Official Title: Implementation of Mandatory Hiatoplasty in Sleeve Gastrectomy: Strategy for Gastro-Esophageal Reflux Disease (GERD) Risk Reduction.Implementation of

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## Abstract.

*Background.* Limited research supports hiatal hernia repair and reduced acid production as protective factors. Despite the scarcity of direct evidence,the multifactorial nature of postoperative GERD underscores the potential significance of hiatoplasty in preventing complications. The inclusion of mandatory hiatoplasty in gastric sleeve protocols is considered a promising advancement for improving patient outcomes and reducing long-term complications.

*Objective.* This study aims to assess the effectiveness of mandatory hiatoplasty during gastric sleeve surgery in decreasing postoperative GERD incidence in patients at a specialized bariatric surgery hospital in Tijuana, Baja California.

*Methodology.* This is a retrospective case series study based on clinical records of patients who underwent some type of bariatric surgery in hospital centers specialized in bariatric and high volume surgery in the city of Tijuana, Baja California, Mexico, from March to June 2022. The following information of interest will be obtained: age, sex, comorbidities, BMI, surgery performed, surgical time, trans and postoperative complications. Once the data capture process has been completed, a descriptive analysis will be performed with the SPSS statistical program in version 26 for MacOS. Means and standard deviation will be obtained for quantitative variables as well as frequencies and percentages for qualitative variables.

**Key words.** Incidence, Complications, Bariatric surgery, Obesity.

## THEORETICAL FRAMEWORK

Obesity is a worldwide epidemic that has been developing over the last decades and represents one of the main public health problems today due to the numerous related comorbidities.

According to the World Health Organization (WHO), 13% of all adults in the world (approximately 650 million) suffer from some degree of overweight or obesity (1). The future scenario is not very encouraging since the WHO also reports that more than 350 million non-adult people suffer from this same condition, in addition, obesity worldwide has had an unexpected increase during the last 30 years; being that the prevalence of obesity and overweight increased up to 40% in some developed countries (1).

Excess body weight increases the risk of a group of cardiometabolic disorders, such as type 2 diabetes mellitus, hypertension, and dyslipidemia, and is associated with an increased risk of coronary artery disease, stroke, and mortality (2).

It is estimated that, if this trend continues, 2.7 billion adults will be overweight, more than 1 billion will be affected by obesity, and 177 million adults will suffer severe obesity-triggered consequences by 2025 (3).

### OBESITY IN MEXICO

According to the National Health and Nutrition Survey 2018-2019 (ENSANUT 2018-2019), the prevalence of overweight for that time span was 39.1% of the Mexican population over 18 years of age (36.6% in women and 42.5% in men), obesity 36.1% (40.2% in women and 30.5% in men) and abdominal adiposity 81.6% (88.4% in women and 72.1% in men), with the northern region of the country being the most affected. Similarly, the prevalence of abdominal adiposity was higher in the northern regions (83%) than in the center of the country (79%) (4).

From 2000 to 2018, the trend of obesity prevalence increased by 42.2% to reach an obesity prevalence of 36.1% by 2018. It was also observed that the higher the degree of obesity, the greater the increase in relative prevalence, so that grade I obesity increased by 28.8% while grade III or morbid obesity increased by 96.5%, indistinctly in men and women. Compared to 2000, all categories of obesity and abdominal adiposity increased by 2018 (4).

The ENSANUT 2021 details a prevalence of overweight and obesity in the population aged 20 years or older of 72.4% (75% in women and 69.6% in men). Likewise, it argues that in 2015 10.8% of all deaths worldwide were attributed to excess weight and in 2016 this figure increased to 12.3%. When comparing only obesity, it is observed that in men there was an increase of 18.6% between 2012 (26.8%) and 2021 (31.8%); while in women the increase was 9.6% in the period 2012 (37.5%) to 2020 (41.1%) (5).

**OBESITY IN BAJA CALIFORNIA**

The ENSANUT 2018-2019 concluded that the north of the country is the region most affected by obesity as such in addition to being one of the regions with the highest prevalence of abdominal adiposity and overweight compared to the southern and central regions of the country (4).

In the same way, the ENSANUT 2012 dictated a prevalence of overweight and obesity for that year of 35% and 39% respectively in the adult population of the state of Baja California, giving a total of almost 75% of the population with one of these conditions (6).

A study by Hernandez et al. in the city of Tijuana in 2014 found a similar prevalence of these entities (74%) in a sample of comparable size with the ENSANUT 2012 (1072 people) being slightly more prevalent in women (43%) than in men (40%) (7).

**OBESITY IN THE UNITED STATES**

In the United States, obesity is also a serious public health problem, 42.4% of the population over the age of majority suffer from obesity, among men the prevalence of obesity was 40.3% while in women it was 39.7%. On the other hand, the prevalence of obesity in its severe form was 9.2% of U.S. adults, being more prevalent in women (11.5%) than in men (6.9%). From 1999 to 2018, the prevalence of obesity has been increasing from 30.5% to 42.4%, likewise severe obesity increased from 4.7% to 9.2% in that same time span (8).

**TREATMENT OF OBESITY**

Through various mechanisms, obesity continues to worsen the cardiometabolic health of people around the world, increasing the risk of a cardiovascular event.

Therefore, it is necessary to establish an effective treatment for obesity, in addition to seeking to improve the associated comorbidities such as diabetes and arterial hypertension (9).

For years, obesity and weight loss have been studied and it has always been concluded that all the metabolic alterations related to obesity can be reduced or even avoided by making different interventions in the lifestyle of individuals (10). The American Heart Association (AHA) and other institutions such as the American College of Cardiology have included in their treatment guidelines for obesity this type of recommendations for healthy lifestyle changes such as exercise and a decrease in the consumption of sugars and fats, with the objective of having a loss of ≥10% of total body weight; however, achieving this objective, even with pharmaceutical treatment is difficult and few people manage to achieve it (11,12).

