal anastomosis dilatation, argon plasma coagulation promotes healing by fibrosis and hence leading to a progressive reduction in the diameter of the opening. This in turn causes delayed gastric emptying resulting in early satiety, which helps in weight reduction.

Gurain., *et al*. 2023 suggested better results when endoluminal endoscopic suturing is combined with argon plasma ablation [11]. This was also supported by a meta-analysis by Brunaldi., *et al*. 2017b which showed the effectiveness of this combination in patients with weight regain after RYGB.

Burnaldi., *et al*. 2017a suggested that performing APC before the anastomotic suturing modality can result in more weight loss, however they also recommended head-to-head studies to adequately assess effectiveness of combination therapies and techniques [2].

Theme 5: Complication rate after APC

All studies included in this literature review reported no major complications. A randomized controlled trial by Brunaldi., *et al*. 2020 showed 5% GJA stenosis rate and Galvao Neto., *et al*. 2021 showed 1.4% total complication rate out of which 1% counts for stenosis [9]. Moon., *et al*. 2018 showed 2.5% overall complication rate [18] and the maximum reported was by Jirapinyo and Thompson, 2020 at a rate of 8% [14].

Theme 6: Follow up period and reported complication rate after APC

The follow up period ranged between 6 and 36 months in the included studies with no significant difference in safety, effectiveness or short and long term complication rate.

A diagram of the innovation or change to be implemented

The diagram of the innovation process summarizes the concept of this project. Starting with the actual standard of care which is revision surgery ending with best practice proposed which is potentially the endoscopic APC.

- **Actual standard of care**: Currently in the writer's practice and as supported by the literature, revision surgery is the standard of care for treating weight regain due to dilated GJA after OLGB [16,20].
- **Challenges and opportunity:** The insight and the idea evolved due the high complication rate associated with revision surgery as well as high cost and other associated issues discussed above as witnessed in the writer's department and supported by the literature [20]. The innovation idea to apply endoscopic APC to tighten the GJA after OLGB was informed to enable technologies, the APC generator was provided with an endoscopic probe emitter to be used endoscopically. The same is already being used in the department for peptic ulcer treatment. The idea was imported to the team involved and presented to the organization as an invention and innovation to proof the principle.
- **Proof of principle:** The principle of using endoscopic APC and the required equipment and staffing is already existent in the department and regularly utilized. With modification to suit the purpose of tightening the GJA by adjusting the settings on the APC generator lead to proof of value.
- **Proof of value:** The complete set up, equipment, staffing and the expertise are easily available, the addition of an extra service of treating weight regain after OLGB increases the value an existing and functional service.
- **Implementation:** The ease of performing the procedure and its availability lead to the implementation of the procedure without resistance. Acceptance by patients, staff and the organization was smoothly achieved.
- **Impact:** The impact of the procedure in terms of commercialization and dissemination will be evaluated after the results of this pilot study are released. Further planning for well-designed research will have to precede the final step of marketing and routine application as best practice.

Diagram of the innovation

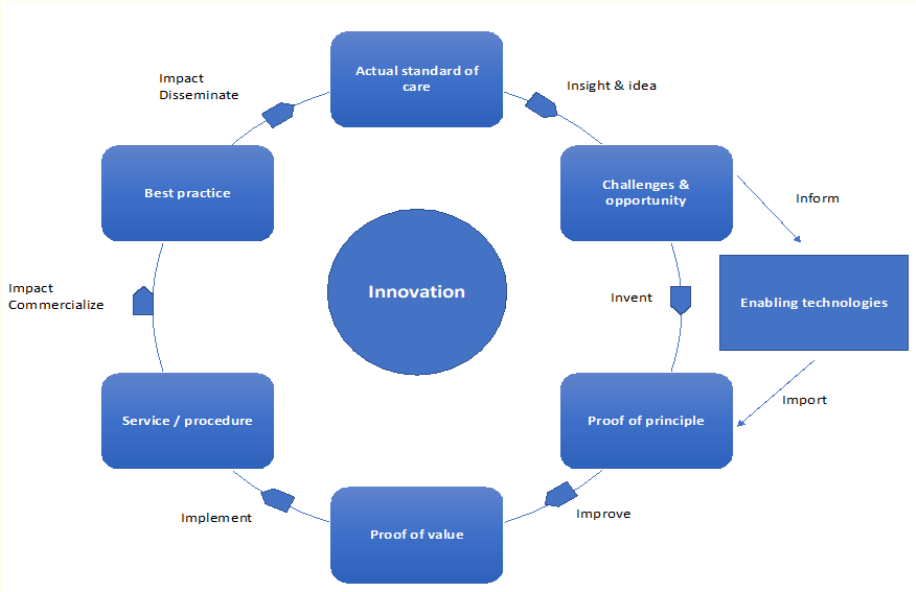

Figure 2

Summary and Conclusions

Four out of the twelve selected papers were systematic reviews and meta-analysis. Two were prospective randomized controlled trials, and five were prospective observational studies. One was a large case series. Number of studies included in the systematic reviews and meta-analysis equal to 87 papers and the total number of candidates' studies were 6,106 patients. The mean age ranges between 37 and 52 years old with male to female proportion strongly towards females. The mean weight loss after APC treatment for weight regain following RYGB ranged between 16 and 23% of EWL at final follow-up appointment. The average follow up period of 14 months in the selected 12 studies and complication rate was relatively low in the APC groups as compared with other modalities including revision surgery. The literature review results support the hypothesis that APC is safe and effective for treating weight regain due to dilated GJA, however the limitations observed weaken the evidence.

