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Manometric and Symptomatic Changes in Patients Undergoing Heller's Myotomy and Fundoplication by Acalasia

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ABSTRACT

Introduction: Achalasia occurs in up to 10 out of every 100,000 people worldwide, is associated with a large number of symptoms that can impact the patient's quality of life; laparoscopic myotomy of Héller with fundoplication represents the gold standard surgery in the treatment of this condition, has shown symptomatic improvement of the patient, However, studies have reported that there are no significant manometric and symptomatic changes in postoperative follow-up, and little has been reported in the literature, particularly in our population.

Objective: To determine manometric and symptomatic changes in patients undergoing heller's myotomy and achalasia fundoplication.

Material and methods: Prospective analytical observational study to be performed in patients undergoing Heller's myotomy and fundoplication due to achalasia performed by the Surgery Service of the UMAE25 of the IMSS, the symptomatology (eckardt) and manometric changes (Chicago) will be evaluated during the pre and post-surgical, it will be established if there are statistically significant differences in the postoperative using t student, Anova and Chi Square with a 95% confidence level and 5% margin of error.

Conclusion: Through this protocol we can conclude thatthere are significant symptomatic and manometric changes in patients undergoing heller's myotomy and fundoplication due to achalasia, in the contrast of an adequate presurgical assessment, the technical knowledge to avoid falling into biases of the operator (surgeon), with an adequate technique and follow-up, as well as close monitoring of patients

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INTRODUCTION

One of the reasons that prompted me to carry out this research work was that achalasia is one of the most complicated pathologies from the approach, diagnosis, procedure, and recovery, achalasia as such is estimated that the incidence of this disease (at least in the USA) is 1 / 100 000 people and 10/100 000 people in terms of prevalence; no association of race and gender is known, However, if there is a relationship with age, having its peak incidence between 30 and 60 years and the lowest in children under 16 years of age, it is of high impact at national and international level. With 6769 cases and 27 076 controls affirms a positive association between autoimmune conditions and viral diseases caused by varicella zoster and human papillomavirus, with the development of achalasia. Even in endemic areas, achalasia is related to Chagas disease, caused by the pathogen Trypanosoma, which causes degeneration of the mesenteric plexus.

It is relevant to highlight that from its bases the nature of the problem lies in the good interpretation of the manometric values, symptoms, the surgical approach and recovery, with the help of the different tools for its correct interpretation, the numbers in terms of relapses and complications contemplate an increase in the first if the initial treatment is pneumatic dilation and in the second if the patient underwent Heller's myotomy. Due to the high prevalence among the adult population, and the morbidity that this entails, this topic was chosen for development and analysis.

THEORETICAL FRAMEWORK

Achalasia manifests with a plethora of essentially gastrointestinal and nonspecific symptoms. [1-4] The most characteristic of the above are neuromuscular dysphagia characteristic to liquids and solids, regurgitation, halitosis, weight loss, heartburn and chest pain precordial; [5] Alvand et al[6] presents three subcategories based on symptom intensity:

- Type I: mostly weight loss.
- Type II: increased severity and frequency of symptoms.
- Type III: mostly chest pain.

Dysphagia can be considered the pivotal symptom, considering that it occurs in 90% of patients. [6] On the other hand, regurgitation occurs in approximately 75% and chest pain in 40%, it is necessary to mention the importance of this symptom that must be differentiated from angina pectoris in older patients or with known comorbidities. Weight loss has a double origin, occurring in 40% of patients, on the one hand, esophageal emptying and on the other the reduction of voluntary food intake, as the patient seeks to avoid the appearance of postprandial symptoms. [6.7]

Patients suffering from achalasia may also manifest extraesophageal symptoms, of which pulmonary abnormalities are the most frequent, occurring in more than half of patients and are due to recurrent aspiration and tracheal compression secondary to esophageal dilation. [7]

Regarding the evaluation of symptoms there are different classifications and scores, however, for the purposes of this work, we focus on the classification of eckardt which suggests questioning the patient about the symptoms: dysphagia, regurgitation, chest pain and weight loss. So 1 point is awarded to "occasionally", 2 points to "daily" or 3 points to "with each meal". [6.7]

