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Research Article

Quality of Life Assessment after Antireflux Surgery: Our Initial Experience

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Abstract

Introduction: Many physicians consider that the mainstay for the treatment of Gastroesophageal Reflux Disease (GERD) is the conventional medical treatment with proton pump inhibitors (PPI) and antihistamines. Laparoscopic fundoplication is increasingly considered as an alternative. This study aimed to determine if antireflux surgery provided an improvement of quality of life more than medical treatment.

Methods: We randomly assigned 2 groups of patients diagnosed with GERD, the first group was on medical treatment and the second group underwent surgery. Symptoms and quality of life of patients in different domains were assessed using the Gastrointestinal Quality of Life Index (GIQLI) questionnaire.

Results: Total GIQLI score was significantly higher in surgical group more than the medical group. In all the questions, surgical group scored higher than medical group except for 3 questions about dealing with daily activities, feeling unfit and participating in leisure activities. Higher subtotals were found in surgical group for each domain: gastrointestinal symptoms, physical function, social function and emotional function.

Discussion: Regurgitation and heartburn were better relieved by surgery, for patients with refractory GERD. Similar outcomes were seen in the LOTUS trial (Long-Term Usage of Esomeprazole vs. Surgery for Treatment of Chronic GERD) and in Catania., *et al*. study.

Conclusion: Surgery improved the quality of life (QOL) more than medication due to better control of symptoms and the cessation of PPI intake after surgery. This result did not provide an improvement in the social, emotional and physical function.

Keywords: *Gastroesophageal Reflux Disease; Laparoscopic Fundoplication; Quality of Life*

Abbreviations

GERD: Gastroesophageal Reflux Disease; PPI: Proton pump inhibitors; GIQLI: Gastrointestinal Quality of Life Index; QOL: Quality of life; COGENT: Clopidogrel and the Optimization of Gastrointestinal Events Trial; SD: Standard deviation

Introduction

Gastroesophageal reflux disease (GERD) is one of the most common benign foregut disorders, caused by reflux of gastric contents into the esophagus. It is a chronic relapsing disease that can affect the patient's quality of life (QOL). Multiple drugs are available now to suppress gastric acidity. However, as no currently available treatment can restore normal esophageal anatomy, some patient may undergo antireflux surgery. The American Gastroenterological Association recommends the use of twice-daily Proton Pump Inhibitors (PPI) therapy for patients with GERD in whom treatment with daily PPI therapy fails. Long-term PPI therapy may be discontinued in patients without GERD symptoms except in those with a history of erosive esophagitis. Another lifelong therapy indication is in Barrett's esophagus.

Antireflux surgery is an option whenever lifelong drug therapy is indicated (i.e. erosive esophagitis or Barrett's esophagus). However, surgery became an absolute indication in patients with erosive gastritis unresponsive to maximal medical therapy, in patients complaining of an increased amount of regurgitation (particularly if it is nocturnal or complicated by aspiration) and in patients that need lifelong treatment but complaining of severe side effects or having contraindications to medical therapy.

Different articles are published about the outcomes of antireflux surgeries. Short term outcomes were evaluated by Wescott., *et al*. [1] and Catania., *et al*. [2] and both showed notable improvements. Long term follow-ups were also satisfactory. Using the GIQLI questionnaire, an evaluation at 10 years of surgery was done [3,4]. Eighty-nine point five percent of patients were still free of significant reflux [3] and if they were given the choice again 89% will select the surgery [4].

Many complications can occur after antireflux surgery. However, death is still extremely a rare complication. Perioperatively, the most worrying complication is the need to convert from laparoscopic to open procedure. Other complications included perforation, pneumothorax, wound infections and incisional hernias. Postoperative and long term complications included: dysphagia, gas bloating and reoperation [5]. The need for medical therapy after surgery is also considered as a complication.

A questionnaire on the usage of antireflux medication was sent to 1008 patients who underwent antireflux surgeries, 37% were found to be on medical therapy again due to reoccurrence of symptoms [6].