The citations count was low even for the higher quality studies reflecting either low interest in this research topic, lack of expertise in the field or organizations/ethical/ funding obstacles. There was no balance in the number of articles evaluating APC, surgery and other endoscopic modalities. Although its apparent and clear that most of the weight regain after gastric bypass surgery is caused by the dilatation of the GJA. The literature lacks randomized and controlled studies with larger series and longer follow-up period. Several gaps were identified, first and most importantly is that the effectiveness of APC in treating weight regain after OLGB was not evaluated in the existing literature. Secondly, the frequency of APC sessions required to achieve optimal outcome was not clearly assessed. Thirdly, the settings on the APC generator were not clearly identified. Lastly, the effect of the APC intervention alone without the impact of the multidisciplinary support was not addressed at all.

Following the thematic review, it was apparent that APC is safe and effective compared to revision surgery and other endoscopic modalities for the treatment of weight regain due to dilated GJA following RYGB and the follow up period ranging between 6 and 36 months didn't show any significant differences in the findings in terms of weight lose however there is a significant difference in the rate of complications in favor of the APC approach. Therefore, the current research study with the planned sample number and follow-up period will make the first stepping stone for further studies to come. It will provide an observation tool as a pilot study to assess the effectiveness of endoscopic APC technique in the treatment of weight regain due to dilated GJA in OLGB.

Research Methodology

Research philosophy

The sample number planed is 20 patients who underwent OLGB and came back seeking help due to weight regain. The study was limited to weight regain specific to dilated GJA. The results of this group of patients will be compared to demographically matched second group who underwent revision surgery to treat weight regain for the same procedure. Follow up period of 6 months is planned. The same modality has been studied intensely in the literature however in application to RYGB surgery. The research idea is relevant as the rate of weight regain after bariatric surgery in general is well reported and noticeable in every bariatric surgical practice. The time frame to complete this project for the given sample number is achievable. For this study, positivism research paradigm will be followed, as the results will rely on statistical prove after numerical data collection which can be studied objectively to reflect the reality [22]. The aim of this research project is to assess the effectiveness and safety of a specific treatment modality for a specific condition, and as per the literature review, this experiment has not been carried out previously, therefore, as well as being considered as an innovation in healthcare, it will adopt the philosophy of positivism to observe the reality of the effect.

Research approach

The approach for this research study is 'deductive' approach where the hypothesis will be tested via data collection and observation. The hypothesis for this project is that APC is a safe and effective method for the treatment of weight regain after OLGB caused by a dilated GJA. This will be tested with quantitative data collection and comparison to the conventional treatment method of revision surgery in terms of the amount of weight loss and complication rate.

Research design

The study will be in a form of an experiment which is conducted to test the hypothesis and hence, deduce a conclusion. A quantitative data collection based on deductive research methodology is applied to a PICO model.

The PICO model for this study comprising of two groups of patients:

Population (Group 1) = Patients with weight regain after OLGB

Intervention = Endoscopic APC

Follow up period = 6 months

Comparison (Group2) = Patients with weight regain after OLGB who underwent revision surgery. Existing retrospective data collection from the medical records with 2 years follow up.

Outcome = Weight loss and complications associated with the intervention.

Study Groups = APC group and Revision Surgery group.

Research strategy

This study is conducted systematically with a clear plan and time frame. Data collection and analysis procedure is clearly set out and a quantitative strategy is used to measure the outcome. The research question is can APC be used safely and effectively to treat weight regain due to dilated GJA after OLGB and the objectives are to assess the safety in terms of complication and effectiveness in terms of weight loss in comparison to the current practice of revising the surgery. The amount of time available from doing the procedure to end of the planned follow up period of 6-months is 12 months. The funding approval and the ethical committee allowance covered 20 cases. The research philosophy adopted was the positivism paradigm with deductive approach and quantitative design strategy. The researcher believes that APC is a safe technique and easy to apply in the hands on an experienced operator. This belief sets the hypothesis of the study.

Research methods

Observational, case-control, prospective, quantitative and non-randomized study which includes 20 eligible patients in a study period of 12 months. Sample size of twenty cases was approved by the ethical committee for the pilot study and then qualified for the departmental research funding program. The selected patients number was based on these factors, however more numbers are recommended as per data from previously published articles pertaining to RYGB procedure, taking into consideration the standard deviation and 95% confidence interval as well as the reported dropout rate.