Once with the result from 0 to 12 points is organized as follows:

- 0-2 points stage 0
- 2-3 stage I
- 4-6 Stage II
- >6 Stage III

However, accurate diagnosis requires the use of cabinet studies, since the intensity of symptoms does not always correlate with manometric findings, for example. [7]

Physiopathology

In a non-pathological situation, coordinated esophageal contractions and relaxation of the lower esophageal sphincter (EY) allow the movement of the food bolus into the stomach and prevent its re-entry into the esophagus. This action is given by the parasympathetic pathways of the EIS, both parasympathetic and inhibitory. The case of patients with achalasia is different, they do not have inhibitory ganglion cells, which translates into a short circuit in neurotransmission and this in turn into a hypertensive and unrelaxed EIS. This process is degenerative and evolves to excessive sphincter contraction, functional obstruction, dilation and finally irreversible aperistalsis. [8]

Diagnosis.

The symptoms alone are not a reliable method, therefore, a high suspicion requires as a first study an esophagogram with barium swallow; in which a characteristic image can be observed in "bird beak", which is formed with proximal esophageal dilation. Subsequently, the use of upper endoscopy is recommended to rule out differential diagnoses such as malignant lesions; Although this study is not entirely accurate, in advanced stages (Eckard III) signs of chronicity such as esophagitis or highly suggestive data of achalasia such as the rosette appearance of the esophagogastric junction can be found. [9]

However, the gold standard remains high-resolution manometry, a study introduced in 1990 by ray clouse and geoff hebbard, which evaluates the motor function of the upper esophageal sphincter, body and lower esophageal sphincter, with >10mmhg as a value suggestive of aperistalsis. Patients undergoing this study have incomplete relaxation of the EIS with swallowing and lower esophageal aperistalsis and combination with high pressure of the eEI at rest; In addition to the above, high-resolution manometry includes a topographic map of esophageal pressure. [10] Like the clinic, the manometry results place the patient in one of the three types of the Chicago classification, whose last update is presented as follows:

Guy	Description of manometry
I	Aperistalsis and not esophageal pressurization.
II	Aperistalsis with ≥20% panesophageal pressurization with swallowing.
III	Spastic contractions and distal integral contractility > 450 mmhg-s-cm in ≥20%.
LSS	Median integrated relaxation pressure in supine and elevated standing, elevated supine intrabolus pressure, and normal peristalsis, with symptoms of dysphagia and/or noncardiac chest pain, and at least one confirmatory supportive test.

Handling

The initial and temporal pharmacological management of achalasia is oriented to smooth muscle relaxation by inhibiting its contraction by making use of calcium channel blockers; or increasing nitric oxide concentrations (and consequently adenosine monophosphate) by applying nitrates. [12] The following options, prior to the surgical option, are endoscopic injection of botulinum toxin and pneumatic dilation. The application of botulinum toxin relaxes the lower esophageal sphincter as it inhibits acetyl choline; However,

this measure is temporary, lasting approximately one year, it is ideal for patients who have relapsed after the surgical procedure, which is not a candidate for surgery or as a bridge procedure between drug therapy and definitive treatment. [13]

For its part, pneumatic dilation is an endoscopic procedure, suggested as the first invasive therapeutic option, which achieves a controlled tear of the circular fibers of the lower esophageal sphincter by applying radial force with a balloon of 3 to 4 cm in diameter placed on a guide. The balloon is inserted by endoscopy and inflated at a pressure of 105 to 1000 mmHg 1 to 4 times. With the above, symptomatic remission of 50% to 93% is achieved, however, up to 30% of patients suffer from recurrence in the following 5 years. [14]

The *gold standard* surgical continues to be Heller's laparoscopic myotomy with partial fundoplication. Myotomy is a laparoscopic procedure created 100 years ago and initially applied in patients with residual dysphagia after pneumatic dilation,15 through which muscle fibers of the EIS are cut, which favors their relaxation and gives a permanent solution to the symptoms of achalasia. The procedure begins with 10 mm ports and cavity inspection, to be followed by the division of the gastrohepatic ligament and the separation of the right esophageal pillar; Subsequently, the phrenoesophageal membrane is sectioned and the gastric vessels are cut. Finally, myotomy of the anterior esophageal wall is performed 6 cm from the IBD. [16]