Education regarding healthy lifestyle habits and even intensive interventions in patients with comorbidities have been a challenge for the personnel in charge of such tasks, a study called Look AHEAD that was developed over 8 years comparing intensive lifestyle interventions in patients with type 2 Diabetes Mellitus (DM2) against education and support groups on diabetes in obese and overweight people, aimed to reduce cardiovascular risk at 10 years of follow-up without achieving such a result (13). However, an analysis of this same study concluded that people who lose ≥10% weight reduce their risk of a cardiovascular event by up to 20% (14).

Furthermore, according to evidence from the American Association of Clinical Endocrinology, a body weight loss of ≥10 % is recommended for the specific prevention of diabetes in obesity (15).

## CHANGES IN CALORIC INTAKE

In patients suffering from obesity, different cardiovascular markers usually show improvement in response to weight change conditioned by caloric restriction (11).

Blood pressure is the marker with the most sensitive response in relation to weight change, different studies have concluded that approximately for each 1% of weight loss or gain, systolic blood pressure can decrease or increase respectively from 0.3 - 0.4 mmHg in those individuals who follow a low calorie diet or with a focus on body fat loss (16, 17). Other markers such as blood glucose, glycosylated hemoglobin, and lipid profile are also highly benefited by dietary changes (18). Not only have diets that restrict caloric intake as such had a good impact on the cardiometabolic

risk of patients, other dietary patterns such as those that restrict sugar and sodium intake or adherence to the "Mediterranean" diet have been shown to improve markers such as blood pressure and multiple markers of inflammation associated with obesity (19).

## EXERCISE

Exercise represents an energy expenditure in large volumes, which has a direct impact on weight and therefore on the cardiovascular risk of individuals (20).
The American College of Sports Medicine suggests that a total of 225-420 minutes of aerobic exercise per week is necessary for a 5 - 7.5 kg weight loss (21). Even so, the AHA states that physical activity alone is not an ideal approach to achieve the initial weight loss goal and must be accompanied by dietary changes (22). Shaw et al. found in their study that combining exercise and diet results in an additional weight loss of approximately 1 kg compared to diet alone, and they report an additional 1.5 kg of weight loss when comparing high-intensity exercise versus low-intensity exercise (23).

## PHARMACOTHERAPY

Guidelines approved in various countries recommend the use of drugs for weight loss in those patients with a BMI greater than 27 with comorbidities associated with obesity or in those whose BMI is greater than 30, in conjunction with diet, exercise and lifestyle changes (9,10).
There are 5 groups of popular drugs approved by the US Food and Drug Administration (FDA) for use in patients with obesity; they have different mechanisms of action with effects on satiety, energy expenditure, caloric absorption, among others. These drugs are: pancreatic lipase inhibitors, phentermine, bupropion, serotonergic agonists and glucagon-like peptide-1 (GLP-1) agonists (24, 25).
Despite the recommendations of the guidelines and the growing number and variety of approaches to treat obesity and mitigate its associated risk, the epidemic continues to grow largely and unabated (9). Because of this, new therapies have emerged over the years, among them emerging one of the most accepted treatments with the best results evidenced during the last years, bariatric surgery (26).

## BARIATRIC SURGERY AND OBESITY

Bariatric surgery was one of the first interventions shown to significantly reduce obesity-associated cardiovascular morbidity and thus mortality (27), and it is the only evidence-based treatment that offers substantial, sustainable and long-lasting weight reduction even in morbidly obese individuals or in those for whom pharmacological and nutritional medical therapy has failed (28).

Although lipid control is now almost entirely a drug therapy, bariatric surgery has been shown to be the most effective way to achieve significant and durable weight loss in obesity (29). Data from long-term and follow-up studies now support that improvements in metabolic risk in association with weight loss after bariatric surgery translate into reductions in adverse cardiovascular outcomes and mortality (10, 30).

Currently the recommendation for performing bariatric surgery is in those patients over the age of 18, with a BMI equal to or greater than 35 with comorbidities associated with obesity or in those with a BMI of 40 or more regardless of the existence or not of comorbidities (11). Bariatric surgery in persons under 18 years of age continues to be a controversial issue, although in extraordinary scenarios it may be indicated in cases of morbid obesity in childhood or adolescence with associated comorbidities and/or failure of previous medical and nutritional treatment (31).

Originally, it was postulated that the various benefits obtained by bariatric surgery were closely related to procedures with restrictive and/or malabsorptive effects (32); however, it is now known that incretin and bile acid signaling (as well as probably alterations in the microbiota) also have an important contribution both to weight loss and to the positive impact on cardiovascular risk (33).

There are multiple bariatric techniques and procedures, currently worldwide and according to reports from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), the most performed is the laparoscopic vertical (or sleeve) gastrectomy (LSG), also known as gastric sleeve, followed by Roux-en-Y gastric bypass (RYGB), considered the gold standard due to its high level of efficacy, single-anastomosis gastric bypass (BAGUA/OAGB), single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S), among others (34).

## SLEEVE GASTRECTOMY

Sleeve gastrectomy has become, during the last decade, the most commonly performed bariatric procedure in the world (35). This procedure has evolved in a hybrid fashion to give rise to the emergence of new techniques and consists of removing portions of the fundus and antrum of the stomach by means of a vertical plication, leaving as a remnant a "sleeve" stomach, significantly restricting its capacity and through which food passes into the small intestine (36).

Vertical gastrectomy or popularly known as gastric sleeve can lead to a weight loss of up to 30% of body weight in the first postoperative year, with a smaller weight loss for up to 5 years (37).

In addition to the restrictive effect that results from removing a portion of the stomach, there are other mediators that are related to satiety and hypocaloric effects such as GLP-1 and Peptide YY (PYY) (38) as well as ghrelin, an orexigenic hormone that significantly reduces its levels due to the reduction of ghrelin secreting cells P-D1 that are found mostly in the gastric fundus (39). Also, gastric sleeve has effects on the microbiota that are believed to be related to weight loss through a reduction in caloric energy absorption (40).