Patients who presented to the bariatric surgical clinic and had undergone OLGB surgery between 2-5 years prior to presentation, weight regain, failure to reach satiety and dilated GJA confirmed on endoscopy and barium meal x-ray. One APC session was given with the same dose as used for the dilated GJA in the RYGB literature and was performed by the same operator to avoid different operators bias. Pre-procedure weight was documented and post-procedure follow up for weight loss was made after 4 weeks, 3 months and, 6 months respectively. Nutritional guidance and support was provided to all patients. The comparison group is those who underwent revision surgery for the same reason and they were retrieved from a retrospective medical records review. Patients demographic data was collected for both groups.

This is a quantitative research where data is collected in numerical fashion highlighting the weight in kilograms, body mass index in kilograms per meter squared, and complication rate in terms of percentage. The follow up time period is documented in months. A database for data analysis was structured on an Excel spreadsheet and then exported to GrapgPad by Dotmatics software to provide data analysis. Data collection and analysis in descriptive statistics is shown in Appendix 3,4,5 and 6.

Demographic data

A total of 51 patients were suitable for inclusion in this study, divided into two groups, n = 20 who received the APC and n = 31 who underwent revision surgery. APC patients group were selected for this study from July 2022 to December 2022, and the revision surgery group were studied retrospectively from medical records. Both groups were similar in age, sex, weight, BMI, excessive weight, and postoperative weight regain. (Appendix 3,4).

Group I (APC) Appendix 3

Patients who underwent APC for weight regain due to a dilated GJA were studied prospectively. Follow-up by a bariatric surgeon and nutritionist was done for a period of 6 months.

For each patient height and weight were recorded as well as weight loss and body mass index. See appendix 3.

Criteria

Inclusion criteria

- Age 18 and 65 years old.
- Have had a OLGB more than 2 years ago
- Weight regain of more than 10% of the lowest weight after the first intervention.
- Agree to sign an informed consent form.

Exclusion criteria

- Presence of a disease unrelated to obesity that is life-threatening.

Appendix 3: Group 1 demographic data (APC group n = 20).

Gender	Mean age	Mean weight pre olgb	Mean duration post olgb	Minimum weight	Mean weight regain	Mean weight loss after apc at final fu
M F	YEARS	KGB BMI	YEARS	KG BMI	KG BMI	KG BMI
7: 13	34	105 41	4	66 26	17 7	10 4

Appendix 4: Group 2 demographic data (Revision group n = 31).

						After revision surgery		
Gender	Mean age	Mean weight pre olgb	Average duration post olgb	Minimum weight	Mean weight regain	Mean weight loss after 6 months	Mean weight loss after 12 months	Complications
M F	YEARS	KG BMI	YEARS	KG BMI	KG BMI	KG BMI	KG BMI	NUMBERS %
9: 22	35.5	101 43	4	62 27	17 9	11 4	15 6	2 LEAK 6 1 BOWEL OBSTRUCTION 3

No	Years since olgb	Weight regain kg	Total weight loss 6 months kg
1	5	16	14
2	6	13	9
3	6	16	10
4	4	14	9
5	3	17	10
6	3	22	16
7	4	18	12
8	5	14	9
9	3	17	11
10	4	13	7
11	3	14	10
12	4	14	9
13	3	17	10
14	5	18	12
15	3	13	6
16	5	14	11
17	3	17	10
18	4	16	9
19	2	14	10
20	4	19	15
21	3	16	11
22	3	15	11
23	5	20	12

24	2	21	13
25	4	19	11
26	6	22	10
27	2	19	11
28	4	16	11
29	3	14	9
30	3	19	12
31	2	22	17
Mean	4	17	11

Appendix 5: Results of studies included in the scoping review (APC for RYGB).

Sample Number (n)	6106
MEAN Age (years)	43
MEAN Post OLGB weight regain %	33%
MEAN Presentation Years after (RYGB)	7
MEAN Weight loss after APC %	19%
MEAN Complication rate %	1%

Appendix 6: Study results: Comparison data APC vs Revision Surgery (OLGB).

Mean	APC	Revision	Difference
Sample Number (n)	20	31	Non-significant
Age (years)	34	35.5	Non-significant
M:F	7:13	9:22	Non-significant
Pre OLGB weight (kg)	105	101	Non-significant
Pre OLGB BMI (kg/m2)	41	43	Non-significant
Post OLGB weight loss (kg)	39	39	Non-significant
Post OLGB BMI loss (kg/m2)	15	16	Non-significant
Post OLGB weight regain (kg)	17	17	Non-significant
Post OLGB BMI regain (kg/m2)	7	9	Non-significant
Presentation Years after (OLGB)	4	4	Non-significant
Weight loss after intervention (kg)	10	11	Non-significant
BMI loss after intervention (kg/m2)	4	4	Non-significant
Complication rate (%)	0	10	Non-significant
Complication rate (n)	0	3	Significant

Appendix 7: Study results APC for OLGB Vs. Literature results APC for RYGB.