Taking into consideration that Heller's myotomy has residual gastroesophageal reflux as its main side effect, anterior dor's fundoplication is used, which reduces the incidence of GERD from 48% to 9%. This combination of treatments has managed to guarantee a success rate of 76 to 100% with follow-up up to 36 months. [17]

Post-operative manometría

The effectiveness of surgical treatment can also be objectively assessed by manometry. For example, csentes et al, in a 30-year prospective study with a population of 64 patients, closely followed up with a symptom questionnaire, biopsy, phmetry, and manometry; They reported 15 patients with procedure failure, 1 patient requiring intervention, 14 patients with severe GERD, and the rest of the patients managed with proton pump inhibitors alone. Regarding manometry, all patients with low or no changes in it were reported. [18] Agrusa et al. On the other hand, they conducted a comparative study with 64 patients of which 25 underwent laparoscopic heller myotomy with partial dor fundoplication, using manometry at the time of completion of the procedure to check the elimination of high pressure areas. Similarly, they affirm that the different preoperative manometric patterns can be a marker of the post-procedure result; For the purposes of their study, they mention an ES pressure with a significant reduction in comparison of the values prior to entering the operating room. [19]

Finally, Ortiz et al. They report a prospective study of 149 patients submitted with achalasia undergoing the procedure mentioned above, with clinical follow-up (including manometric) of 6 to 15 years. At 1 year of the intervention, 104 patients were evaluated with manometry, showing a significant decrease, with respect to the preoperative value, of the resting pressure of the lower esophageal sphincter. Although no equally important changes in sphincter pressure were subsequently reported, the authors mention that none of the patients had a "normal" postoperative manometry. [20]

PROBLEM STATEMENT

Magnitude. Achalasia is an esophageal motility disorder that occurs in up to 10 out of every 100,000 people worldwide, is associated with a large number of symptoms; manometry represents the main method of diagnosis and postsurgical clinical follow-up.

Transcendence. Hellller's myotomy associated with fundoplication has been reported as the surgery with the highest reported success rates, however it is not exempt from recurrence and persistence of symptoms, therefore studies are required to establish symptomatic and manometric changes in patients who undergo this procedure in order to establish its effectiveness in symptomatic reduction and manometric changes in patients with achalasia.

Vulnerability. All patients undergoing surgery for the correction of achalasia are at risk of presenting symptoms after their intervention.

Given this evidence and scientific uncertainty, the following research question arises:

What are the manometric and symptomatic changes in patients undergoing heller's myotomy and achalasia fundoplication?.

JUSTIFICATION

The treatment of achalasia due to its etiology represents a challenge for the surgeon, although surgical interventions such as heller myotomy and fundoplication have reported high success rates, symptomatic persistence occurs in up to 30% of cases, this persistence is associated with a decrease in the patient's quality of life, as well as an impact on the perception of perceived quality of medical care.

Heller's myotomy is a widely performed surgery in our institution, so its treatment and success rates represent one of the main concerns for both the attached physician and the doctor in training, studies are required to establish the symptomatic and physiological changes of the different therapeutic alternatives available, to demonstrate that Heller's myotomy is a surgery that significantly reduces symptoms and findings Manometric evidence could be generated for timely treatment with this technique in our population, it is for this reason that the realization of this study is considered relevant not only for the researcher but for the institution itself.

HYPOTHESIS

There are significant symptomatic and manometric changes in patients undergoing heller's myotomy and fundoplication due to achalasia.

OBJECTIVES

General Objective

To determine manometric and symptomatic changes in patients undergoing heller's myotomy and achalasia fundoplication.

Specific Objectives

- To establish the prevalence of achalasia in the general surgery service of our institution.
- To know the sociodemographic and general characteristics of patients with achalasia
- To know the mean score of the Eckardt Achalasia Symptomatology Scale in patients undergoing Heller myotomy and fundoplication
- To know the main presurgical manometric alterations in patients undergoing heller's myotomy
- To determine the prevalence of postsurgical symptoms in patients undergoing heller's myotomy and fundoplication.
- To know the manometric and symptomatic changes in the postoperative month of patients with achalasia undergoing heller's myotomy and fundoplication.
- To establish associations between the sociodemographic characteristics, presurgical and postsurgical findings of patients undergoing these surgical procedures for achalasia.