The gastric sleeve has been shown to have the greatest improvement in metabolic risk compared to any other bariatric procedure (41-43). The metabolic risk markers that have benefited the most are: reduction of blood pressure, glycosylated hemoglobin and inflammatory markers, among others that have not yet been fully studied (44).

## COMPLICATIONS ASSOCIATED WITH SLEEVE GASTRECTOMY

Bariatric surgery has become for many the best method to treat obesity, especially in severe cases and due to the multiple benefits obtained after this type of procedure; however, as with any major surgery, there is a risk of complications, and although in the bariatric field they are relatively uncommon, when they occur they may require a multidisciplinary management that is not simple (45).

Sleeve gastrectomy, as a leading technique in metabolic and bariatric surgery, has gained popularity for its effectiveness in achieving considerable weight loss in a short period of time. However, this procedure is not without complications. The most common complications include bleeding, nutritional deficiencies and leakage (46).

One of the most prominent chronic complications of gastric sleeve is the development of postoperative de novo gastroesophageal reflux disease (GERD),

which can range from esophagitis to more serious conditions such as Barrett's esophagus and esophageal cancer (47). The prevalence of GERD in the Western population is estimated at 7.7%, and its pathogenesis is multifactorial, involving factors such as hypotonia of the lower esophageal sphincter (LES), inadequate transient relaxations of the LES, and the contribution of hiatal hernia (48).

In this context, mandatory hiatoplasty emerges as a potentially valuable strategy to mitigate the risk of postoperative GERD in patients undergoing gastric sleeve.

Although specific research on mandatory hiatoplasty in this procedure is limited, the literature suggests that repair of hiatal hernias and decreased acid production by fundus resection are protective factors against postoperative GERD (47). Therefore, it is plausible to consider that the inclusion of hiatoplasty as a mandatory step in the gastric sleeve could contribute significantly to the reduction of the incidence of postoperative GERD.

This perspective finds support in the understanding of the complexity and multifactoriality of postoperative GERD. Hiatoplasty, by repairing hiatal hernias and potentially improving lower esophageal sphincter function, could play a key role in preventing this type of complication. Given the importance of minimizing the risks associated with bariatric surgery, the implementation of mandatory gastric sleeve hiatoplasty represents a promising strategy that deserves careful consideration in the design of surgical protocols.

Although direct evidence on the efficacy of mandatory hiatoplasty in this setting is still limited, the potential benefits in terms of reduced risk of postoperative GERD warrant further investigation and consideration of this technique in surgical practice.

Its inclusion in gastric sleeve protocols could therefore represent a significant advance in improving patient outcomes and decreasing long-term complications related to this procedure.

## JUSTIFICATION

Magnitude and impact. The development of a protocol that includes mandatory hiatoplasty in the gastric sleeve is essential given the postoperative complications associated with this procedure. The gastric sleeve, recognized for its effectiveness in achieving significant weight loss, also presents inherent risks such as bleeding, nutritional deficiencies and leakage, with GERD being one of the most worrisome chronic complications. This condition impairs the patient's quality of life and can also trigger more serious problems such as Barrett's esophagus and, in extreme cases, esophageal cancer. Therefore, reducing these complications by adopting mandatory hiatoplasty can have a significant impact on the long-term safety and well-being of patients undergoing bariatric surgery.

Significance. The transcendence of implementing a protocol with mandatory hiatoplasty in the gastric sleeve lies in its potential to positively alter surgical practice in bariatric surgery. The inclusion of this procedure could represent a significant advance in the prevention of postoperative GERD, a complication that significantly affects the patient's quality of life and increases the burden on the health care system

due to the need for prolonged treatment and follow-up. Furthermore, by considering the multifactoriality of the pathogenesis of GERD, mandatory hiatoplasty aligns with a comprehensive view of surgical management, addressing key factors such as hiatal hernia and lower esophageal sphincter function. This perspective could, therefore, set a new standard in bariatric surgery, focusing on prevention and long-term care.

Feasibility. From a feasibility standpoint, the development and implementation of this protocol are feasible. The hiatoplasty technique, although requiring specialized surgical skills, is a well-established procedure and can be effectively integrated into gastric sleeve practice. In addition, growing concern about postoperative complications in bariatric surgery has generated substantial interest in improving existing techniques and adopting new approaches that can reduce these risks. With adequate resources for training and skill development, as well as institutional support, implementation of this protocol is not only feasible, but also a progressive step toward safer and more effective surgical care in the treatment of obesity and its comorbidities.

## PROBLEM STATEMENT AND RESEARCH QUESTION

The increasing prevalence of obesity worldwide has led to an increased reliance on surgical interventions such as sleeve gastrectomy for its effective treatment. Despite its success in significant weight loss and improvement of related comorbidities, gastric sleeve is not without postoperative complications, one of the most worrisome being the development of postoperative GERD. This problem stands out for its frequency and severity, significantly affecting the quality of life of patients and presenting challenges in post-surgical clinical management.

The incidence of postoperative GERD in patients undergoing gastric sleeve surgery is a growing concern. The prevalence of GERD in the general population is considerable, and its occurrence or exacerbation after bariatric surgery represents a significant clinical problem. Moreover, the management of postoperative GERD involves additional costs for both the patient and the health care system, in terms of long-term medication, clinical follow-up and, in some cases, surgical reintervention.

The complexity of this problem lies in the multifactorial nature of its etiology. Factors such as hypotonia of the lower esophageal sphincter and the presence of hiatal hernia contribute to the development of GERD. Therefore, it is imperative to explore surgical strategies that can mitigate this risk. One such strategy is mandatory hiatoplasty during sleeve gastrectomy, which, although not extensively investigated in this specific setting, has the potential to address one of the key etiologic factors of postoperative GERD.