	RYGB	OLGB
Sample Number (n)	6106	20
MEAN Age (years)	43	34
MEAN weight regain %	33%	45%
MEAN Presentation Years after (RYGB)	7	4
MEAN Weight loss after APC %	19%	27%
MEAN Complication rate %	1%	0

- Pregnancy and breastfeeding
- Presence of Helicobacter pylori (to be reconsidered for the procedure after eradication).

Group II (REVISION SURGERY) Appendix 4

Patients who underwent revision surgery for weight regain due to dilated GJA. Data retrieved retrospectively from the medical records department. Follow-up by a bariatric surgeon and nutritionist was done for a period of 12 months in quarterly intervals.

For each patient height and weight were recorded as well as weight loss and body mass index. See appendix 4.

Criteria

Inclusion criteria

- Age 18 and 65 years old.
- Have had a OLGB more than 2 years prior to revision surgery.
- Weight regain of more than 10% of the lowest weight after the first intervention.

Exclusion criteria

- Incomplete medical records
- Loss to follow up after revision surgery

Studied outcomes include primary and secondary measures. Primary outcome measures are weight loss assessment after 4 weeks, 3 months and 6 months' post APC and compared to the control group II the revision surgery group. Assessed parameters are weight loss in kilograms and body mass index in kilograms per meter squared, and secondary outcomes include side effects and complications such as bleeding, ulceration and stricture.

Sample

Sampling for the APC group was selected from patients who presented with weight regain after OLGB due to widened GJA and fitted into the inclusion criteria from July to December 2022. Sampling for the revision surgery group who fitted into the inclusion criteria were selected from a retrospective chart review over a 5-years period from 2014 to 2019. Those patients had revision surgery for weight regain after OLGB due to widened GJA.

Recruitment

This is an observational study funded locally by the academic division of the department of surgery which allowed a specific sample number of 20-cases and a specific time frame of 6-months to do the procedure. Therefore, the recruitment of samples for the study group were done prospectively form patients who presented to the outpatients' clinic complaining of weight regain after OLGB due to dilated GJA and complied with the inclusion criteria. The comparison group samples were selected from a retrospective chart review for 5-years. The data needs were defined as patients who underwent OLGB from 2014 to 2019 and underwent revision surgery for weight regain specifically due to dilated GJA.

Data collection instruments

For the study group data collection included the demographics, pre-original surgery weight, minimum weight achieved, weight regain and time period since original surgery. Weight loss after APC in a 6-months follow up and complication rate were prospectively collected for each case. All patients signed an informed consent form for the procedure and to be included in the study.

For the comparison group, quantitative data was collected including the demographics, pre-original surgery weight, minimum weight achieved, weight regain, time period from the original surgery and weight loss 6 months after revision surgery. Compli-

cations data was also collected for post revision surgery and outcome. Microsoft Excel sheets were used to tabulate the numerical data and informed consent was obtained from every patient to be able to use their data for this research study as well as maintaining the confidentiality by using the file numbers with no patient names visible.

Data analysis

GraphPad by dotmatics t-test calculator was used to statistically compare the results of the two groups. Unpaired t-test comparing means and the p-value was calculated for each research question. Clinical and statistical significance were evaluated.

Ethics

The study proposal was granted approval by the Ethical Committee in the organization headed by the medical director and granted in accordance with the ethical standards laid out by the local healthcare authority. Informed consent was obtained from all selected candidates of both groups.

Leadership of the project

The researcher adopted a transformational leadership style by empowering and influencing the team with clear and effective communication, taking into consideration their level of skills and readiness to accomplish the task. To gain their interest and enthusiasm, weekly meetings in the form of literature review sessions and teaching were conducted. The team members will be given the chance to be involved in any publications or presentations in conferences pertaining to this project as well further research opportunity to develop the studied innovation . Situational leadership style was also demonstrated by meeting the expectations of the team members taking into consideration their perception and interest levels and adapting to their skills and development needs [21]. Giving clear instructions and allocating the duties and responsibility of each team member reflects the task behavior of the leader, whereas clear communication and guidance reflects the relational behavior. Therefore, the writer demonstrated the balance in multiple behaviors like directing, coaching, participation and delegating as well as high level of emotional intelligence to achieve successful completion of the project.

Findings and Discussion

Introduction

An unpaired t-test calculator from GraphPad Dotmatics was used to compare the means of the two groups to determine if there is a significant difference.

Post treatment weight loss comparison between the means of APC group (n = 20), and the revision surgery group (n = 31) revealed a p-value of 0.38 which is a non-significant difference. The table below shows the results from the t test calculator demonstrating the standard error of difference being 0.676.