The increase use of PPI is not only due to their efficacy and potency, but also due to their large safety margin. Serious side effects of PPIs are extremely rare, but recent reports and studies are questioning safety of long term use of PPIs. COGENT (Clopidogrel and the Optimization of Gastrointestinal Events Trial) didn't show any interaction between Clopidogrel and Omeprazole [7]. Other studies showed a significant risk of hip fractures in patients using PPIs for more than one year [8,9]. The relation between PPIs and the development of osteoporosis is attributed to possible calcium malabsorption caused by the drugs [10]. This conclusion is refuted by many other reports [11,12]. Other possible associations with PPIs intake include Clostridium difficile infections, pneumonias, interstitial nephritis and iron and vitamine B12 deficiencies.

Aim of the Study

The aim of this study is to evaluate the utility of antireflux surgery in the management of GERD and to determine if it provides an improvement in QOL more than medical treatment.

Materials and Methods

Retrospectively, two groups, the first on medical treatment and the second underwent surgery, were compared using the GIQLI questionnaire. This evaluation was not done before in the Arab world, and more specifically in Lebanon.

Patients on medical treatment

Patients were selected from the out-patients-department of Rafic Hariri University Hospital in Beirut. All the patients included in this group were above 18 years of age, diagnosed with GERD (complained initially from regurgitation and heartburn, confirmed by gastroduodenoscopy), with negative medical history of gastrointestinal disorders, and have been treated with empirical therapy of at least 8 week-course of PPIs, 20 mg once daily, or 40 mg once daily, or 20 mg twice daily if there was partial response. Medications were taken at least 30 minutes before meals. The PPIs used were Omeprazole, Rabeprazole and Esomeprazole, belonging to a wide variety of generic and brand names.

To note that there is no significant difference between the different PPIs concerning efficacy [13].

The questionnaire was filled during a direct interview with the patients, after obtaining their consent to participate anonymously in the study. Forty questionnaires were collected.

Patients who underwent surgery

Patients were selected using the same hospital's database. We included all the patients who underwent Laparoscopic Nissen fundoplication during the last five years. All of them were above 18 years of age, diagnosed with GERD (complained initially from regurgitation or heartburn), with negative medical history of gastrointestinal disorders and have been treated with empirical therapy of at least 8 week-course of PPIs, 20 mg once daily, or 40 mg once daily, or 20 mg twice daily if there was partial response. The questionnaire was filled during a direct interview with the patients, also after obtaining their consent to participate anonymously in the study. Forty questionnaires were collected.

Quality of life assessment

The GIQLI questionnaire has been developed initially by Eypasch., et al. to assess the QOL outcomes in patients with gastrointestinal disorders [14]. It has been translated to English, German, Dutch, Spanish and French and validated for a variety of gastrointestinal conditions.

The GIQLI questionnaire is a method for assessment of health-related quality of life for patients with gastrointestinal disease and in daily clinical practice. It comprises 36 questions that can be divided into 5 domains: gastrointestinal symptoms (19 questions), physical function (7 questions), social function (4 questions), emotional function (5 questions) and one question about trouble in medical treatment (question number 24). The question number, its content and the domain under which it falls are shown in table 1.

Each question is graded from 0 to 4, with 0 being the worst option and 4 the best option. Summing the points, the score will range theoretically from 0 to 144. Eypasch., *et al*. have found that a healthy control population will score 125.8 when completing this questionnaire.

Between all the questions, question 27 (about regurgitation) and question 35 (about heartburn) target the most specific GERD symptoms. Other questions explore issues related to GERD such as question 9 (need for selective food restriction).

Statistical analysis

The results for all items were expressed as means ± SD (standard deviation) of the mean. The unpaired Student t test was used to compare each question (item) for both groups. A two-tailed t test was used for comparison of total scores and scores in each of the five domains, for medical and surgical groups.