METHODOLOGY

Study design.

Prospective analytical observational study.

Place of study. The study will be carried out in the Surgery Service of the UMAEe No. 25 of the Mexican Institute of Social Security, cataloged as a third-level unit in addition to being a unit of concentration receiving patients from second-level hospitals in four states of northeastern Mexico (Tamaulipas, Coahuila, Nuevo León, San Luis Potosi).

Population.

The study population will be patients diagnosed with achalasia undergoing heller's myotomy and fundoplication who attend postsurgical follow-up at the surgery service of the UMAE25 of the IMSS, in the city of Monterrey, Nuevo León.

SELECTION CRITERIA

Inclusion Criteria

- Patients diagnosed with achalasia undergoing heller's myotomy and fundoplication who attend a post-surgical control appointment at the surgery service of the IMSS UMAE25 during the study period.
- Patients with any sociodemographic characteristic
- Patients with any degree and symptomatology of achalasia
- Patients with presurgical manometric assessments.
- Patients with and without pre-surgical pneumatic dilation.
- Patients undergoing postsurgical symptomatic and manometric evaluation.
- Patient with and without symptomatic persistence of postoperative achalasia
- Patients who access their voluntary participation by signing the informed consent

Exclusion Criteria

- Patients with a history of previous surgical interventions for the treatment of achalasia.
- Patients undergoing other types of surgical procedures for the management of achalasia.
- Patients with known diagnosis of myasthenia gravis.
- Patients without presurgical esophageal manometric assessments.
- Patients with cognitive impairment that prevents them from answering the pre- and post-surgical symptomatic assessment survey
- Patients who do not access their voluntary participation by signing the informed consent

Removal Criteria

- Patients with incomplete to impossible to collect data
- Patients who incompletely answer the symptomatology survey during pre- and post-surgical
- Patients with surgical complications requiring admission to the intensive care unit
- Patients with surgical complications that require the change of surgical procedure during the transoperative period.
- Patients who decide to eliminate their participation in the study.

Variables and Indicators

The main variables of the research are presented below, the rest of the variables are shown in the operationalization of the variables.

Dependent Variables

Symptomatic Post-Surgical Assessment Scale Score for Achalasia (eckartd)

Conceptual definition: symptomatic classification system which consists of evaluating the symptomatic presence of dysphagia, regurgitation, chest pain and weight loss. So 1 point is awarded to "occasionally", 2 points to "daily" or 3 points to "with each meal" obtaining a maximum of 12 points.
Operational definition: score of the achalasia symptomatology scale.
Measurement scale: discrete quantitative
Unit of measurement: ratio of 0-12 points.

Symptomatic postsurgical classification of achalasia

Conceptual definition: classification of severity of achalasia symptoms according to the score obtained on the eckartd

scale which is classified in 1v degrees being grade i the mildest and grade iv the most severe.
Operational definition: classification in symptomatic grades of achalasia according to eckardt scores grade 1 0-2 points grade ii 2-4 points, grade iii 4-6 points, grade iv more than 6 points.
Measuring scale: qualitative ordinal
Unit of measurement: polytomics i-iv degrees.

Chicago Grometric Postsurgical Classification
Conceptual definition: classification of achalasia according to the degrees of involvement observed during the manometry and registration of the manometric parameters of the lower esophageal sphincter and peristaltic waves.
Operational definition: classification according to manometric findings using the Chicago scale which can be in 4 types: type i aperistalsis and non-esophageal pressurization, type ii aperistalsis with more than 20% esophageal pressurization, type iii spastic contractions and distal integral contractility of more than 450mmhg in more than 20%, type iv obstruction of the eei.
Measuring scale: qualitative ordinal
Unit of measurement: polytomics i-iv types.

