The Mexican consensus on gastroesophageal reflux disease. Part II

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Abstract
Aims: To update the themes of endoscopic and surgical treatment of Gastroesophageal Reflux Disease (GERD) from the Mexican Consensus published in 2002.
Methods: Part I of the 2011 Consensus dealt with the general concepts, diagnosis, and medical treatment of this disease. Part II covers the topics of the endoscopic and surgical treatment of GERD. In this second part, an expert in endoscopy and an expert in GERD surgery, along with the three general coordinators of the consensus, carried out an extensive bibliographic review using the Embase, Cochrane, and Medline databases. Statements referring to the main aspects of endoscopic and surgical treatment of this disease were elaborated and submitted to specialists for their consideration and vote, utilizing the modified Delphi method. The statements were accepted into the consensus if the level of agreement was 67% or higher.
Results: Twenty-five statements corresponding to the endoscopic and surgical treatment of GERD resulted from the voting process, and they are presented herein as Part II of the consensus. The majority of the statements had an average level of agreement approaching 90%.
Conclusions: Currently, endoscopic treatment of GERD should not be regarded as an option, given that the clinical results at 3 and 5 years have not demonstrated durability or sustained symptom remission. The surgical indications for GERD are well established; only those patients meeting the full criteria should be candidates and their surgery should be performed by experts.

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The components of the Group are listed in Annex.

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Introduction

The aim of the 2011 Mexican Consensus on Gastroesophageal Reflux Disease (GERD) was to update the 2002 Mexican Consensus on GERD, based on new international scientific evidence regarding this disease. For editorial purposes, the consensus was divided into three parts: part I deals with epidemiology, pathophysiology, diagnosis, and medical treatment; part II covers the endoscopic and surgical management of GERD, and part III deals with GERD in the pediatric population. The present article corresponds to part II of the consensus.

Methods

The general coordinators selected six GERD experts as coordinators for each of the tasks (definition and clinical manifestations of GERD in adults, epidemiology and pathophysiology of GERD in adults, GERD diagnosis in adults, medical treatment of GERD in adults, endoscopic and surgical treatment of GERD in adults, and GERD in pediatrics). The coordinators of each task carried out a thorough review of the bibliography, using the Embase, Cochrane, and Medline databases. After the review, each task coordinator elaborated a series of statements that covered the main aspects of the particular assigned topic.

The proposed statements were electronically sent to the coordinators of each of the working groups for a first anonymous vote in which all the members of the 2011 GERD Study Group panel participated. The only options for voting on each statement were «in agreement» or «in disagreement». When there was disagreement, the participants were asked to give a written explanation of why they did not agree with the statement. The results of this first vote were registered, analyzed, and sent to each of the coordinators, together with the comments given by the participants. When agreement with a statement was ≥75%, it was left unchanged to go on to the next voting round. When disagreement with a statement was ≥75%, it was eliminated from the Consensus. When statements obtained less than 75% agreement or disagreement, the coordinator of each working group was asked to rewrite the statement, taking into account the comments made by the participants, and to send the bibliography that supported the proposed statement. This bibliography was distributed to all the participants.

The second anonymous electronic vote included the statements that had more than 75% agreement in the first vote and those that had been rewritten as a result of the comments made in the first voting process. The methodology of this second vote was exactly the same as the one used in the first.

Once the feedback from the second anonymous voting process was received, the coordinators elaborated a final document for each task in which every statement was individually upheld by bibliographic support. The document was then presented to the entire working group for a final face-to-face vote, maintaining anonymity by using electronic voting systems. For this final phase, the gastroenterologists specializing in adults voted on the statements corresponding to tasks one through 5. In this final voting process, the votes were cast according to the following 6-point scale: A- in complete agreement; B- in agreement, but with minor
The Mexican consensus on gastroesophageal reflux disease. Part II

concerns; C- in agreement, but with major concerns; D- in disagreement, but with major concerns; E- in disagreement, but with minor concerns; or F- in complete disagreement. Consensus was declared when 67% or more of the participants concurred on a category of agreement (A, B, or C).

The elaboration of the Mexican Consensus on Gastroesophageal Reflux Disease was funded by Laboratorio Astra-Zeneca and had the academic backing of the Asociación Mexicana de Gastroenterología.

