Brazilian Journal of Videoendoscopic Surgery

Original Article

Evaluation of Health-Related Quality of Life (HRQL) in Patients with Gastroesophageal Reflux Disease (GERD) Before and After Nissen Fundoplication Surgery

Avaliação da Qualidade de Vida no Pré e Pós-Operatório dos Pacientes com Doença do Refluxo Gastroesofágico (GERD) Submetidos à Cirurgia de Fundoplicatura à Nissen

GUILHERME DE CASTRO SANTOS[1]; PEDRO RIBEIRO DA MOTA[1]; DREYFUS SILVA FABRINI[2]; BRUNO VARGAS ANICETO[3]; FÁBIO LOPES QUEIROZ[4]; EUDES ARANTES MAGALHÃES[5]

[1.] Resident, General Surgery Clinic, IPSEMG/HGIP; [2.] Resident, Plastic Surgery Clinic of the FHEMIG Network; [3.] Staff Surgeon, General Surgery Clinic, IPSEMG/HGIP; [4.] Coordinator, General Surgery Residency, HGIP/IPSEMG; [5.] Coordinator, General Surgery Clinic, HGIP/IPSEMG.

ABSTRACT

Objectives: Evaluate quality-of-life in patients with Gastroesophageal Reflux Disease (GERD) before and after Nissen fundoplication surgery. **Materials and Methods**: Eighteen patients with GERD refractory to medical management underwent Nissen fundoplication surgery between June 2006 and December 2007. All surgeries began laparoscopically. The Gastroesophageal Reflux Disease – Health-Related Quality of Life (GERD-HRQL) questionnaire was the instrument used to evaluate quality-of-life. The questionnaire was administered under the supervision of the same interviewer at the time of hospitalization and 90 days after surgery, during outpatient follow-up or by telephone. **Results**: For all the questions in the questionnaire – except those related to dysphagia – there was a statistically significant ($p<0.05$) reduction in the post-operative averages in relation to the preoperative averages. Averages of the sum of the 10 questions were 27.1 ($\pm$6.61) pre-operatively and 6.61 ($\pm$2.27) post operatively. The difference between the means was statistically significant ($p<0.05$), consistent with an improvement in symptomatology after surgical treatment. **Conclusions**: Laparoscopic or open Nissen fundoplication surgery, in addition to correcting the pathophysiologic defects of GERD, demonstrated its ability to provide patients with this disease with a significant improvement in symptomatology and quality-of-life.

Key words: Fundoplication. Gastroesophageal reflux. Quality of life. Hiatal hernia.

Bras. J. Video-Sur, 2010, v. 3, n. 1: 024-029

Accepted after revision: October, 21, 2009.

INTRODUCTION

Gastroesophageal Reflux Disease (GERD) affects 40% of the adult population,[1, 2] and is frequently responsible for high rates of morbidity and for considerable impact of the quality of life of the patient. This impact, in some circumstances, is greater than that caused by diseases such as diabetes mellitus, arterial hypertension, acute myocardial infarct and arthritis.[2-4] The treatment of this condition includes lifestyle and diet modification, pharmacotherapy – today considered the first line of treatment – and surgery.[5]

In the past, anti-reflux surgery was performed primarily to treat complications of GERD, such as hemorrhages and stenoses.[1] With the advent of fundoplication via videolaparoscopy in 1991,[5-7] however, surgical treatment has been indicated with increasing frequency. Objective endoscopic, manometric, and pH criteria suggest that laparoscopic fundoplication is capable of restoring the physiologic anti-reflux barrier and, thereby, control of chronic gastroesophageal reflux in 95% of casos,[8] with low rates of morbidity and mortality.[5, 9, 10] It has been observed that these objective parameters don't always correlate with patient satisfaction or with an improvement in the quality of life and symptomatology. For this reason, the evaluation of quality of life provides information that complement the traditional objective criteria,[2, 11, 12] and thus in recent years has been considered an important factor in the strategies for the treatment of the disease.