Results

The mean GIQLI score was 118.92 in the surgical group, significantly higher than the mean GIQLI score of 104.88 in the medical group ($p < 0.0001$). Scores of each question in both groups were compared in table 1. Two questions were more specific for GERD disease: Regurgitation and heartburn. Significantly higher scores were observed in the surgical group for both questions ($p < 0.0001$ which means extremely significant statistically).

Question	Content	Category	Medical Group	Surgical Group	p-Value
1	Abdominal pain	GI symptoms	2.78 (0.80)	3.10 (0.71)	0.0520
2	Epigastric fullness	GI symptoms	2.75 (0.78)	3.18 (0.84)	0.0216
3	Bloating (gas excess)	GI symptoms	2.53 (0.91)	3.45 (0.64)	< 0.0001
4	Flatulence	GI symptoms	2.83 (0.81)	3.23 (0.53)	0.0110
5	Belching	GI symptoms	2.65 (0.86)	3.08 (0.86)	0.0303
6	Abdominal noises	GI symptoms	3.03 (0.86)	3.15 (0.53)	0.4378
7	Frequent bowel movement	GI symptoms	3.03 (0.66)	3.35 (0.58)	0.0218
8	Enjoyment in eating	GI symptoms	2.15 (1.29)	3.15 (0.86)	< 0.0001
9	Selective food restriction	GI symptoms	2.35 (0.80)	3.28 (0.78)	< 0.0001
10	Dealing with daily stress	Emotional function	2.90 (0.78)	3.25 (0.87)	0.0615
11	Sadness due to illness	Emotional function	2.83 (0.84)	3.13 (0.79)	0.1049
12	Anxiety due to illness	Emotional function	3.05 (0.85)	2.93 (0.69)	0.4721
13	Happiness in life	Emotional function	2.88 (0.91)	3.15 (0.66)	0.1266
14	Frustration to illness	Emotional function	3.35 (0.80)	3.43 (0.59)	0.6360
15	Fatigue	Physical function	3.18 (0.81)	3.40 (0.78)	0.2097
16	Feeling unwell	Physical function	2.73 (1.13)	3.18 (0.84)	0.0473
17	Waking during the night	Physical function	2.88 (0.85)	3.48 (0.64)	0.0006
18	Change in appearance	Physical function	3.05 (0.81)	3.45 (0.88)	0.0376
19	Loss of strength	Physical function	2.85 (0.86)	3.25 (0.84)	0.0390
20	Loss of endurance	Physical function	2.98 (0.66)	3.40 (0.81)	0.0120
21	Feeling unfit	Physical function	3.38 (0.63)	3.35 (0.77)	0.8739
22	Dealing with daily activity	Social function	3.28 (0.72)	3.05 (0.75)	0.1736
23	Doing leisure activities	Social function	3.30 (0.69)	3.15 (0.80)	0.3718
24	Trouble from medical treatment		2.45(0.93)	2.90 (0.98)	0.0388
25	Personal relationships	Social function	3.35 (0.92)	3.48 (0.68)	0.4917
26	Sexual problems	Social function	3.58 (0.64)	3.65 (0.62)	0.5955
27	Regurgitation	GI symptoms	2.70 (0.65)	3.55 (0.64)	< 0.0001
28	Slow speed of eating	GI symptoms	2.68 (0.76)	2.90 (0.78)	0.1957
29	Dysphagia	GI symptoms	2.93 (0.89)	3.25 (0.71)	0.0741
30	Urgent bowel movements	GI symptoms	3.13 (0.79)	3.58 (0.50)	0.0032
31	Diarrhea	GI symptoms	2.58 (1.06)	3.60 (0.55)	< 0.0001
32	Constipation	GI symptoms	2.75 (0.63)	3.45 (0.55)	< 0.0001
33	Nausea	GI symptoms	2.75 (0.63)	3.03 (0.77)	0.0839
34	Blood in stool	GI symptoms	3.35 (0.89)	3.75 (0.49)	0.0153
35	Heartburn	GI symptoms	2.35 (1.10)	3.33 (0.69)	< 0.0001
36	Fecal incontinence	GI symptoms	3.63 (0.54)	3.88 (0.40)	0.0216

Table 1: *Contents of GIQLI questionnaire, the different categories and GIQLI score for each question for both groups presented as Mean (SD).*

Question 24 asked about any trouble from medication intake, the surgical group scored higher in this question and this was statistically significant (p = 0.0038).