Results

In the final vote, a total of 92 statements concerning adults were discussed, 85 of which (92.4%) were accepted completely or with major or minor concerns. The percentages for each statement are specified throughout the article. Part II presents the statements that refer to the endoscopic and surgical management of GERD.

V. The endoscopic and surgical treatment of gastroesophageal reflux disease

68. Currently, the endoscopic treatment for GERD should not be contemplated as an option due to the fact that the long-term results (3 to 5 years) have not shown durability or symptom remission

Level of agreement: A (in complete agreement) 100%.

69. In GERD complications, especially in Barrett’s esophagus with high grade dysplasia (HGD), first-line endoscopic treatment is: endoscopic mucosal resection and radiofrequency ablation, which should be performed only in referral centers and by highly qualified endoscopists

Level of agreement: A (in complete agreement) 100%.

70. Objective documentation of GERD is essential before considering surgery

Level of agreement: A (in complete agreement) 100%.

Before contemplating surgery it is indispensable to have objective documentation of GERD. This is obtained through endoscopy that shows the damage to the mucosa presenting as esophagitis, stricture, or Barrett’s esophagus. In the absence of endoscopic evidence, 24-hr pH-metry is the study of choice.

71. All patients that are surgical candidates should undergo preoperative endoscopy

Level of agreement: A (in complete agreement) 100%.

Endoscopy is the study every patient that is a candidate for antireflux surgery should have. This study also aids in making the diagnosis and enables the identification of other alterations.

72. pH-metry is indicated in patients evaluated for surgery that have no endoscopic evidence of damage to the mucosa

Level of agreement: A (in complete agreement) 100%.

pH-metry is essential in patients in whom GERD diagnosis cannot be established through endoscopy.

73. An esophagram is occasionally indicated as a preoperative study in order to have improved anatomic definition, especially in patients with hiatal hernia and short esophagus

Level of agreement: A (in complete agreement) 90%; B (in agreement but with minor concerns) 10%.

The barium esophagram is useful for having a more accurately defined anatomy, particularly in patients presenting with large hiatal hernias or short esophagus.

74. Preoperative manometry is useful for ruling out a motor disorder of the esophagus that contraindicates surgery (for example, achalasia). Its inclusion in the preoperative evaluation is recommended, but there is no conclusive evidence that it needs to be carried out in all patients, and its application can be individualized

Level of agreement: A (in complete agreement) 75%; B (in agreement but with minor concerns) 25%; C (in agreement but with major concerns) 5%.

Many experts recommend ordering esophageal manometry in all patients that are candidates for antireflux surgery. However, there is no conclusive evidence in the literature supporting this as a measure for all patients.

75. Surgical treatment can be considered in patients with an objective diagnosis of GERD and some of the following:

- Patients that choose surgical treatment even though they have a good response to medical management (due to quality of life, prolonged use of medication, etc.)
- Young patients or those with a life expectancy greater than 10 years
- Patients with uncontrolled regurgitation with acid suppression
- Patients with symptoms associated with non-acid reflux
- Patients with a large hiatal hernia (>5 cm)
- Patients with aspiration pneumonia

Level of agreement: A (in complete agreement) 45%; B (in agreement but with minor concerns) 40%; C (in agreement but with major concerns) 15%.

In addition to the conditions mentioned, other indications for surgical treatment can include patients that have extravesophageal manifestations of GERD (asthma, snoring, cough, chest pain). In this regard, it is recommended to
consider statements 87 and 88 of this consensus that are presented further ahead.

GERD-associated complications such as stricture are also indications for anti-reflux surgery.\textsuperscript{10} In the case of Barrett’s esophagus, surgical indication is clear when the patient has associated symptoms such as heartburn and regurgitation.\textsuperscript{11} When the patient is completely asymptomatic, the indication is more controversial. Up to the present, surgery has not been shown to diminish the long-term risk for cancer.\textsuperscript{12,13}

76. Surgery should be offered to adequately selected patients

\textit{Level of agreement: A (in complete agreement) 95%; B (in agreement but with minor concerns) 5%}.

Adequately selected patients should be regarded as those that meet the criteria listed in statement 75 of this consensus.

77. Surgery is associated with good quality of life. For this to hold true, surgery should be performed with minimal morbidity and in adequately selected patients

\textit{Level of agreement: A (in complete agreement) 65%; B (in agreement but with minor concerns) 15%; C (in agreement but with major concerns) 10%, D (in disagreement but with major concerns) 5%; F (in total disagreement) 5%}.