However, the adoption of mandatory gastric sleeve hiatoplasty presents not only technical challenges, but also involves considerations of surgeon training, hospital resources, and acceptance of new surgical protocols. The need for a more preventive and comprehensive approach to bariatric surgery is clear, but requires a solid evidence base and adaptation of current surgical practices. This context raises a significant issue: should mandatory hiatoplasty be integrated into the gastric sleeve to reduce the incidence of postoperative GERD and improve long-term outcomes for patients undergoing bariatric surgery?

## HYPOTHESIS

### Alternative hypothesis

Mandatory hiatoplasty performed during gastric sleeve surgery significantly reduces the incidence of postoperative gastroesophageal reflux disease (GERD) compared to gastric sleeve performed without mandatory hiatoplasty.

### Null hypothesis

Mandatory hiatoplasty performed during gastric sleeve surgery does not have a significant impact on reducing the incidence of postoperative gastroesophageal reflux disease (GERD) compared to gastric sleeve performed without mandatory hiatoplasty.

## OBJECTIVES

### General

To evaluate the efficacy of mandatory hiatoplasty performed during gastric sleeve surgery in reducing the incidence of postoperative gastroesophageal reflux disease (GERD) in patients undergoing this procedure in a hospital specializing in bariatric surgery in Tijuana, Baja California.

### Specific

**Demographic characteristics and comorbidities in patients undergoing gastric sleeve with hiatoplasty:** These patients usually have significant obesity, often accompanied by comorbidities such as type 2 diabetes, hypertension, sleep apnea, and gastroesophageal reflux disease (GERD). Demographic characteristics may vary, but the prevalence of obesity and its associated comorbidities is high in many regions, including Tijuana, Baja California.

**Incidence of postoperative GERD in patients undergoing gastric sleeve with mandatory hiatoplasty:** Hiatoplasty is often performed to reduce the risk of postoperative GERD by repairing a herniated hiatus during gastric sleeve surgery. However, the exact incidence of postoperative GERD can vary and depends on factors such as surgical technique, patient anatomy and postoperative management.

**Comparison of postoperative complication rates, including GERD:** Postoperative complications may include, but are not limited to, bleeding, infection, sleeve stenosis, and GERD recurrence. Comparison of complication rates between patients with and without mandatory hiatoplasty may provide insight into the effectiveness of this technique in mitigating specific risks.

**Postoperative quality of life analysis:** Postoperative quality of life can be significantly improved after bariatric surgery due to weight loss and improvement of comorbidities. Specific measures may include, but are not limited to, physical mobility, self-esteem, relief of symptoms of comorbidities, and overall satisfaction with the results of surgery.

**Evaluation of the safety and technical feasibility of mandatory hiatoplasty:** The integration of hiatoplasty into gastric sleeve surgery should be evaluated in terms of technical feasibility, safety, and effectiveness in preventing recurrence of hiatal hernias and GERD. This may involve analysis of complication rates, specific surgical techniques, and long-term.

## MATERIALS AND METHODS

### Research design

A retrospective case series will be performed.

### Universe of study

Electronic clinical records of patients over 18 years of age of indistinct gender who underwent gastric sleeve with hiatoplasty for obesity or overweight management in a hospital center specialized in bariatric surgery in Tijuana, Baja California.

### Study period

March 2024 - July 2024.

### Sample size

To calculate the sample size, the formula for prevalence studies for infinite populations was used, considering a confidence interval of 95% and a margin of error of 5%. The formula is presented below:

$$n= \frac{Z_{a/2}^2 (p*q)}{d^2}$$

where,

$Z_{a/2}$ = Z-score of a normal distribution a/2= 1.96

p= 20%

q= 100-p = 70%.

$d^2$ =margin of error= 10

**n= a minimum of 275 patients is required**

### Sampling

Non-probabilistic sampling will be used.

### Inclusion and non-inclusion criteria

*Inclusion criteria*

- Patients over 18 years of age.
- Gender indistinct.
- Overweight, obesity grade I, II, III, super obesity or super-super obesity.

- Underwent gastric sleeve with hiatoplasty for obesity management at a high volume Tijuana hospital dedicated to bariatric surgery.

*Non-inclusion criteria*

- Patient records with incomplete information.

**Description of the study**

1. This study will be subject to review by the Research and Research Bioethics Committees of the hospital in question. Since this is a retrospective study, informed consent is not required.

2. After approval, the electronic clinical records of overweight and obese patients who meet the inclusion criteria and who underwent bariatric surgery for obesity management in Tijuana during the study period will be reviewed.

3. The following information of interest will be obtained from the file: age, sex, comorbidities, BMI, type of procedure, duration of surgery, final bleeding, immediate postoperative and transoperative complications. Patient follow-up information will also be obtained, which is obtained both in person for patients who can attend follow-up consultations and remotely by e-mail after sending a medical questionnaire and subsequent response from patients who reside in another city or country and therefore cannot attend their follow-up consultations in person.

4. Finally, the data will be captured in SPSS for statistical analysis.

5. To measure the quality of life of patients and the effectiveness of surgery, the Bariatric Analysis and Reporting Outcome System (BAROS) scale will be used.