The objective of the study is to evaluate the impact of Nissen fundoplication surgery, via open or videolaparoscopic technique, on the quality of life of patients with Gastroesophageal Reflux Disease refractory to medical management.

METHODS

Patients

Eighteen patients of both sexes with gastroesophageal reflux disease (GERD) refractory to clinical treatment and who underwent Nissen fundoplication surgery between June 2006 and December 2007 were enrolled. The study was approved by the Institutional Ethics Committee. All subjects were 18 or older and agreed to participate in all steps of the study.

Surgery

The procedure was performed by the General Surgery service of the institution. All surgeries were initiated laparoscopically.

Data

Research data were obtained by medical record abstraction and by interview. Quality of life was assessed using the Gastroesophageal Reflux Disease – Health Related Quality of Life (GERD-HRQL) questionnaire.[13,14] Developed by Velanovich and cols., the GERD-HRQL consists of 10 questions that specifically address GERD symptoms – each scored on a 0 to 5 scale – and an additional question which evaluates the patient's satisfaction with his or her current condition (Table 1). The best possible aggregate score is 0 (absence of symptoms), and the worst is 50 (very severe symptoms).[15] The questionnaire was administered by the same interviewer upon admission to the hospital and 90 days after the surgery, during an outpatient visit or by telephone.

Statistical Analysis

The data was analyzed using the EPI-INFO statistical program. Values with a $p < 0.05$ were considered statistically significant.

Table 1 - *The GERD-HRQL questionnaire.*

Scale
0. No symptoms
1. Symptoms noticeable, but not bothersome
2. Symptoms noticeable and bothersome, but not every day
3. Symptoms bothersome everyday
4. Symptoms affect daily activities
5. Symptoms are incapacitating- unable to do daily activities
Questions
1. How bad is your heartburn?
2. Heartburn when lying down?
3. Heartburn when standing up?
4. Heartburn after meals?
5. Does heartburn change your diet?
6. Does heartburn wake you from sleep?
7. Do you have difficulty swallowing?
8. Do you have pain with swallowing?
9. Do you have gassy or bloating feelings?
10. If you take medication, does it affect your daily life?
How satisfied are you with your present condition?
❑ Satisfied ❑ Neutral ❑ Dissatisfied

RESULTS

Eighteen patients participated in the study: fifteen (83.3%) women and three (16.6%) men. The average age was 58.2 years (20-74 years). All patients had a history of episodes of heartburn prior to the surgery, and 15 (83.3%) reported intermittent or persistent reflux for average period of 6.3 years (1 – 20 years). Only one (5.5%) patient reported dysphagia. With regard to atypical symptoms, 4 (22.5%) patients reported chronic cough and 2 reported hoarseness (11%). Endoscopic and radiologic findings were as follows: 15 patients (83.5%) had sliding hiatal hernia, with a average size of 5.0 cm (2 – 15 cm). One patient, who had undergone videolaparoscopic fundoplication surgery five years earlier, was found on endoscopic exam to have a voluminous post-operative hernia. Nine patients (50%) had esophagitis, which was rated according to the Savary-Miller classification as follows: 4 grade I, 4 grade II e 1 grade III. Lesions suggestive of Barrett's esophagitis were observed in three patients, all subsequently confirmed by anatomic pathology examination.

All patients underwent Nissen fundoplication surgery. All surgeries were initiated laparoscopically, but in four patients (22.5%) conversion was necessary because of technical difficulties during the procedure. A 360° valve was fashioned in all patients, with an average size of 2.5 cm (2-4). Average surgical time was 152 minutes (90-240).

With the exception of questions 7 and 8, which relate to symptoms of dysphagia, for all of the questions of the GERD-HRQL questionnaire, there was a statistically significant ($p<0.05$) reduction in the mean post-operative measures in relation to the pre-operative mean. The average of the sum of the ten questions was 27.1 ($\pm$6.61) pre-operatively and 6.61 ($\pm$2.27) post-operatively. The difference between the means was statistically significant ($p<0.05$), reflecting an improvement in symptomatology of the patients after surgical treatment. All were dissatisfied with their condition in the pre-operative period. In the post-operative period, all reported that they were satisfied with the results.