Independent variables
Heller's myotomy and fundoplication
Conceptual definition: surgical procedure performed in patients with residual dysphagia after pneumatic dilation, through which muscle fibers of the eEI are cut, which favors their relaxation and gives a permanent solution to the symptoms of achalasia.
Operational definition: refers to the performance of heller's myotomy and fundoplication.
Measuring scale: nominal qualitative
Unit of measurement: dichotomous (0.- no 1.- yes).

Surgical time
Conceptual definition: period of time elapsed from the beginning to the end of the surgical procedure.
Operational definition: surgical time expressed in minutes
Measurement scale: discrete quantitative
Unit of measurement: ratio 0-600 minutes.

Intraoperative findings
Conceptual definition: findings obtained in the direct visualization of esophageal tissue once the surgical procedure has been performed
Operational definition: intraoperative findings associated with achalasia which may be hypertrophy of the EIS, esophageal lesions, esophageal dilation among others.
Measuring scale: nominal qualitative
Unit of measurement: polytomic (0.- none, 1.- esophageal dilation, 2.- esophageal lesions, 3.- hypertrophy of the EIS, among others).

Surgical complications.
Conceptual definition: series of unexpected events that are associated with the unfavorable development of the surgical procedure or postsurgical results.
Operational definition: refers to the type and presence of surgical complications.
Measuring scale: nominal qualitative
Unit of measurement: polytomic (0.- none, 1.- esophageal injury 2.- hemorrhage others).

Time to diagnosis
Conceptual definition: period of time from diagnosis of achalasia to surgery
Operational definition: period of time from diagnosis to surgical treatment expressed in months
Measurement scale: discrete quantitative.
Unit of measurement: ratio 0-200 months

Gender
Conceptual definition set of biological characteristics that define as male or female or some combination of both in consideration of their sex.
Operational definition: patient-referred sex
Measuring scale: nominal qualitative
Unit of measurement: male/female

Age
Conceptual definition: time elapsed since birth; which is measured by the years of life.
Operational definition: patient-reported age; expressed in years.
Measurement scale: discrete quantitative
Unit of measurement: ratio 18-60years.

Weight
Conceptual definition: force exerted by a body on a fulcrum, caused by the action of the local gravitational field on the mass of the body
Operational definition: weight expressed in kilograms.
Measurement scale: continuous quantitative
Unit of measurement: ratio 0-250kg

Size
Conceptual definition: A conventional measure used to indicate the relative size of a person.
Operational definition: height expressed in meters.
Measurement scale: continuous quantitative
Unit of measurement: ratio 0-2m.

Body mass index
Conceptual definition: mathematical reason that associates the mass and size of an individual
Operational definition: body mass index (weight/height$^{\text{ratio }2}$) expressed in kg/m2
Measurement scale: continuous quantitative
Unit of measurement: ratio 0-50kg/m^2.

Nutritional status

Conceptual definition: subjective measurement of a person's nutritional status through the interpretation of body mass index.

Operational definition: category of nutritional status according to the body mass index which can be: i.- malnutrition, ii.- normal weight, iii.- overweight, iv.- obesity i, v.- obesity ii and vi. - Obesity III

Measuring scale: qualitative ordinal

Unit of measurement: i-vi degrees.

Comorbilidades

Operational definition: presence of one or more disorders in addition to the primary disease or disorder.

Conceptual definition: patient-reported comorbidities.

Measuring scale: nominal qualitative

Unit of measurement: polytomic (1.- dm, 2.- hta, 3.- irc, 4.- hypothyroidism, 5.- other)

Operationalization of variables.

The operationalization of both dependent and independent variables was carried outaccording to the table in Annex 3

SAMPLE

Sample technique. Non-probabilistic for convenience and consecutive cases.

Sample size. The formula will be used for the calculation of the minimum sample size required for a study with a finite population based on the number of heller myotomies and fundoplications performed per month in similar periods (10 x month for a period of 6 months of study), hypothesis of a tail, using a confidence level of 95% and margin of error of 5%.

Where:

N= population size, e= margin of error, z= zeta score for 95% which is equal to 1.96, p=0.05.