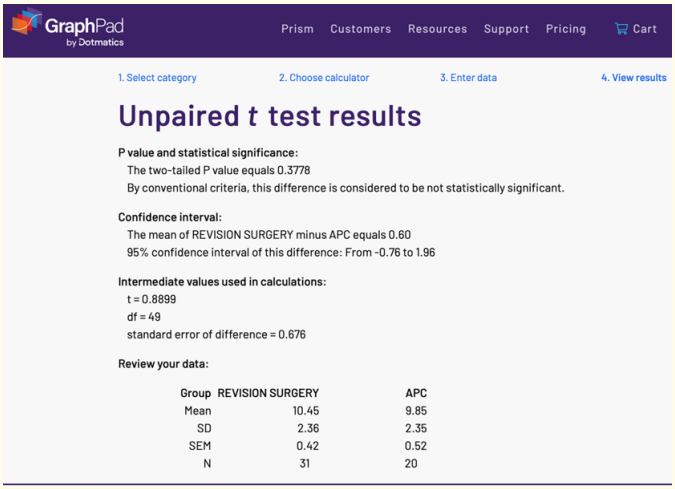

Figure 3

The comparison between the two groups in terms of complications revealed a p-value of 0.16 which statistically non-significant however clinically significant due to the severity of the complications in terms of the associated length of hospital stay, full recovery and cost burden on the organization. The calculation results shown below demonstrate a standard error of difference being 0.067.

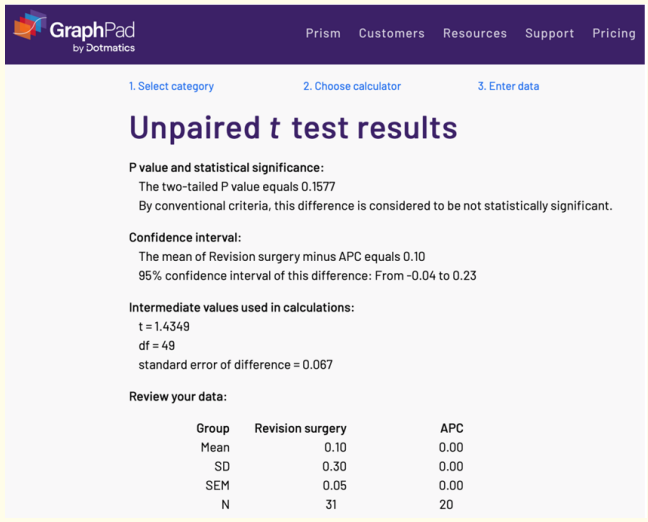

Figure 4

The importance of standard error of difference is that it measures the amount of discrepancy expected in the sample estimate as compared to the true value in the population. The smaller the value and closer to zero reflects the true value. As seen from the calculation above the standard error of the difference in terms of complication is 0.067 and in terms of post treatment weight loss is 0.676. This means that the 10% complication rate after revision surgery reflects near to the true value of the population undergoing this modality, and the non-significant difference in weight loss between the two groups needs more assessment and evaluation with larger sample numbers and longer follow up period.

Findings: (Appendix)

Results of Group 1: APC group (Appendix 5)

Sample number is twenty with seven males and thirteen females. Age at presentation with weight regain in a mean of thirty-four years old and average of four years postoperative. Mean weight before OLGB is 105 kg and BMI 41 kg/m^2 and the average weight loss after OLGB showed a mean of 39 kg and BMI reduction of 15 kg/m^2. The weight regains after the mean 4 years following the OLGB averaged at 17 kg and 7 kg/m^2 of BMI drop. Range of maximum follow up period after APC was 6 months and the mean weight loss after APC was 10 kg and 4 kg/m^2 of BMI drop. Complication rate was zero, there were no reported complications at last follow up.

Results of Group 2: Revision surgery group (Appendix 6)

Sample number of thirty-one cases with nine males and twenty-two females and an average age of presentation at 35.5 years old, four years after the OLGB surgery. Mean weight before OLGB was 101 kg and BMI of 43 kg/m2, post-surgery weight loss of 39 kg and 16 kg/m^2 of BMI drop. The weight regains after the mean 4 years following surgery was 17 kg and 9 kg/m^2 of BMI increase. Weight loss after 6 months of revision surgery averaged at 11 kg and 4 kg/m^2 BMI drop and after 6 months the numbers were 15 kg and 6 kg/m^2 respectively. The complication rate was 10% breaking into 2 staple line leak and 1 bowel obstruction. There were no mortalities.

Comparison Results for APC vs Revision Surgery

The only significant difference proven between the two groups is the complication rate. There were no complications reported in the APC group as opposed to 10% complications in the revision surgical group. Two patients suffered from staple line leak and one developed bowel obstruction, all of whom were successfully treated with reoperation.

The results of this study support the safety and effectiveness of the APC procedure seeming it superior to revision surgery, as the rate of weight loss is identical and the only significant difference is the complication rate.