DISCUSSION

Gastroesophageal Reflux Disease is considered an important public health problem. The vast majority of patients have periodic mild symptoms. In a small proportion, the gastroesophageal reflux causes intense symptoms and may evolve to complications such as severe esophagitis, esophageal stenosis, Barrett's metaplasia, and adenocarcinoma of the esophagus.[16, 17] Dent and cols.[18, 19] state that "reflux disease may be present when heartburn occurs two or more days per week, based on the negative impact the frequency of this symptom has on health-related well-being". In recent years, various studies have demonstrated that with GERD, both clinical and surgical treatments are capable of significantly improving patients' symptomatology and quality of life.[18,20-24] Nevertheless, some studies have shown that patients who have undergone laparoscopic fundoplication have better symptom control, and are more satisfied and have better global improvement of measures of quality of life as compared with those treated with nonsurgical methods.[15]

The GERD-HRQL questionnaire used in this study demonstrated its ability to evaluate satisfactorily the results obtained with surgical treatment. The outcome measures traditionally used to assess the prognosis of a surgical treatment are morbidity and mortality rates, length of hospital stay, complications and resolution of symptoms.[25] A successful operation, therefore, should eliminate typical symptoms and minimize the short and long-term post-operative complications, and have biochemical, physiological, and clinical parameters that are reproducible. For the patients, however, these results rarely are important. Their priorities are a perception of health and well-being.[26] In recognition of these differences, the need for an evaluation of quality of life has been mentioned in the various consensus documents.[8,27,28] Velanovich[13] compared one instrument specific for GERD developed by him (the GERD-HRQL) to a generic scale that evaluates quality of life (the SF 36), and found that only the GERD-HRQL was able to predict the patient's satisfaction with the outcome of the fundoplication.[1] It is suggested, therefore, that this questionnaire is more responsive to the effects of treatment and more sensitive to changes in symptoms.[13, 29]

Significant improvement of quality of life is observed in patients after fundoplication surgery. Various authors corroborate this result, with success rates exceeding 80%.[1, 2, 8, 17, 25, 26, 30] Kamolz and cols. argue that the improvement in symptoms related to GERD is the principal expectation of patients who undergo surgical treatment.[18] Still, some of patients remain oligosymptomatic. Several studies have shown that symptoms related to stress in patients with GERD,

various comorbidities such as psychiatric disorders, dyspepsia, or aerophagia, can affect the results of the surgery even when the physiologic correction is successful.[2, 18, 31-34] All these studies show that the relief of GERD and improvement in quality of life are more complex than simply the rectification of the underlying pathophysiology of the disease.[35] Contini and cols.[25] further argue that "pre-operative functional dyspepsia, which is not affected by fundoplication[2], or inadequately rigorous selection of the patients – whose symptoms may be unmasked by the surgery – contribute to suboptimal results". In this context, Slim and cols.[2] affirm that dyspeptic symptoms are considered one of the contra-indications for anti-reflux surgery in the absence of documented GERD.

Among all the issues, the greatest impact of the surgery was observed in relation to the use of medications for the control of symptoms of the disease. Nevertheless, according to Madan and cols.[36], despite high levels of satisfaction with the results of surgical treatment, 80% of patients continue to or return to using proton pump inhibitors over the medium to long term. Additional studies, conducted for longer periods, will be necessary in order to verify this assertion.

In contrast with the typical symptoms, no improvement in dysphagia was observed after surgical treatment. Pre-operative dysphagia is present in up to 20% dos patients who undergo surgery for GERD, and it is believed that dysphagia is related to the presence of hypersensitivity to acid, hiatal hernia, and altered peristalsis.[6, 37-39] Moreover, this symptom is common in the early postoperative period, and appears to be slightly more frequent in total as compared with partial fundoplication.[37] Still, approximately 80% of the patients recover the ability to eat normally after the second week. Overall, in a study carried out by Fumagalli and cols.,[37] only 3.3% of patients required treatment for this condition, and two-thirds of these were successfully treated with endoscopic dilatation.