Development of the formula:

n = (1.96 2 x 0.5(1-0.5) / 0.05)2 / 1+ (1.96 2 x 0.5 (1-0.5) / 0.05^2 x 60)

N = (3.8416x0.5(1-0.5) / 0.0025) / 1 + (3.8416x0.5(1-0.5) / 0.0025 x 60)

N= (0.96 / 0.0025) / 1+ (0.96/0.15)

N = 384 / 7.4

N= 51.89

N = 52 participants

Statistical Analysis

For the analysis plan, a database will be made in Microsoft Office excel data processing program in its 2019 version, once the database is captured, statistical analysis will be performed in the IBM Stata statistical program in its mp14 version.

For the verification of the normality of distribution of the variables will be used the statistical test of kolmogorov-smirnov, the descriptive data will be expressed in means of central tendency such as median mean or mode in the form of proportions or frequencies and measures of dispersion (standard deviation) according to the type of variables, the nominal variables will be expressed in frequency means and proportions by frequency tables.

For the hypothesis test, t student or Mann Whitney's U will be used for the comparison of quantitative variables (symptomatic Eckardt score, EEI pressure, among others) in the presurgical and post-surgical, for the categorical variables of more than 2 groups anova or Fisher's exact test will be used, for the categorical variables of 2 groups chi 2 will be used with odds ratio. All tests will be conducted with a 95% confidence level and 5% margin of error. The results will be expressed in the form of a frequency table and graphically by drawing up box, cake or bar graphs according to the variables.

Ethical Aspects

1.- The researcher guarantees that this study adheres to the legislation and regulations of the General Health Law on Health Research, which provides greater protection to the study subjects.

2.- In accordance with article 22 of the Regulations of the General Health Law on research, informed consent shall be formulated in writing and with the following requirements:

- The responsible investigator undertakes that such consent will be obtained according to the rules that guide the consent process under information in clinical studies, research, or clinical trials with the participation of human beings, and undertakes to obtain two originals of the informed consent letter (ICC) duly completed and signed, ensuring that one of these originals is delivered to the participating subject or his family member or legal representative and that the Second will be safeguarded by himself as responsible investigator, for at least five years after the completion of the research study.
- The researchers undertake to keep the confidentiality of the participants in the study, to guarantee that confidentiality will not collect information that allows personal identification such as name, social security number, among others. In addition, access to information will be encrypted and access will only be provided to research collaborators.
- It shall be prepared by the principal investigator, indicating the information referred to in Article 21 and taking into account the other applicable legal provisions.
- It will be reviewed and, where appropriate, approved by the research ethics committee of the health care institution.
- Indicate the names and addresses of two witnesses and their relationship to the subject of the investigation.
- It must be signed by two witnesses and by the subject of the investigation or his legal representative, as the case may be. If the research subject does not know how to sign, he will print his fingerprint and in his name will sign another person designated by him

- It shall be made out in duplicate, leaving a copy in the possession of the research subject or his legal representative.

3.- The procedures of this study adhere to the ethical standards, the regulations of the General Health Law on Research and will be carried out in full compliance with the following principles of the "Declaration of Helsinki" (and its amendments in Tokyo, Venice, Hong Kong and South Africa) where the researcher guarantees that:

a) A thorough search of the scientific literature on the subject to be carried out was carried out.
b) This protocol will be submitted for evaluation by the local scientific research committee of the Mexican Social Security Institute.
c) This protocol will be performed by scientifically qualified persons and under the supervision of a team of clinically competent and certified physicians in their specialty.
d) This protocol will keep the confidentiality of people. All authors will sign a letter of confidentiality about the protocol and its results in a way that guarantees to minimize the impact of the study on their physical and mental integrity and personality.
e) All patients who meet the inclusion criteria will be invited to participate in the study.
f) This protocol will be suspended if it is proven that the risks outweigh the potential benefits.
g) The publication of the results of this research will preserve the accuracy of the results obtained.
h) Each potential participant will be sufficiently informed of the objectives, methods, benefits and possible risks expected and the inconvenience that the study could entail.
i) Persons who are free not to participate in the study and to revoke their participation at any time will be informed and that written informed consent will be requested, which must be freely accepted by patients.
j) At the time of obtaining informed consent to participate in the research project, the researcher will exercise particular caution if people maintain a relationship of dependency with him or if there is a possibility that they consent under duress. In this case, informed consent will be obtained by a researcher not engaged in the research and completely independent of this official relationship.
k) In this protocol, an informed consent letter authorized by the parents or guardians will be obtained

4.- The principles contained in the Nuremberg Code and the Belmont Report shall be fully respected.