There are several factors which can affect the accuracy of the findings:

- There is no guidelines regarding the endoscopic follow up after APC and some studies suggest monthly endoscopy to assess the healing process of the GJA. This is not possible for this study due to restrictions in funding.
- The unavailability of non-invasive means to assess the measurement of the diameter of the GJA without the use of endoscopy, which is again neither feasible nor affordable.
- Absence of information about change of life style and dietary adjustments after APC deeming the results biased and inaccurate.
- Absence of information on pharmacotherapy after APC as patients can purchase weight lose medication from the shelf in local pharmacies without disclosing the fact to the medical team.
- The added benefit of joining support groups and behavioural therapy can enhance the results giving false interpretation of the outcomes and data collected.
- The possibility of added benefits for patients who decide to perform regular physical exercise and general change of lifestyle behaviours.

Comparison Results for APC for RYGB (literature) Vs. APC for OLGB (study)

Regarding the application of APC in RYGB, the literature review revealed a sample number of more than 6000 patients, the average age on presentation was 43 years old and the number of years from the initial surgery averaged at 7 years. The weight regains amounted to 33% out of which 19% was lost after APC in 6 months follow up. In comparison, this study shows a sample number of 20 cases with a mean age of 34 and the number of years from initial surgery averaged at 4 years. The weight regains amounted to 45% out of which 27% was lost after APC in 6 months follow up. So, when comparing both procedures it is clear that the patient population after RYGB are presenting with less weight regain on a longer time period, however the weight loss after APC is higher in the OLGB group, and the mean age is younger in this group. These observations in the differences highlights the importance of this study and

the gap in knowledge about treating the same problem but in a different procedure with different surgical anatomy and different physiological concept of mechanism of action (see Appendix).

Discussion

The findings of the study support positive answers to the questions. APC can help support weight loss in patients who have regained the weight after OLGB surgery. It is safe and well tolerated by patients as no side effects or complications were noticed up until the last follow up stage. The procedure has proved its clinical effectiveness as similar results to those after revision surgery were achieved.

The present study demonstrated the efficacy of APC in reducing the diameter of gastrojejunal anastomosis after OLGB surgery by causing ablation and fibrosis, leading to a reduction in the amount of food intake and hence weight loss. This is suggested as a short-term treatment for weight regain after OLGB procedure because the literature proves that over the long-term weight regain can reoccur. In the present study, weight loss after APC in 6 months' follow-up was 10 kgs and 4 BMI points. Although this might look like a significant benefit however it a short-term observation and the long-term results must be studied. These results are consistent with data presented by Moon., *et al*. 2018 which analyzed 558 patients undergoing APC after RYGB in Brazil and the United States over 12 months follow up period [18]. After this period the results were against all expectations in that weight regain reoccurred again, so weight loss after APC cannot be relied upon over the long term in patients who regained the weight after RYGB. As an expectation from the trends in the literature about RYGB, the same results might be observed in patients with weight regain after OLGB who had undergone APC as a treatment, therefore more studies are needed to understand the differences and the prevalence's involved. Given all that, APC use is still encouraging because of the low complication rate as compared to revision surgery and other interventions. In this study, there were no complications at all in the maximum 8 months follow up period. The literature pertaining to APC in RYGB patients reported between 1.4–8% complication rate such as stenosis and bleeding [11]. Complication rate following revision surgery is reported to exceed 20% in most of the literature as well as the presence of mortality rate. The higher complication rate in revision surgery is attributed to performing surgery on thick, fibrotic and potentially devascularised tissue leading to ischemia and necrosis and hence failure of the surgery [26].

Since this treatment modality (APC) was not studied or evaluated for the treatment of weight regain after this specific surgery (OLGB), the application is considered innovative and the results are observational and preliminary. From a surgeon's point of view, it is clear that this procedure can potentially be safe, clinically effective and cost effective if performed in conjunction with other supporting treatments and therapies, such as a multidisciplinary approach and behavioral therapy. To stay away from guessing and speculations, this study was carried out with a quantitative methodology in the initial observatory stage. Qualitative date will be incorporated at later stages along with randomization and larger numbers. As compared to the other procedure (RYGB), the results are almost identical in terms of the short-term benefit and low complication rate. However, due to the different anatomical nature of the two procedures, perhaps it's best not to compare the results at this stage. OLGB must be studied individually and the effect of APC evaluated separately.

Dissemination plan

The future plan is to expand on the study and strengthen its evidence. Larger sample number, longer follow up period and randomization will be planned. Standardizing the service by producing a consensus and guidelines where a multidisciplinary approach is adopted.