A high prevalence of hiatal hernia (83.5%) was observed in our study sample. The role of hiatal hernia in GERD is still controversial. Still, the weight of current epidemiologic and physiologic data supports its importance in patients with more severe presentations of esophagitis, peptic stenosis, or Barrett's esophagus.[40] Moreover, Fass and cols.[41] affirm that the absence de hiatal hernia, as well as female gender and younger age, are associated with non-erosive reflux disease and, therefore, milder forms of the disease. Accordingly, the high prevalence of this condition in the sample may explain, in part, the refractoriness of symptoms to medical management, which is one of the inclusion criteria for patients entering this study.

CONCLUSION

Open or laparoscopic Nissen fundoplication surgery, in addition to correcting the pathophysiologic defects of GERD, has demonstrated it ability to provide patients who suffer from the disease a significant improvement in symptomatology and in quality of life. It can, therefore, be performed safely and with results that are acceptable to those patients refractory to medical management and in those unsatisfied with their present condition.

RESUMO

***Objetivos**: Avaliar a qualidade de vida de pacientes portadores de Doença do Refluxo Gastro-Esofágico (GERD) antes e após a fundoplicatura à Nissen. **Materiais e Metodos**: Participaram do estudo 18 pacientes portadores de GERD refratários ao tratamento clínico e que foram submetidos à cirurgia de fundoplicatura à Nissen entre junho de 2006 e dezembro de 2007. Todas as cirrgias foram iniciadas por via laparoscópica. Utilizou-se como instrumento de avaliação da qualidade de vida o questionário GERD-HRQL (Gastroesophageal Reflux Disease – Health Related Quality of Life). O questionário foi aplicado aos pacientes sob supervisão do mesmo avaliador no momento da admissão hospitalar e 90 dias após a cirurgia, durante retorno ambulatorial ou através de telefone. **Resultados**: Em relação ao questionário, observou-se em todas as questões uma redução estatisticamente significativa ($p<0,05$) nas médias pós-operatórias em relação às pré-operatórias, com exceção das questões que se referem a symptoms disfágicos. As médias da soma de todas as questões no pré e no pós-operatório foram, respectivamente, 27,1 ($\pm$6,61) e 6,61 ($\pm$2,27). A diferença entre as mesmas apresentou significância estatística ($p<0,05$), traduzindo melhora nos sintomas dos pacientes após o tratamento cirúrgico. **Conclusões**: A cirurgia de fundoplicatura a Nissen, aberta ou laparoscópica, além de corrigir os defeitos fisiopatológicos da GERD, provou-se capaz de proporcionar aos pacientes portadores da doença uma melhora significativa na sintomatologia e na qualidade de vida.*