**Definition and operationalization of the study variables**

| Variable | Conceptual definition | Operational definition | Measurement units | Type of Variable |
|---|---|---|---|---|
| **Age** | Years a person has lived since birth | Patient's age, recorded in the file. | Years | Quantitative |
| **Sex** | Difference in physical and sexual characteristics that distinguish men from women. | Classification of the patient as male or female | Male<br>Female | Qualitative Nominal |
| **Chronic comorbidities** | Long-standing diseases directly related to obesity | Additional diseases recorded in the patient's record | None<br>Diabetes mellitus<br>Hypertension<br>Cardiovascular<br>GERD<br>Dyslipidemia<br>Hypothyroidism<br>SAOS<br>Depression<br>Another | Qualitative Nominal |
| **BMI** | Universal unit for estimating the amount of body fat a person has. | BMI value recorded in the file, or calculated from weight and height, as: Weight (Kg)/ Size (m)2. | Kg/m2 | Continuous quantitative |
| **Obesity level** | Excess or a general excessive accumulation of fat in the body | Degree or level of obesity in the patient.<br>Grade I: 30-34.9 $Kg/m^2$<br>Grade II: 35-39.9 $Kg/m^2$<br>Grade III: >=40 $Kg/m^2$<br>Superobesity >50 $Kg/m^2$<br>Super-super-obesity >60 $Kg/m^2$ | I<br>II<br>III<br>Superobesity<br>Super-super-obesity | Qualitative ordinal |
| **Duration of surgery** | Time of the surgical process. | Time of surgery recorded in the file | Minutes | Quantitative |
| **Trans-operative complications** | Adverse events developed during surgery | Perioperative complications recorded in the record | None<br>Bleeding<br>Pneumothorax<br>Organ injury<br>Vascular injury<br>Other | Qualitative Nominal |
| **Postoperative complications** | Adverse events developed after surgery | Postoperative complications recorded in the record or mentioned by the patient at follow-up | None<br>GERD<br>Bleeding<br>Leakage<br>Obstruction<br>Diarrhea<br>Embolism<br>Other | Qualitative Nominal |

## STATISTICAL ANALYSIS

A database will be created in Excel, which will be downloaded into the statistical package SPSS v.26 in its MacOS version for data processing.

A descriptive analysis will be performed. For qualitative variables with frequencies and percentages. For quantitative variables, the descriptive analysis will consist of mean and standard deviation. In case quantitative variables have a non-parametric distribution, median and interquartile range will be used as descriptive statistics.

**ETHICAL CONSIDERATIONS**

The present research project was submitted to evaluation by the Local Health Research and Bioethics Committees for assessment and acceptance.

Since this is a retrospective study and has no bioethical implications as such, article 17 of the regulations of the General Health Law on Health Research will be taken into consideration, which classifies it as risk-free since the information will be obtained from clinical records.

Adheres to the Declaration of Helsinki of the World Medical Association.

Establishing Ethical Principles for Medical Research Involving Human Subjects, adapted by the 8th World Medical Assembly, Helsinki Finland in June 1964. As well as the last amendment made by the last General Assembly in October 2013, and the Taipei Declaration on Ethical Considerations on Health Databases and Biobanks that officially complements the Declaration of Helsinki since 2016; as reported by the World Medical Assembly.

Absolute confidentiality of the data will be maintained. This is in accordance with the Federal Law for the Protection of Personal Data, NOM-004-SSA3-2012, of the clinical file (sections 5.4, 5.5 and 5.7).

## RESOURCES, FINANCING AND FEASIBILITY

*Material resources*

- Printer, sheets, laptop, pens are required.

*Human Resources*

- Surgeon: Dr. Alejandro Lopez Ortega
- Physician Assistant: Dr. Helmut Heribert
- Methodological Assistants: Dr. Alejandro González Ojeda, Dr. José Aldo Guzmán Barba, Dr. Isaac Esparza Estrada, Dr. Sergio Jiram Vazquez Sánchez

*Financial resources*

Material resources will be provided by the investigators and no additional funding will be required from the hospitals.

**SCHEDULE OF ACTIVITIES.**

| Schedule of activities | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | January 2023 | | | February-March 2024 | | | March 2024 | | | April 2024 | | | June-July 2023 | | | |
| **1.- Bibliographic search** | R | R | R | | | | | | | | | | | | | |
| **2.- Protocol design** | | | | R | R | R | | | | | | | | | | |
| **3.- Approval of the protocol** | | | | | | | R | R | R | | | | | | | |
| **4.- Execution of the protocol** | | | | | | | | | | R | R | R | | | | |
| **5.- Data analysis and elaboration of results** | | | | | | | | | | | | | P | P | P | P |

R: Completed P: Pending

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# ANNEXES.

## APPENDIX 1. DATA COLLECTION FORM

### "Implementation of Mandatory Hiatoplasty in Sleeve Gastrectomy: Strategy for Gastro-Esophageal Reflux Disease (GERD) Risk Reduction."

Identification sheet

**ID:** **Fecha:** _____

**Name:** _____Gender : M ☐ F ☐ Other ☐ **Age:** _____ years.

**Teléfono:** _____**Email:** _____

**Marital Status:** Single ☐ Married ☐ Divorced ☐ Common-law ☐

Country of residence:Mexico ☐ USA ☐ Other: _____

**National** ity:Mexico ☐ USA ☐Other: _____

**Occupation:**

_____

**Attending Physician:** Dr. Ortiz ☐ Dr. Almino ☐ Other: _____

**Planned Surgery:** Sleeve ☐ Y-Roux ☐ SADIS/SD ☐ Mini-Gastric Bypass (MGB) ☐

Rev Sleeve ☐ Band ☐ Rev Bypass☐ Other: _____

**Planned surgery date:** _____

**Size:** _____ metersWeight **(before diet):** _____ kgIMC : _____

**HR:** _____ bpm **FR:** _____ rpm **BP:** _____ mmHg **T:** _____ °C

Background

**Allergies:** Denied ☐ Penicillin ☐ Sulfonamides ☐ AAS ☐

Otro: _____

**Smoking:** Denied ☐ Active ☐ Inactive ☐ Inactive time (years): _____

Cigarettes per week:_____

Years:_____

**Alcoholism:** Denied ☐ Active ☐ Inactive ☐

Social ☐ / Drinks per week:_____ _____

Years:_____

**Toxicomania:** Denied ☐ Active ☐ Inactive ☐

Type of drug used: Marijuana ☐ Cocaine ☐ Ecstasy ☐ LSD ☐

Heroin ☐ Fentanyl☐ Other:_____ Years: _____

**Previous hospitalizations:** denied ☐ Yes ☐ How long ago? _____

Motivo:

_____

_____

_____

Blood type: A ☐ B ☐ AB☐ ☐ ☐ ☐

**Previous transfusions:** denied ☐ Yes ☐ How long ago? _____

Motivo:

_____

_____

Heredofamiliares

**Diabetes:** Denied ☐ Father ☐ Mother ☐ Grandparents ☐ Siblings ☐ Children ☐

**Hypertension:** Denied ☐ Father ☐ Mother ☐ Grandparents ☐ Siblings ☐ Children ☐

**Cardiac:** Denied ☐ Father ☐ Mother ☐ Grandparents ☐ Siblings ☐ Sons ☐ Sons.

**Cancer:** Denied ☐ Father ☐ Mother ☐ Grandparents ☐ Siblings ☐ Children ☐Psychiatric**:** Denied ☐ Father ☐ Mother ☐ Grandparents ☐ Siblings ☐ Children ☐Endrocrine**:** Denied ☐ Father ☐ Mother ☐ Grandparents ☐ Siblings ☐ Children ☐

Personal

**Diabetes:** No ☐ Yes ☐ **Time of evolution:** _____ years **Are you in control?** No ☐ Yes ☐

**Treatment used:**

☐ No treatment ☐ Insulin: _____ IU/day.

☐ Metformin: _____ mg/day ☐ Hypoglycemic: _____

☐ Other: _____

**Arterial Hypertension:** No ☐ Yes ☐ **Time of evolution:** ____ years **Is it under control?** No ☐ Yes ☐

**Treatment used**:

☐ No treatment ☐ ACEI: _____

☐ ARA 2: _____ ☐ BetaBlocker: _____

☐ Ca Antagonist:_____ ☐ Diuretic: _____

**Other Cardiovascular Diseases:** No ☐ Yes ☐

**Enfermedad(es):** _____

**Time of evolution:** _____ years

**Treatment used:** _____

**Cancer:** No ☐ Yes ☐ In recurrence ☐

**Type of cancer:** _____

**Time of evolution:** _____ years

**Treatment used:** _____

**Psychological/Psychiatric Illnesses:** No ☐ Yes ☐

**Enfermedad(es):**

_____

**Time of evolution:** _____ years

**Treatment used:** _____

**Endocrine Diseases:** No ☐ Yes ☐

**Enfermedad(es):** _____

**Time of evolution:** _____ years

**Treatment used:** _____

**GERD:** No ☐ Yes ☐

**How was the diagnosis made?**

Not performed ☐ Endoscopy ☐ SEGD ☐ Phmetry ☐ Other: _____

**Treatment:**

☐ IBP: _____

☐ Antacids: _____

☐ H2RA: _____

☐ Otro: _____

**Previous abdominal surgeries:** No ☐ Yes ☐

**☐ Cholecystectomy How many years ago?:**_____

**☐ Appendectomy How many years ago?:**_____

**☐ Hysterectomy How many years ago?:**_____

**☐ Hernioplasty How many years ago?:**_____

☐ BariatricSleeve ☐ Y-Roux ☐ MGB ☐ Band ☐ Gastric balloon ☐

Otra: _____

**How many years ago:**

_____

☐ **Caesarean section How many:** _____**How many years ago (last):**

_____

**☐ Other:** _____

**Nausea (that required medication) or vomiting in previous surgeries?** No ☐ Yes ☐ No ☐ No ☐ Yes ☐ No

**Respiratory symptoms:** Denied☐ Rhinorrhea☐ S ☐ Dyspnea ☐ Cough☐

Other: _____

_____

**Sleep apnea (STOP-BANG):**

Do you have loud snoring (heard from another room): Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ No

**Do you feel tired during the day:** Yes ☐ No ☐

Have you ever been told if you pause your breathing while sleeping: Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ No