In all GIQLI questions, the surgical group scored higher than the medical group, except for 3 questions about dealing with daily activities, feeling unfit and participating in leisure activities. To mention that in these last 3 questions, there was no significant difference statistically (p > 0.05).

Higher subtotals were found in the surgical group for each domain: gastrointestinal symptoms, physical function, social function and emotional function. This difference was significant in the gastrointestinal symptom domain (p < 0.0001) whereas in physical function (0.0647), social function (0.6874) and emotional function (0.1526) the difference was not statistically significant. Results were summarized in table 2, and compared in figure 1.

	Medical Group	Surgical Group	P-Value
Total GIQLI score	104.88	118.92	< 0.0001
Symptoms	52.90	63.25	< 0.0001
Physical function	21.03	22.93	0.0647
Social function	13.50	13.33	0.6874
Emotional function	15	15.88	0.1526
Trouble with treatment	2.45	2.90	0.0038

Table 2: *GIQLI score for each domain of both groups.*

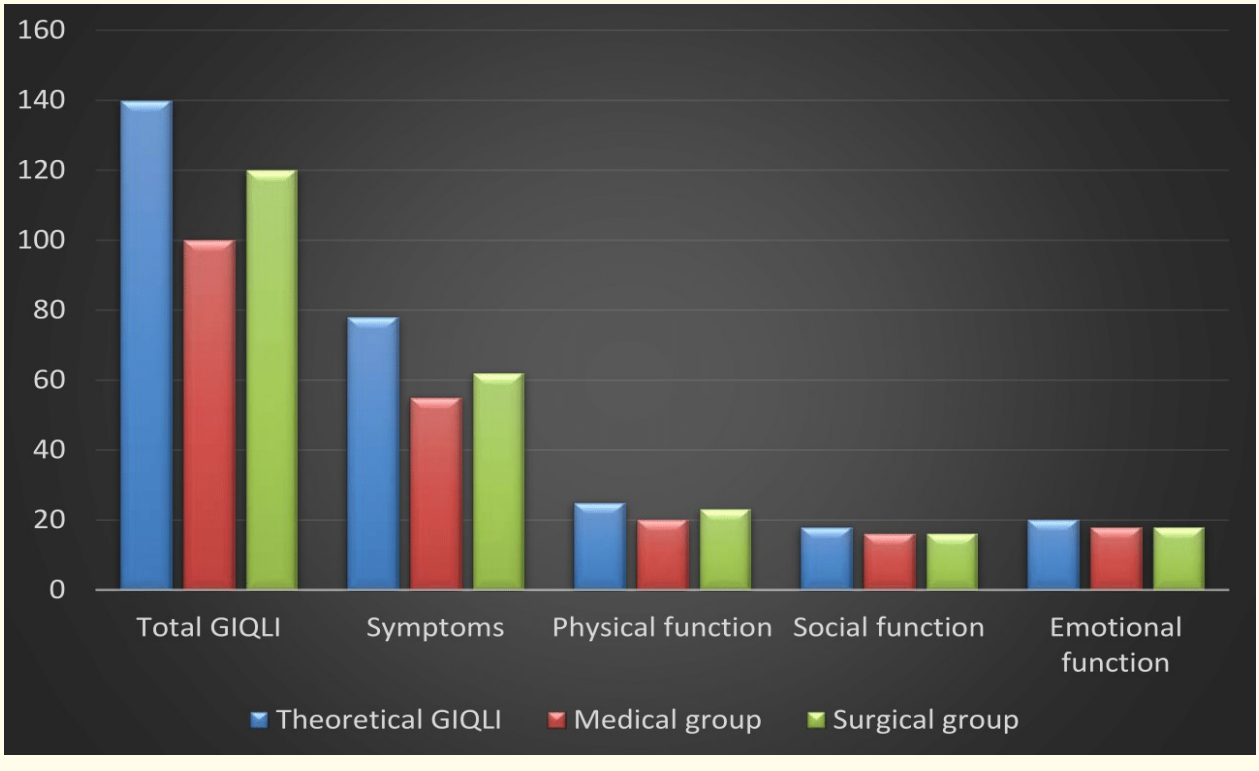

Figure 1: *GIQLI score for each domain in both groups compared to theoretical maximal score.*

Discussion

The American College of Gastroenterology issued the Guidelines for the management of GERD.

Treatment of this disease consists mostly on medical therapy, using PPIs, or surgery (fundoplication, whether it was open or laparoscopic).

There are multiple studies addressing the effectiveness of antireflux therapy and their impact on the quality of life.

One of the most important studies is the LOTUS trial (Long-Term Usage of Esomeprazole vs Surgery for Treatment of Chronic GERD) [15]. A total of 554 patients were divided into 2 groups randomly, the first was assigned to continue esomeprazole therapy and the second was assigned to undergo surgery. After 5 years of follow-up, a remission rate of 92% was estimated for Esomeprazole group and 85% for the surgery group ($p = 0.048$). In conclusion there was no significant difference in remission rates between these 2 groups.

The GIQLI scoring system is chosen amongst other scores because of its ability to turn the QOL into a measurable entity.

The patients' assessment of the disease and the treatments' impact on their lives are reflected by the items used in the questionnaire. The latter is not a diagnostic tool, and it measures the perception of the well-being subjectively [14].