Antireflux surgery has demonstrated an improvement in quality of life similar to or greater than that of patients that receive medical treatment.\textsuperscript{14-18} In a recent Cochrane systematic review it was concluded that the short-term and mid-term quality of life is superior to that produced with medical treatment.\textsuperscript{19}

78. A standardized surgical technique has better results

\textit{Level of agreement: A (in complete agreement) 80%; B (in agreement but with minor concerns) 10%; D (in disagreement but with major concerns) 5%; F (in total disagreement) 5%}.

Surgical technique standardization is advisable because it has been shown to have good results.\textsuperscript{20}

79. Surgery performed in high-volume centers with adequate selection and surgical technique has better results

\textit{Level of agreement: A (in complete agreement) 100%}.

The learning curve for antireflux surgery has been well documented and shows that there are fewer complications when there is greater experience.\textsuperscript{21-23}

80. Laparoscopic surgery is the option of choice and should be preferred over open surgery due to its better early progression (shorter hospital stay, earlier return to daily activities, and fewer complications) and the same long-term results

\textit{Level of agreement: A (in complete agreement) 95%; B (in agreement but with minor concerns) 5%}.

Numerous studies show that there are significantly fewer complications after laparoscopic surgery compared with open surgery and the long-term results are similar.\textsuperscript{24-42}

81. Both total fundoplication and posterior partial fundoplication are effective in controlling reflux

\textit{Level of agreement: A (in complete agreement) 80%; B (in agreement but with minor concerns) 15%; C (in agreement but with major concerns) 5%}.

Many studies have evaluated the differences between total and partial fundoplication. Significant differences have not been shown with respect to the incidence of esophagitis, pyrosis, persistent acid reflux, or the Visick score. There is significantly more dysphagia, bloating, flatulence, and reoperation rate after total fundoplication compared with the partial procedure.\textsuperscript{3,25,40-57} On the other hand, no difference in the progression of patients with esophageal dysmotility has been demonstrated in relation to the type of fundoplication.\textsuperscript{57,58}

82. Robotic-assisted surgery is safe and effective and has a similar short-term progression, but a higher cost, in the countries and centers in which this technology is available

\textit{Level of agreement: A (in complete agreement) 90%; B (in agreement but with minor concerns) 10%}.

The use of robotic-assisted surgery in antireflux surgery has been shown to have similar results.\textsuperscript{59-64} However, the cost is higher and surgery duration is longer with robotic surgery.\textsuperscript{59,63,64}

83. There is a higher incidence of failure in antireflux surgery in patients with morbid obesity (a BMI > 35 accompanied with comorbidities or a BMI > 40 with or without them) and gastric bypass is a better antireflux surgery in these patients because it also improves other diseases

\textit{Level of agreement: A (in complete agreement) 80%; B (in agreement but with minor concerns) 20%}.

There are studies showing that antireflux surgery is less effective in patients with obesity compared with normal weight individuals.\textsuperscript{65-68} However, other studies have shown no differences between obese and non-obese patients. Laparoscopic gastric bypass is an extremely effective surgery for resolving reflux. It also resolves numerous comorbidities in patients with morbid obesity and therefore is recommended as an antireflux procedure in these patients.\textsuperscript{69-76}
84. Age has not been demonstrated to significantly affect the results of antireflux surgery in well selected patients that have adequate surgical risk

Level of agreement: A (in complete agreement) 60%; B (in agreement but with minor concerns) 20%; C (in agreement but with major concerns) 10%; D (in disagreement but with major concerns) 5%; F (in total disagreement) 5%.

Age has not been shown to affect the results of antireflux surgery.77

85. Patients with hiatal hernia > 3 cm have a greater incidence of anatomic failure

Level of agreement: A (in complete agreement) 65%; B (in agreement but with minor concerns) 30%; D (in disagreement but with major concerns) 5%.

Surgery in patients with atypical symptoms such as chest pain, chronic cough, snoring, otitis media, recurrent pneumonia, and chronic bronchitis tends to be less effective than in patients with typical symptoms.78,79

86. The patients with extraesophageal symptoms have a poorer response to surgery compared with those that have typical symptoms

Level of agreement: A (in complete agreement) 80%; B (in agreement but with minor concerns) 20%.