**Collar diameter >40 cm:** Yes ☐ No ☐

Current condition and physical examination

**Current condition and time of evolution:** _____
_____
_____

**Previous nutritional treatment:** No ☐ Yes ☐Which one :
_____

**Previous medical treatment:** no ☐ yes ☐ which one :
_____

**Neurológico**

**Conscientious:** Yes ☐ No ☐ **Orientated:** Yes ☐ No ☐ **Cooperative:** Yes ☐ No ☐

**Musculoskeletal:**

Mobility:Normal ☐ Limited ☐ None ☐ **Muscle tone:** Preserved ☐ Altered ☐

**Skin and adnexa**

**Hydration**: Good ☐ Fair ☐ Poor ☐

**Coloration:** Normal ☐ Pallor ☐ Icteric ☐ Other: _____

**Head and neck**

**Symmetrical:** Yes ☐ No ☐ **Palpable masses:** No ☐ Yes ☐

**Chest**

**Cardiac:** Normal ☐ Murmur ☐ Arrhythmia ☐ Frémito ☐ Other: _____

**Pulmonary:** Normal ☐ Wheezing ☐ Rales ☐ Rales ☐ Other: _____

**Abdomen**

**Pain:** No ☐ Yes ☐ Superficial ☐ Deep ☐ **Location:** _____

**Palpable masses:** No ☐ Yes ☐Location :_____
_____

**Previous incisions:** No ☐ Yes ☐Type/Location : _____
_____

**Megaliths:** No ☐ Liver ☐ Spleen ☐ Other: _____

**Hernias:** No ☐ Umbilical ☐ Inguinal ☐ Other: _____

**Extremities:** Intact: No ☐ Yes ☐ Edema: No ☐ Yes ☐

Capillary filling: Normal ☐ Abnormal ☐

Pre-surgical

**Date of surgery:**_____ **Wearing of TED stockings:** No ☐ Yes ☐

**Was electrolyte and carbohydrate loading performed at 2 hrs prior to surgery:** No ☐ Yes ☐

**Pre-operative diet:** No ☐ Yes ☐How many **days:** 1-3 ☐ 4-7 ☐ 8-14 ☐ >15 ☐

**Did you lose weight?** No ☐ Yes ☐How many **g/kg did you lose:**

_____

**Pre-surgical weight (after diet):** _____ kg

**Laboratories:**

**Hb** _____ mg/dl **Hto** _____ **Platelets** _____miles **Leukocytes** _____ miles

**Glucose** _____ mg/dl **HbA1c:** _____% **Urea** _____mg/dl Creatinine_____ mg/dl

**TP** _____sec TPT _____ sec **INR**_____ **TGO** _____ **TGP** _____

**Total cholesterol** _____ **mg/dlTriglycerides** _____ mg/dl

**Previous studies:**

**TAC:** No ☐ Yes ☐ Result:_____

_____

**USG:** No ☐ Yes ☐ Result:_____

_____

**Endoscopy:** No ☐ Yes ☐ Result_ _____

_____

**BP figures:** _____mmHg **Capillary glucose figures (if diabetic[a]):** _____ mg/dl

Anesthesia

**ASA classification:** I ☐ II ☐ III ☐ IV ☐ V ☐ VI ☐ **Use of general anesthesia:** No ☐ Yes ☐

**Antibiotic prophylaxis:** No ☐ Yes ☐

**Antibiotic used:** Ceftriaxone ☐ Levofloxacin ☐ Cefazolin ☐ Ciprofloxacin ☐

Otro: _____

**Antithrombotic prophylaxis:** None ☐ Enoxaparin ☐ Rivaroxaban ☐ Acetylsalicylic acid ☐

Otro: _____

**Antiemetic prophylaxis:** None ☐ Ondansetron ☐ Metoclopramide ☐ Domperidone ☐

Corticosteroid: _____ Other:

_____

**Use of opioids:** none ☐ Fentanyl ☐ Morphine ☐ Tramadol ☐ Methadone ☐ Nalbuphine ☐

Buprenorphine ☐ Oxycodone ☐ Other: _____

**Use of blood products:** No ☐ Yes ☐Number **of packages**:_____

**Type of blood products:** Blood ☐ Platelets ☐ Plasma ☐

**Complications related to anesthesia:** No ☐ Yes ☐

**Which one(s):**

_____

**How was it resolved?** _____

Transsurgical

**Surgery Performed:** Sleeve ☐ Y-Roux ☐ SADIS/SD ☐ MGB ☐ Band ☐ Rev Bypass ☐

Rev Sleeve ☐ Other: _____

**Stapler type:** Manual ☐ Electric ☐ Other: _____

**Number of cartridges (staples) used:** _____

**Type of cartridges (staples) used:** White ☐ Blue ☐ Yellow ☐ Green ☐ Black ☐

***Contest as applicable**

**Probe size used:** _____ **FrCommon handle** size **:** _____ cm

**Pouch size:** _____ **cmBiliopancreatic loop** size **:** _____ cm

**Food handle size:** _____ cm

**If MGB, was the gastric remnant resected (Modified Mini Bypass):** No ☐ Yes ☐

**Grapevine line reinforcement:** No ☐ Invaginating ☐ Transcriptional ☐

**Sutures used:** Prolene ☐ Monocryl ☐ PDS ☐ Other: _____

**Was a tightness test performed:** No ☐ Yes ☐

**Gap Closure:** No ☐ Yes ☐

**Suture type:** Prolene ☐ Ethibond ☐ Monocryl ☐ PDS ☐ Other:_____

**Port (trocar) closure:** No ☐ Yes☐

**Use of sealants (glue):** No ☐ Yes ☐

**Use of drainage:** No ☐ Yes ☐Type **of drainage:** Open ☐ Closed ☐ Other: _____

**Total operative time:** _____min **Total bleeding:** _____ ml

**Patient's final sta**tus: Stable ☐ Delicate ☐ Serious☐ Finished ☐

**Trans-surgical complications:** None ☐

**Bleeding:** No ☐ Yes☐ Amount: _____ml

**Adjacent organ injury:** No ☐ Yes ☐ Injured organ: _____

**Failure to grapple:** No ☐ Yes ☐

**Otra:** _____

**How was it resolved?** _____

_____

Post-surgical 24 hrs

**Early wandering (<6 hrs):** No ☐ Yes ☐

**Nausea that required medication during the first 24 hrs:** No ☐ Yes ☐

**Use of antiemetics:** no ☐ Ondansetron ☐ Metoclopramide ☐ Domperidone ☐
Corticosteroid☐: Other: _____

**Pain that required medication during the first 24 hrs:** No ☐ Yes ☐ No ☐ Yes ☐ No

**Use of analgesics:** Ketorolac ☐ Paracetamol ☐ Lysine Clonixinate ☐
Metamizole ☐ Diclofenac ☐ Ketoprofen ☐ Parecoxib ☐ Ibuprofen ☐
Otro: _____

**Opioid use (24 hrs):** None ☐ Morphine ☐ Tramadol ☐ Methadone ☐
Nalbuphine ☐ Buprenorphine ☐ Oxycodone ☐ Fentanyl ☐
Otro: _____

**Use of antibiotics:** No ☐ Ceftriaxone ☐ Levofloxacin ☐ Cefazolin ☐ Ciprofloxacin ☐
Ampicillin ☐ Clindamycin ☐ Other:_____

**Drainage output (24 hrs):** _____ cc **Characteristics:** Hemic ☐ Serohaematic ☐ Serous ☐ Biliary ☐
Intestinal ☐ Other: _____