***Descritores**: Fundoplicatura. Refluxo Gastroesofágico. Qualidade de Vida. Hérnia Hiatal.*

REFERENCES

1. Rattner DW. Measuring improved quality of life after laparoscopic Nissen fundoplication. Surgery 2000; 127(3):258-263.
2. Slim K, Bousquet J, Kwiatkowski F, Lescure G, Pezet D, Chipponi J. Quality of life before and after laparoscopic fundoplication. Am J Surg 2000; 180(1):41-45.
3. Revicki DA, Wood M, Maton PN, Sorensen S. The impact of gastroesophageal reflux disease on health-related quality of life. Am J Med 1998; 104(3):252-258.
4. Stewart AL, Greenfield S, Hays RD et al. Functional status and well-being of patients with chronic conditions. Results from the Medical Outcomes Study. JAMA 1989; 262(7):907-913.
5. Wang W, Huang MT, Wei PL, Lee WJ. Laparoscopic antireflux surgery for the elderly: A surgical and quality-of-life study. Surg Today 2008; 38(4):305-310.
6. Dallemagne B, Weerts J, Markiewicz S et al. Clinical results of laparoscopic fundoplication at ten years after surgery. Surg Endosc 2006; 20(1):159-165.
7. Geagea T. Laparoscopic Nissen's fundoplication: preliminary report on ten cases. Surg Endosc 1991; 5(4):170-173.
8. Granderath FA, Kamolz T, Schweiger UM, Pointner R. Quality of life, surgical outcome, and patient satisfaction three years after laparoscopic Nissen fundoplication. World J Surg 2002; 26(10):1234-1238.
9. Terry M, Smith CD, Branum GD, Galloway K, Waring JP, Hunter JG. Outcomes of laparoscopic fundoplication for gastroesophageal reflux disease and paraesophageal hernia. Surg Endosc 2001; 15(7):691-699.
10. Hunter JG, Trus TL, Branum GD, Waring JP, Wood WC. A physiologic approach to laparoscopic fundoplication for gastroesophageal reflux disease. Ann Surg 1996; 223(6):673-685.
11. Granderath FA, Kamolz T, Schweiger UM, Pasiut M, Wykypiel H, Jr., Pointner R. Quality of life and symptomatic outcome three to five years after laparoscopic Toupet fundoplication in gastroesophageal reflux disease patients with impaired esophageal motility. Am J Surg 2002; 183(2):110-116.
12. Kamolz T. Quality of life for patients with gastroesophageal reflux disease. Surg Endosc 2003; 17(4):664.
13. Velanovich V, Vallance SR, Gusz JR, Tapia FV, Harkabus MA. Quality of life scale for gastroesophageal reflux disease. J Am Coll Surg 1996; 183(3):217-224.
14. Velanovich V. Using quality-of-life measurements to predict patient satisfaction outcomes for antireflux surgery. Arch Surg 2004; 139(6):621-625.
15. Fernando HC, Schauer PR, Rosenblatt M et al. Quality of life after antireflux surgery compared with nonoperative management for severe gastroesophageal reflux disease. J Am Coll Surg 2002; 194(1):23-27.
16. Stein HJ, Barlow AP, DeMeester TR, Hinder RA. Complications of gastroesophageal reflux disease. Role of the lower esophageal sphincter, esophageal acid and acid/alkaline exposure, and duodenogastric reflux. Ann Surg 1992; 216(1):35-43.
17. Antoniou SA, Delivorias P, Antoniou GA et al. Symptom-focused results after laparoscopic fundoplication for refractory gastroesophageal reflux disease-a prospective study. Langenbecks Arch Surg 2008.
18. Kamolz T, Granderath F, Pointner R. Laparoscopic antireflux surgery: disease-related quality of life assessment before and after surgery in GERD patients with and without Barrett's esophagus. Surg Endosc 2003; 17(6):880-885.
19. Dent J, Brun J, Fendrick AM, Fennerty MB, Janssens J, Kahrilas PJ. An evidence-based appraisal of reflux disease management - the Genval Workshop Report. Gut 1999; 44(Sl-16).
20. Kamolz T, Granderath PA, Bammer T et al. Mid- and long-term quality of life assessments after laparoscopic fundoplication and refundoplication: a single unit review of more than 500 antireflux procedures. Dig Liver Dis 2002; 34(7):470-476.
21. Lundell L, Miettinen P, Myrvold HE et al. Continued (5-year) followup of a randomized clinical study comparing antireflux surgery and omeprazole in gastroesophageal reflux disease. J Am Coll Surg 2001; 192(2):172-179.
22. Bammer T, Hinder RA, Klaus A, Klingler PJ. Five- to eight-year outcome of the first laparoscopic Nissen fundoplications. J Gastrointest Surg 2001; 5(1):42-48.
23. Spechler SJ, Lee E, Ahnen D et al. Long-term outcome of medical and surgical therapies for gastroesophageal reflux disease: follow-up of a randomized controlled trial. JAMA 2001; 285(18):2331-2338.
24. Wiklund I, Bardhan KD, Muller-Lissner S et al. Quality of life during acute and intermittent treatment of gastro-oesophageal reflux disease with omeprazole compared with ranitidine. Results from a multicentre clinical trial. The European Study Group. Ital J Gastroenterol Hepatol 1998; 30(1):19-27.
25. Contini S, Bertele A, Nervi G, Zinicola R, Scarpignato C. Quality of life for patients with gastroesophageal reflux disease 2 years after laparoscopic fundoplication. Evaluation of the results obtained during the initial experience. Surg Endosc 2002; 16(11):1555-1560.
26. Balci D, Turkcapar AG. Assessment of quality of life after laparoscopic Nissen fundoplication in patients with gastroesophageal reflux disease. World J Surg 2007; 31(1):116-121.
27. Fuchs KH, Feussner H, Bonavina L, Collard JM, Coosemans W. Current status and trends in laparoscopic antireflux surgery: results of a consensus meeting. The European Study Group for Antireflux Surgery (ESGARS). Endoscopy 1997; 29(4):298-308.