RESULTS

Study participants were 40.38% (n=21) male and 59.61% (n=31) female. They were distributed according to the age groups of 20-29 years, 30-39 years, 40-49 years, 50-59 years, 60-69 years, 70-79 years and 80-89 years in 15.38% (n=8), 8.62% (n=5), 19.23% (n=10), 21.15% (n=11), 28.84% (n=15), 3.84% (n=2) and 1.92% (n=1), respectively. According to their BMI, 5.76% (n=3) were classified as underweight, 46.15% (n=24) normalweight, 44.23% (n=23) overweight and 3.84% (n=2) with type I obesity. In addition, 15.38% (n=8) had alcoholism/smoking, 17.30% (n=9) prediabetes, 19.23% (n=10) hypertension (HTN)/rheumatoid arthritis, while 3.84% (n=2) hypothyroidism; Some patients had 2 or more comorbidities simultaneously and 51.92% (n=27) were completely absent. The average time since diagnosis of achalasia in patients was 28 months with extreme values of 4 and 120. The clinical manifestations present in patients were weight loss in 90.38% (n=47) of cases, dysphagia to solids in 11.58% (n=6), retrosternal pain in 55.76% (n=29), regurgitation in 67.30% (n=35), dysphagia to solids and liquids in 76.92% (n=40) and vomiting in 3.84% (n=2); 2 or more of these came to coexist in some patients.

The surgical techniques used in the study were Heller's myotomy + Dor type fundoplication in 69.23% (n=36) of cases, Heller myotomy + Toupet-type fundoplication in 17.30% (n=9) of cases, Heller's myotomy + Dor type fundoplication + primary stomach closure in 3.84% (n=2) of cases, Heller's myotomy + Guarner fundoplication in 3.84% (n=2) of cases, Heller's myotomy in 1.92% (n=1) of cases, Heller's hiatal plasty/myotomy + Toupet-type fundoplication in 1.92% (n=1) of cases, and Heller's myotomy + LAPE + intestinal resection in 1.92% (n=1) of cases. The mean surgical time was 170.92 minutes with extreme values of 90 and 305. 76.92% (n=40) of the patients had no complications, while 13.46% (n=7) suffered from warned esophageal injury, 5.76% (n=3) from warned stomach injury, 1.92% (n=1) from intestinal perforation and 1.92% (n=1) from aspiration chemical pneumonitis.

The preoperative Eckardt score had a mean of 8.55 and a mode of 9, being 3.84% (n=2) of 3 points, 3.84% (n=2) of 4 points, 1.92% (n=1) of 5 points, 11.53% (n=6) of 6 points, 7.69% (n=4) of 7 points, 13.46% % (n=7) of 8 points, 21.15% (n=11) of 9 points, 15.38% (n=8) of 10 points, 9.61% (n=5) of 11 points and 11.53% (n=6) of 12 points; under these conditions, 7.69% (n=4) of the patients belonged to class II, 13.46% (n=7) to III and 78.84% (n=41) to class IV, the latter being the mode. In contrast, the postoperative period had a mean of 0.98 and a mode of 0, with a score of 0 in 38.46% (n=20) of cases, 1 in 36.53% (n=19) of cases, 2 in 13.46% (n=7) of cases and 3 in 11.53% (n=6) of cases; now, 88.46% (n=46) of patients were class I and 11.53% (n=6) class II.

