



and Other Interventional Techniques

Laparoscopic fundoplication

Is there a correlation between pH studies and the patient's quality of life?

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Abstract

Background: The effectiveness of laparoscopic Nissen fundoplication (LNF) was assessed in patients with chronic gastroesophageal reflux disease (GERD) using pH study and different quality-of-life indexes. We correlated both types of data and hypothesised that improvement in quality of life following LNF does not necessarily correlate with improvement in pH values.

Methods: Seventy patients presenting with typical symptoms of GERD (14 with Barrett's esophagus) underwent LNF between May 1997 and December 2000. All patients were evaluated both prior to and 3 months after surgery using 24-h pH study, endoscopy, and a validated quality-of-life questionnaire.

Results: Following LNF, reflux was reduced to normal in all but six patients. However despite persistent reflux, the Gastrointestinal Quality of Life Index (GQLI), of these six patients improved postoperatively from 79.5 ± 12.2 to 111.7 ± 8.3 . These results correlate with those of patients who had normal postoperative pH studies—namely, 88.5 ± 19.3 to 112 ± 16.7 . There was no difference in quality-of-life improvement between patients with Barrett's esophagus and those without it.

Conclusion: There is only a weak correlation between quality-of-life assessment and pH study. Because the patient's quality of life is likely to improve following LNF, an objective means parameter of assessing the effectiveness of antireflux surgery, such as pH study or endoscopy, is recommended.

Key words: Gastroesophageal reflux disease — Laparoscopic fundoplication — pH study — Gastrointestinal Quality of Life Index

In the past decade, laparoscopic fundoplication has become the standard surgical therapy for patients with chronic gastroesophageal reflux disease (GERD). Numerous reports

describing the efficacy of this procedure have been published, focusing on surgical outcome, relief of patient's symptoms, and physiological parameters such as pH studies, endoscopy, and esophageal manometry. Most of them demonstrated that Nissen fundoplication is highly effective in reducing exposure of the esophagus to acid reflux [2, 5, 7, 14, 16]. More recently, quality-of-life assessment has been added to discussions concerning the best treatment for GERD [17]. Patients with chronic GERD have a poor quality of life but hope that antireflux surgery will afford some improvement. Recent studies using different quality-of-life indexes, have shown a significant improvement in patients who undergo laparoscopic fundoplication [6, 11, 15]. Nevertheless, none of these reports has correlated the data of quality-of-life assessment with the objective criteria provided by pH studies.

In our clinical practice, we learned that patients presenting with severe GERD symptoms do not necessarily exhibit severe reflux on pH study, and vice versa. Because the patients' symptoms have a major impact on their quality of life, we decided to correlate the subjective criteria of quality of life with the objective criteria yielded by pH studies. We postulated that improvement in quality of life following laparoscopic fundoplication does not necessarily correlate with improvement in the objective pH study. This correlation was expected to be particularly weak in patients with Barrett's esophagus.

The typical symptoms of GERD are a more reliable indicator for the presence of the disease and have been shown to be a strong predictor of outcome [1]. Consequently, symptom improvement is a better reflection of the effectiveness of surgical therapy. Therefore, our study was limited to patients presenting with typical symptoms of GERD.

Materials and methods

Patients

Between June 1997 and December 2000, 70 patients with typical symptoms of GERD underwent laparoscopic fundoplication at the University of

Göttingen. Five of them did not take part in follow-up or refused postoperative pH monitoring or endoscopy, leaving 65 patients for further evaluation. The workup of patients with GERD included a thorough history and examination, pre- and postoperative pH study, and endoscopy. Quality of life was assessed using the standardized Gastrointestinal Quality of Life Index (GQLI), as previously reported by Eypasch et al. [4]. The GQLI was used to survey the patients both prior to and 3 months following surgery. Typical symptoms were heartburn, retrosternal pain, regurgitation, and dysphagia. Cough, chest pain, and asthma were considered to be atypical symptoms.

All patients included in the study presented with typical symptoms of GERD; 14 patients were found to have Barrett's esophagus on histology. All patients with a severe esophageal motility disorder ($n = 4$) were subjected to a Toupet fundoplication and therefore excluded from this study.