Surgery in patients with atypical symptoms such as chest pain, chronic cough, snoring, otitis media, recurrent pneumonia, and chronic bronchitis tends to be less effective than in patients with typical symptoms.78,79

87. The patients presenting with extraesophageal symptoms that have a better response to surgical treatment are those whose symptoms are correlated with episodes of reflux detected through pH-metry or intraluminal impedance.

Surgery should not be considered in patients with no symptom correlation in these studies

Level of agreement: A (in complete agreement) 95%; B (in agreement but with minor concerns) 5%.

The correlation of symptoms with reflux episodes detected through pH-metry or intraluminal impedance is a predictor of a better response in patients with atypical symptoms.80,81

88. Good response to preoperative medical treatment is a predictor of good response to surgery. Surgery should not be considered in patients that do not have at least a partial response to a PPI

Level of agreement: A (in complete agreement) 95%; B (in agreement but with minor concerns) 5%.

Symptom response to a proton pump inhibitor (PPI) is a predictor of good response to antireflux surgery. However, good results have also been demonstrated in patients with GERD without such response or with a partial response.82

89. Surgical reintervention is safe and effective when performed by surgeons with experience in reoperation in high volume centers, but it is associated with a longer surgery duration and a higher complication rate than the primary procedure

Level of agreement: A (in complete agreement) 85%; B (in agreement but with minor concerns) 10%; D (in disagreement but with major concerns) 5%.

Compared with the primary procedure, revision surgery requires longer surgery duration, there is a higher percentage of conversion, and it has more complications.83-87 Nevertheless, patient satisfaction has reached 89% with an elevated percentage of symptom resolution.87-90

90. Antireflux surgery has been proved to be a safe and effective option for the treatment of GERD

Level of agreement: A (in complete agreement) 90%; C (in agreement but with major concerns) 10%.

Numerous controlled and randomized studies have shown the effectiveness of antireflux surgery in patients with complete PPI response, as well as in patients with partial response.14-17,91-93 When manometry and pH-metry studies are carried out, surgery results in significantly less exposure to acid and greater inferior esophageal sphincter pressure compared with medical treatment.14,15,18,94,95 In order for surgery to compete with medical treatment, it must have a minimum of morbidity and cost.

91. Antireflux surgery does not eliminate the need for future surveillance in patients with Barrett’s esophagus

Level of agreement: A (in complete agreement) 100%.

Surgery does not change the surveillance recommendations for patients with Barrett’s esophagus and it is not the only therapeutic option for these patients.

92. Antireflux surgery has not been shown to reduce the long-term risk for cancer in patients with Barrett’s esophagus

Level of agreement: A (in complete agreement) 100%.

There is no evidence showing that antireflux surgery reduces the long-term risk for cancer.101

Conclusions

Presently, endoscopic treatment of GERD should not be regarded as an option due to the fact that long-term results (3 to 5 years) have not shown durability or sustained symptom remission. The indications for surgical treatment are well established; this therapeutic option should be offered to those patients that are good candidates and the surgery should be performed by experts.
Conflict of interest

Alejandra Noble Lugo: speaker for Takeda, AstraZeneca, Alfa Wasserman and Menarini; Angélica Hernández Guerrero: speaker for AstraZeneca and Glaxo-SmithKlein; Antonio Ramos de la Medina: Waterman and Janssen; Francisco Huerta Iga: advisor for Takeda, speaker for Takeda, AstraZeneca, Menarini and Glaxo-SmithKlein; José Luis Tamayo de la Cuesta: advisor and speaker for Takeda, AstraZeneca, Alfa Wasserman, and Janssen; speaker for Menarini; José María Remes Troche: advisor for Takeda, Alfa Wasserman and Janssen, speaker for Takeda, AstraZeneca, and Bristol, researcher for Sanofi-Pasteur; Miguel Ángel Valdovinos Díaz: advisor for Takeda, speaker for Takeda, Given, Mayoly Spindler, Ferrer, and Menarini, researcher for Takeda and Ferrer; Ramón Carmona Sánchez: advisor for Takeda and Alfa-Wasseran, speaker for AstraZeneca. The physicians Gonzalo Torres Villalobos and Juan Pablo Pantoja Millan declare that they have no conflict of interest.

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Appendix. The 2012 Mexican Consensus on GERD Group

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References

The Mexican consensus on gastroesophageal reflux disease. Part II

237