Summary and Conclusion

Patients recruitment started in July 2022 and the last enrolled patient was treated in December 2022. Minimum follow up period of 4 months and maximum of 8 months, making the average follow up period of 6 month which is in keeping with most of the literature. For the APC group the mean number of years after OLGB and presentation to clinic with weight regain is 4 years and the average maximum weight loss after surgery is 37kg and 13 BMI units. The reported weight regain as an average for the 20 cases is 17 kgs and 7 BMI units after the mean of 4 years from surgery. The mean weight lose 1-2 months after APC is 5kg with 2 BMI points and the same mean was found in 4-6 months follow up, making the total average of 10kg weight loss after APC and total of 4 BMI points. The numbers for the revision surgery group showed to be similar in terms of the number of years for presentation and weight loss after surgery. The average weight regain was reported at 17kg and 7 BMI units with identical weight lase 6 months after APC at 11kg and 4 BMI points. Retrospective data was available for 12 months follow up after APC in the revision surgery group and showed to be 15 kg and 6 BMI points.

There were no complications reported in the APC group, however in the surgical group, 10% complication rate was observed, two anastomosis leakage and one bowel obstruction secondary to internal herniation, all of which were successfully treated with re-operation. There were no mortalities in any of the groups.

The current study concludes that APC can effectively treat weight regain after OLGB in the short term. Additionally, it is a safe procedure with low complication rates. Nevertheless, recurrence of weight gain is a potential possibility highlighting the importance of long-term follow-up studies with larger sample numbers. Bearing in mind that APC can be an additional tool to treat weight regain and it is important to consider that even invasive surgical interventions might not result in satisfactory long term outcomes. Therefore, a multidisciplinary approach and behavioral therapy is vital and fundamental.

Conclusions and Recommendations

Introduction

Assessing the effect of APC after OLGB started as an observational study for the purpose of this module's assignment, with the plan to continue in the future with larger sample number and longer follow up period. This study results will add knowledge to aid accuracy in patient selection leading to better outcomes as well as guidelines and protocols for the use of this modality. Although a small study however provides a base and a stepping stone for further development and research, ultimately to provide safe and effective patient care. The ability to see the gap in healthcare and innovate a solution was clearly demonstrated. Compassionate and transformational leadership styles were adopted by the writer and successfully applied to gain support from peers and managers, achieve team work and ethical approval as well as funding.

The key contributions of the study for the innovation

Since the prevalence of obesity as a chronic disorder is on the rise, the rate of bariatric surgeries performed is also on the rise. Performing surgery on obese patients with associated metabolic disorders is considered a high-risk intervention however the benefits outweigh the risk. One of the major problems facing patients and healthcare providers is the weight regain and the return of metabolic disorders resulting from the weight coming back. It is clear from the global literature that a high proportion of patients who underwent weight loss surgery will regain the weight within four to six years later. In most cases a re- intervention must be considered. As these patients are categorized as high risk from a surgical point of few, surgical revision carries both a morbidity and mortality rate. There are continuous attempts to try and provide a non-invasive strategy for treatment with lower complications and similar benefits.

The writer of this research focuses on innovating a specific non-invasive modality to restore the surgical anatomy after OLGB to treat the weight regain issue. A technique where endoscopy is used rather than surgical laparoscopy, simple sedation as opposed to general anesthesia, day care stay instead of hospital admission, and considerably lower complication rate with similar benefits to revision surgery. This study offers an observation to the effect of using endoscopic APC to narrow a dilated GJA after OLGB. Although small and observational, it shows positive results in terms of safety and effectiveness. This research can be considered as an innovation in healthcare because the technique of endoscopic APC was not studies previously on OLGB procedures and the effectiveness and safety are unknown. The comparison with other surgical procedures like RYGB showed different age of presentation and different pattern of weight regain and benefit after APC making it impossible to compare or assume the effectiveness of APC for OLGB based on the results from RYGB studies.

The findings of the study in the context of the literature and the practical application

The hypothesis is "APC can be used safely and effectively as a treatment for weight regain after Omega Loop Gastric Bypass".

Primary outcome measures are:

- The effectiveness of the procedure in terms of weight lose
- The safety of the procedure in terms of complications

Secondary outcome measures are:

- Cost effectiveness in terms of total cost of the procedure compared to revision surgery
- Availability of the technology and staff needed to perform the procedure
- Ease of application in terms of surgeons training requirement
- Acceptance of the procedure by patients, staff and the organization

Two groups of patients were selected and compared. A group who underwent APC and a second group who had revision surgery done as a treatment for weight regain after OLGB. The groups matched for all the studied parameters, and the only significant difference was the complication rate in favor of the APC technique (Appendix).

The importance and impact of leadership

The innovation idea which has been studied in this project was driven by compassion with patients suffering of weight regain even after a major intervention. Obesity being a chronic disorder and is associated with long term diseases, the psychological and the physical burden on affected patients and there families is tremendous.