**Was there a need for surgical reintervention:** No ☐ Yes ☐: No ☐: Yes ☐: No
**Motivo:** _____
_____
_____

**Blood pressure (24 hr):** _____ **mmHgCapillary glucose (24 hr):** _____ mg/dl

In-hospital follow-up

**At how many hours post surgery did you mobilize:** 2-5 ☐ 6-12 ☐ 12-24 ☐ >24 ☐

**Did you perform breathing exercises (min 3 times a day):** No ☐ Yes ☐

**How many hours after surgery was the enteral line resumed?**

_____

**How many days post-surgery was the drain removed?**:_____

**Did you perform barium swallow test:** No ☐ Yes☐ **Result:** Normal ☐ Leakage ☐

**Days of in-hospital stay:** _____

**Antithrombotic prophylaxis scheme at discharge:** None ☐ Enoxaparin ☐ Rivaroxaban ☐ Apixaban ☐ Other: _____

Otro: _____

**Need for surgical reintervention prior to discharge:** No ☐ Yes ☐

Motivo: _____

**BP figures (at discharge):** _____ **mmHgCapillary glucose figures (at discharge):** _____ mg/dl

Respiratory complications

**SatO2 (ambient):** _____

None ☐ Atelectasis: No ☐ Yes ☐ **Pneumothorax:**No ☐ Yes ☐

**Venous thromboembolism/VTE:** No ☐ Deep Venous Thrombosis ☐ PET ☐

**Other:**

_____ **Did you req**uire supplemental O2: No ☐ Yes ☐SatO2 **(supplemental):**

_____

**How was it resolved?** _____

Other complications

**Leakage:** No ☐ Yes ☐**Urinary** Retention **:**
No ☐ Yes ☐
**Dysphagia:** No ☐ Yes ☐**Liver** dysfunction **:**
No ☐ Yes ☐Hemorrhage**:** No ☐ Yes ☐Constipation **:**
No ☐ Yes ☐Infection**:** No ☐ Yes ☐Pancreatitis**:**
No ☐ Yes ☐**Intestinal** obstruction**:** No ☐ Yes ☐Diarrhea **:**
No ☐ Yes ☐Diarrhea **:** No ☐ Yes ☐
**Renal insufficiency:** No ☐ Yes ☐ No ☐ No ☐ Yes ☐ No

**How was it resolved?** _____
_____
_____
_____

**Complications according to Clavien-Dindo Classification:**

***Classify according to the need for the use of the following medications, interventions and/or occurrence of complications in the patient's hospital course (one or more options, not necessarily all, e.g., a normal post-surgical course is classified as 1 as the use of solutions and analgesics is necessary).**

☐ 1. Use of solutions, antiemetics, analgesics, antipyretics, need for physiotherapy.

☐ 2. Use of drugs other than above, blood products, parenteral nutrition.

☐ 3a. Surgical, endoscopic or radiological re-intervention without the use of general anesthesia.

☐ 3b. Surgical, endoscopic or radiological re-intervention with use of general anesthesia.

☐ 4a. Single organ dysfunction (dialysis included).

☐ 4b. Multiple organ dysfunction.

☐ 5. Death.

## APPENDIX 2. FOLLOW-UP FORMAT

Follow Up Questionnarie

Please answer the following questions based on the present or how you currently feel

Weight *

Texto de respuesta corta

Did you describe your weight in kilograms or pounds? *

- ○ Kg
- ○ Lbs

Please select the checkboxes that best describes your current conditions (if any) compared to before your surgery

If you don't have any medical conditions, please skip this question

| | Aggravated | Unchanged | Improved | Resolved |
|---|---|---|---|---|
| Diabetes | ○ | ○ | ○ | ○ |
| Hypertension | ○ | ○ | ○ | ○ |
| Dyslipidemia | ○ | ○ | ○ | ○ |
| Apnea | ○ | ○ | ○ | ○ |
| Depression | ○ | ○ | ○ | ○ |
| Anxiety | ○ | ○ | ○ | ○ |
| Reflux | ○ | ○ | ○ | ○ |
| Insomnia | ○ | ○ | ○ | ○ |

If you were taking medications, has there been any change in your medication consumption after your surgery? *

- ◯ I did not take any medication
- ◯ Yes, now I take a lower dosage and/or less medications
- ◯ No, there were no changes
- ◯ Yes, now I take a higher dosage and/or more medications

Please specify the medications and dosages you are currently taking

Texto de respuesta larga

Do you suffer from frequent diarrhea? *

- ◯ No
- ◯ Yes

Does your diarrhea require medication?

- No
- Yes

Do you have very foul-smelling flatulence? *

- No
- Rarely
- Occasionally
- Frequently

Do you have very foul-smelling stools? *

- No
- Rarely
- Occasionally
- Frequently

Have you suffered any fractures after your bariatric surgery? *

- No
- Yes

Where on your body and in what year did the fracture occur?

Texto de respuesta larga

Have you ever been told that you have thinner bones or osteoporosis? *

- No
- Yes

**Quality of Life**

Please answer the following questions based on how you currently feel

Usually, I feel... *

| | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|
| Very bad about myself | ○ | ○ | ○ | ○ | ○ | Very good about myself |

I enjoy physical activities... *

| | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|
| Nothing at all | ○ | ○ | ○ | ○ | ○ | Very Much |

I feel comfortable in social gatherings... *

| | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|
| Nothing at all | ○ | ○ | ○ | ○ | ○ | Very Much |

I am able to work... *

| | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|
| Nothing at all | ○ | ○ | ○ | ○ | ○ | Very Much |

The pleasure I get out of sex is... *

| | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|
| Nothing at all | ○ | ○ | ○ | ○ | ○ | Very Much |

**Reflux Scale**

Please answer the following questions based on how you currently feel

How bad is your heartburn? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

Heartburn when lying down? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

Heartburn when standing up? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

Heartburn after meals? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

Does heartburn change your diet? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

Does heartburn wake you from sleep? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

Do you have difficulty swallowing? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

Do you have pain with swallowing? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

Do you have bloating or gassy feelings? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

Do you have bloating or gassy feelings? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

If you take medications, does this affect your daily life? *

| | 0 | 1 | 2 | 3 | 4 | 5 | |
|---|---|---|---|---|---|---|---|
| Non symptoms | ○ | ○ | ○ | ○ | ○ | ○ | Symptoms are incapacitating and unable to do daily activities |

How satisfied are you with your present condition? *

- ○ Satisfied
- ○ Neutral
- ○ Dissatisfied