28. Archer SB, Sims MM, Giklich R et al. Outcomes assessment and minimally invasive surgery: historical perspective and future directions. Surg Endosc 2000; 14(10):883-890.
29. Velanovich V. Comparison of generic (SF-36) vs. disease-specific (GERD-HRQL) quality-of-life scales for gastroesophageal reflux disease. J Gastrointest Surg 1998; 2(2):141-145.
30. Mobius C, Stein HJ, Feith M, Feussner H, Siewert JR. Quality of life before and after laparoscopic Nissen fundoplication. Surg Endosc 2001; 15(4):353-356.
31. Kamolz T, Bammer T, Granderath FA, Pointner R. Comorbidity of aerophagia in GERD patients: outcome of laparoscopic antireflux surgery. Scand J Gastroenterol 2002; 37(2):138-143.
32. Kamolz T, Granderath FA, Pointner R. Does major depression in patients with gastroesophageal reflux disease affect the outcome of laparoscopic antireflux surgery? Surg Endosc 2003; 17(1):55-60.
33. Velanovich V, Karmy-Jones R. Psychiatric disorders affect outcomes of antireflux operations for gastroesophageal reflux disease. Surg Endosc 2001; 15(2):171-175.
34. Kamolz T, Granderath F, Pointner R. Laparoscopic antireflux surgery: disease-related quality of life assessment before and after surgery in GERD patients with and without Barrett's esophagus. Surg Endosc 2003; 17(6):880-885.
35. Kamolz T, Granderath F, Pointner R. Laparoscopic antireflux surgery: disease-related quality of life assessment before and after surgery in GERD patients with and without Barrett's esophagus. Surg Endosc 2003; 17(6):880-885.
36. Madan A, Minocha A. Despite high satisfaction, majority of gastro-oesophageal reflux disease patients continue to use proton pump inhibitors after antireflux surgery. Aliment Pharmacol Ther 2006; 23(5):601-605.
37. Fumagalli U, Bona S, Battafarano F, Zago M, Barbera R, Rosati R. Persistent dysphagia after laparoscopic fundoplication for gastro-esophageal reflux disease. Dis Esophagus 2008; 21(3):257-261.
38. Ravi N, Al-Sarraf N, Moran T, et al. Acid normalization and improved esophageal motility after Nissen fundoplication: equivalent outcomes in patients with normal and ineffective esophageal motility. Am J Surg 2005; 190(3):445-450.
39. Bessell JR, Finch R, Gotley DC, Smithers BM, Nathanson L, Menzies B. Chronic dysphagia following laparoscopic fundoplication. Br J Surg 2000; 87(10):1341-1345.
40. Mattioli S, D'Ovidio F, Pilotti V et al. Hiatus hernia and intrathoracic migration of esophagogastric junction in gastroesophageal reflux disease. Dig Dis Sci 2003; 48(9):1823-1831.
41. Fass R, Fennerty MB, Vakil N. Nonerosive reflux disease—current concepts and dilemmas. Am J Gastroenterol 2001; 96(2): 303-314.

Correspondence Address:
GUILHERME DE CASTRO SANTOS
Rua Guajajaras 712 / 1502, Centro
Belo Horizonte, Minas Gerais 30180-100
E-mail: gcs2000@gmail.com
Phone: (31) 3213-2314