Healthcare organizations are challenged to provide high quality care due to the hight expenses and expertise needed to treat this condition. The writer of this project has lead the research with adopting a combination of compassionate and transformational leadership style. With transparency and clear communication the team was formed and and by creating the atmosphere of traust and respect the team was lead believe in the importance of the innovation. The gap in the service was communicated and explained to the hierarchy of the management and the ethical committee. With transformational leadership qualities, the writer was able to gain funding approval and support from different departments to push the idea of the project forward. The medical records department provided the data in a clear tabulated form, information technology team helped to unlock the HMIS system to allow data to be available in a eunanamous way so patients confidentiality is protected, endoscopy room staff assisted in the preparation of the procedure and setting up the equipmet, nurses and doctors helped in the follow up process and data entry. Most importantly 'patients', there was no dropout rate or lose to follow up patients. All recruited candidates understood the procedure, signed an informed consent form and attended their follow up appointments promptly. This project fills an important gap in knowledge and if expands to more detailed research it can lead to the creation of guidelines for treatment which can be applicable worldwide.

Limitations and weaknesses of this study

There are several weaknesses and limitations to this study which must be considered:

- **Small sample number:** For more accurate results, a larger sample number is needed to represent the examined population. As per the 95% Confidence Interval calculation from RYGB papers a much larger sample number is required to be observed.
- **Short follow up period:** A longer follow up period is needed to evaluate the long term benefits and side effects, as weight regain can result eventually after a longer term follow up. If surgery has failed over the long term, then surely the same can apply to non-invasive non-surgical modalities.
- **Study design:** An observation study might be good enough just for initial observation, however for more accurate and representative results, randomization is needed. Not only randomization of patients but also the healthcare organization and medical personnel providing the service. This will help to allow for variations in experiences and including qualitative measures.
- **Representation of the results:** As almost all weight lose services incorporate a multidisciplinary approach to the treatment for example dietary and lifestyle changes support, it is difficult to assess the effectiveness of the APC modality without introducing a bias in the results. If pharmacotherapy and dietary support is added to the modality then it is difficult to judge the real effect of APC alone for weight loss.
- **Reflection of reality:** As many patients will take the opportunity of going through another procedure to learn from their failed experiences and decide to strictly adhere and comply with a tight program which might on its own lead to weight loss. So the effect of APC will not reflect the reality.
- **Budget and funding:** Due to restriction in budgeting and funding of the projects, there will be limitations to sample size and number of sessions the procedure can be repeated to evaluate the real effect.
- **Bias factors:** Several bias factors must be considered, examples are, APC settings, frequency of sessions, sample number and study design as mentioned previously.
- The trust and loyalty between the patients and the writer 'their doctor' is immense, patients showed their appreciation and followed up promptly. All recruited patients understood the nature of the treatment and signed an informed consent form. There were no dropout rate and no loss to follow up. Although a positive note, however can lead to limitations and bias, the 'Doctor Patient' relationship, passion and compassion is expected in every bariatric service due to the vulnerability of these patients and their need for continuous support, but in this department, the surgeons are more involved in the non-surgical needs of patients' care. The writer takes an active role in patient empowerment and support, and often joins the counselling groups and other disciplines during their consultation. Although this is not a requirement from surgeons as per their job description, but the writer as a surgeon feels strongly about supporting every individual patient as much as practically possible. This might introduce a bias to the compliance data if the study to be performed elsewhere.

- Another limitation is the uncertainty about the continuity of the research cycle, due to restrictions in budgets and funding, the same group of researchers might be restricted and unable to progress further in the research process.
- The issue of intellectual property rights is considered by the write as a limitation, since Argon beam was used for many decades in ophthalmic surgery, then came the innovation of using it in other disciplines such as the gastrointestinal tract, liver surgery and gastric ulcer treatment. This research is about the use of APC in bariatric surgery as a treatment modality for weight regain after OLGB which was not studied before, the question whether this idea is an innovation or development remains controversial.

Areas for future research

Refereeing back to the primary outcomes of this project, larger studies with randomization and longer follow up are required to validate the results. The combination of APC with any other modality must be studied separately one at a time to understand the real affect and the benefits of any conjunction therapy. It is beneficial to thoroughly review the literature and understand how this modality benefited patients who have undergone other bariatric procedures, but care must be taken to focus only on the surgical procedure being studied, bearing in mind the anatomical differences and physiological variations in different bariatric surgical procedures. Studies with larger numbers, longer follow up period, randomized and controlled are needed to accurately conclude the safety and effectiveness of APC for weight regain after OLGB in terms of weight loss and complication rates. The low citation number for the literature reviewed may indicate difficulties and obstacles in carrying out sound research on this topic even though the gap and the opportunity clearly exist.

Regarding the secondary outcome measures, the literature has proven a major gap and deficiency in procedural cost effectiveness comparing the total cost of APC to revision surgery. Qualitative studies will help to evaluate acceptance to the procedure by patients, staff and the organization. Mixed qualitative and quantitative study designs will help to assess ease or complexity of the technique as well as the availability and staff requirement in organizations providing bariatric surgical services.

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