When calculating the comparison of the different surgical techniques, Ji^2Ji^2=52 is obtained, greater than the critical value 12.59 (taken for the margin of error of 5%), so Heller's myotomy + Dor type fundoplication turned out to be a more effective surgical intervention to reduce the Eckardt score if compared, together, with the rest of the techniques used in this study. On the other hand, although under a similar order of ideas, a Student's t value equal to 22.75 is obtained (greater than the corresponding critical value 1,690 with a margin of error of 5%) when analyzing the pre and postoperative score

with respect to Heller's myotomy + Dor-type fundoplication, so it is concluded that it is effective in reducing the Eckardt score; Likewise, the value of Student's t when comparing the pre- and post-surgical scores when Heller myotomy + Toupet-type fundoplication was performed was 21.99 (higher than its critical value of 2,306 associated with a margin of error of 5%), so it is concluded that it is a useful intervention to reduce the Eckardt score. In the rest of the surgical interventions, 100% of successful cases were observed to reduce the score, except in the case of Heller's myotomy + LAPE + intestinal resection, since the score remained identical.

The resting pressure of the preoperative lower esophageal sphincter (LES) had a mean of 21.70 mmHg with 80.76% (n=42) less than 30 mmHg, while its postsurgical counterpart was 16.18 mmHg with 36.53% (n=19) less than 15 mmHg. When calculating the Ji^2 =8.38, this is a value less than 12.59 (the corresponding critical value for the margin of error of 5%), so it is considered that all interventions are equally effective in reducing the pressure of the LES at rest. Then, when calculating Student's t for the pressures measured before and after Heller's myotomy + Dor type fundoplication, t = 2.65 is found (Ji^2greater than 2,030, the critical value associated with the margin of error of 5%), so it is considered a useful intervention to reduce the resting pressure of the LES; in its analogous case with Heller's myotomy + Toupet type fundoplication it is found that t = 0.81 (less than 2.306, the critical value related to a margin of error of 5%), so it is not considered a useful intervention for the purposes described above. In the cases of Heller's myotomy and Heller's hyatal plasty/myotomy + Toupet-type fundoplication, only one intervention was performed that reduces the pressure of the LES at rest, while in all the rest of the interventions the reduction is not achieved. According to the Chicago preoperative classification, 9.61% (n=5) of patients were considered class I, 88.46% (n=46) class II and 1.92% (n=1) class III. The length of the preoperative LES had an average of 3.29 cm and after surgery it rose to 3.54 cm, with an increase in this variable in 59.61% (n=31) of the cases. Preoperative FVC had a mean of 4.62 cm/s, increasing to 4.73 cm/s after the intervention; 38.46% (n=20) increased after surgery, while 61.53% (n=32) decreased or remained the same. The mean preoperative IRP was 39.29 mmHg and the postoperative 6.15 mmHg was 6.15 mmHg. 100% of the surgical interventions resulted in a reduction of this. The mean presurgical wave amplitude was 44.20 mmHg, after the intervention it increased to 48.45. The increase occurred in 42.30% (n=22) of the cases, on the other hand, 57.69% (n=30) of the cases decreased or remained at the same value after surgery.

DISCUSSION

There is a relationship with age, having its peak incidence between 30 and 60 years, [2] which has been consistent with our study. Likewise, the symptoms reported in the literature were consistent with our study population, where the most prevalent were neuromuscular dysphagia characteristic of liquids and solids, regurgitation, halitosis, weight loss, heartburn and chest pain; [5] Dysphagia, in fact, is considered the primary symptom, present in 90% of patients. [6]

Most have LES pressure <30 mmHg, all with decreased peristalsis or aperistalsis and presurgical IRP mostly <15 mmHg, but not postsurgical with an IRP >15 mmHg.

We rely on the Eckardt classification which suggests asking the patient about the symptoms: dysphagia, regurgitation, chest pain and weight loss. Most of our patients were in the preoperative stage IV, with a high satisfaction rate in the postoperative (I-II).

As for diagnosis, the gold standard, placing the majority of our population in type 2, which coincides with what is reported in the literature worldwide. [11]

The gold standard surgical continues to be Heller's laparoscopic myotomy with partial fundoplication, which showed a substantial remission of the eckardt, especially in the Dor type, although it is not a complicated procedure, where the most common was the esophageal lesion warned. [17]

CONCLUSIONS

Through this protocol we can conclude thatthere are significant symptomatic and manometric changes in patients undergoing heller's myotomy and fundoplication due to achalasia, in the contrast of an adequate presurgical assessment, the technical knowledge to avoid falling into biases of the operator (surgeon), with an adequate technique and follow-up, as well as close monitoring of patients.

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