Our patients represent cases of GERD refractory to medical treatment, complaining mainly of persistent regurgitation and heartburn despite PPI use according to the guidelines for the management of reflux disease. In this study, two groups were analyzed, 40 patients in the medical group (treated by PPI for at least 8 weeks) and 40 patients in the surgical group (underwent laparoscopic Nissen fundoplication). The mean total GIQLI score was higher in the surgical group (118.92) than in the medical group (104.88) with a P value < 0.001, meaning that laparoscopic fundoplication was more effective than conventional medical treatment in controlling GERD and lead to a better QOL, as it was seen with Spechler [16].

There was more regurgitation and heartburn in patients receiving medical treatment, since the GIQLI score for the typical symptoms of GERD was found to be higher in the surgical group than those who were on medical treatment, with a P value < 0.0001. Similar outcome was found in the LOTUS trial [15].

Patients who underwent the fundoplication scored higher than those who are on medical therapy in the question 24 concerning medication intake with a P value = 0.0038 which was expected since the surgical patients were not on medical therapy anymore.

Concerning the emotional status, the physical and the social domains in the GIQLI questionnaire, the patients that scored higher were those who underwent the antireflux surgery, but the results were statistically insignificant with a P value > 0.05. Whether they were on medical therapy or post-surgery, the patients were socially active and emotionally stable.

In the gastrointestinal symptoms domain, the mean GIQLI score in the surgical group (63.25) was higher than the mean GIQLI score in the medical group (52.9) with a P value < 0.0001. This part of the questionnaire is directly related to the GERD disease and patient's satisfaction. Similar results were found in the LOTUS trial [15] and in Catania., *et al*. study in 2007 [2], concerning the symptoms related directly to GERD (regurgitation and heartburn). Results and discussion must illustrate and interpret the reliable results of the study.

Conclusion

Laparoscopic Fundoplication is an effective treatment modality of GERD, and it improves the patient's QOL significantly more than conventional medical therapy with respect to regurgitation and heartburn.

Surgery adequately controls these symptoms, but it doesn't have any superior impact than medical therapy concerning the patient's social, emotional, or physical status.

Conflict of Interest

The authors have no conflict of interest to declare.

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