Manometry and endoscopy

Gastroesophageal manometry and endoscopy were performed routinely prior to and 3 months after surgery. The esophageal mucosa was graded according to the classification of Savary and Miller.

24-h ambulatory pH study

Intraesophageal pH was monitored using a one-lead electrode (Medtronic, Duesseldorf, Germany). The episodes of total, upright, and supine times of pH <4 were measured and processed by a XPH 2.1 program (Standard Instruments Inc.). Abnormal reflux was defined as >4.5% of total time pH <4 [10]. In all patients, acid-blocking agents were discontinued ≥ 10 days prior to monitoring.

Assessment of quality of life

The GQLI is a validated questionnaire. This test contains 36 items that provide an overall score (0–144) as well as five domains (gastrointestinal symptoms, emotional status, physical function, social function, and outcome of medical treatment). The comparable score of a healthy normal population has been assessed as 122.6.

In addition to the validated GQLI, patients were asked to answer the following four questions concerning self-assessment of surgical outcome:

1. How do you assess the outcome of surgery? (Improved/cured or stable/worsened)
2. Are you satisfied with the operative result? (Yes or no.)
3. Do you feel well after surgery? (Yes or no.)
4. Would you undergo LNF again? (Yes or no)

Surgical technique

The indication for surgery in these patients was chronic GERD unresponsive to medical treatment with abnormal exposure of the esophagus to a pH < 4. All patients underwent laparoscopic 360° Nissen fundoplication using a five-port technique. The hiatus and the gastric fundus were completely mobilized, routinely severing the short gastric vessels. A posterior hiatal repair was performed with nonabsorbable suture. The 360° fundoplication was fixed around a 60-F dilator placed in the esophagus. Length of the floppy fundoplication was routinely 3 cm.

Statistical analysis

The nonparametric Wilcoxon test for paired samples was used to compare the pre- and postoperative scores of the GQLI. A p value of < 0.05 was considered to be statistically significant.

Table 1. Patient data

Characteristic	<i>n</i>
Total no. of patients	70
No. of patients lost to follow-up	5
Sex	m: 42 f: 28
Age (yr), mean (range)	49 (31–76)
Intraoperative complications	
Splenic injury	2
Conversion (for splenic injury)	1
Postoperative complications	
Persistent reflux	6
Temporary swallowing discomfort	27
Dysphagia >3 mon	3
Reoperation due to dysphagia	1
Diarrhea	4
Complaints of bloating	22

Results

Outcome of surgery

Patient data are presented in Table 1. Two intraoperative splenic lesions were managed laparoscopically; a third one forced the surgeon to convert to achieve hemostasis. There were no deaths. Temporary swallowing discomfort was the most common early symptom following surgery, occurring in 27 patients; but the condition resolved in all but three patients within 3 months. Dysphagia (>3 months) was seen in three patients, leading to reoperation in one patient with correction from 360° to a Toupet partial fundoplication. The two other patients improved 6–12 months following surgery, such that no further intervention was necessary. In seven patients, the pleural cavity was opened intraoperatively; however, there was no need for drainage.

Assessment of the quality of life

The results of the pre- and postoperative pH studies and the GQLF are presented in Figs. 1 and 2. The postoperative improvement in quality of life was statistically significant in all groups. Table 2 compares patients with normal and abnormal postoperative pH studies in terms of the five domains of the GQLI. The two groups showed a similar improvement in GQLI in all domains. Of 65 patients, 14 had Barrett's esophagus. To assess whether patients with evidence of Barrett's esophagus behave differently from those without it, our patients were subdivided into two groups.—group 1, without Barrett's esophagus; and group 2, with Barrett's esophagus. The patients' self-assessment of their outcomes is shown in Table 3. Ninety-six percent reported that they were improved or cured by the laparoscopic anti-reflux surgery.

Correlation between pH studies and quality of life

Ambulatory 24-h pH study prior to and 3 months after surgery revealed a reduction in exposure of the esophagus to pH <4 to normal in all but six patients. As expected, these six patients exhibited persistent esophagitis in postoperative endoscopy (preoperatively: 3× grade 3, 3× grade 2; postoperatively: 1× grade 3, 4× grade 2, 1× grade 1). Esophagitis

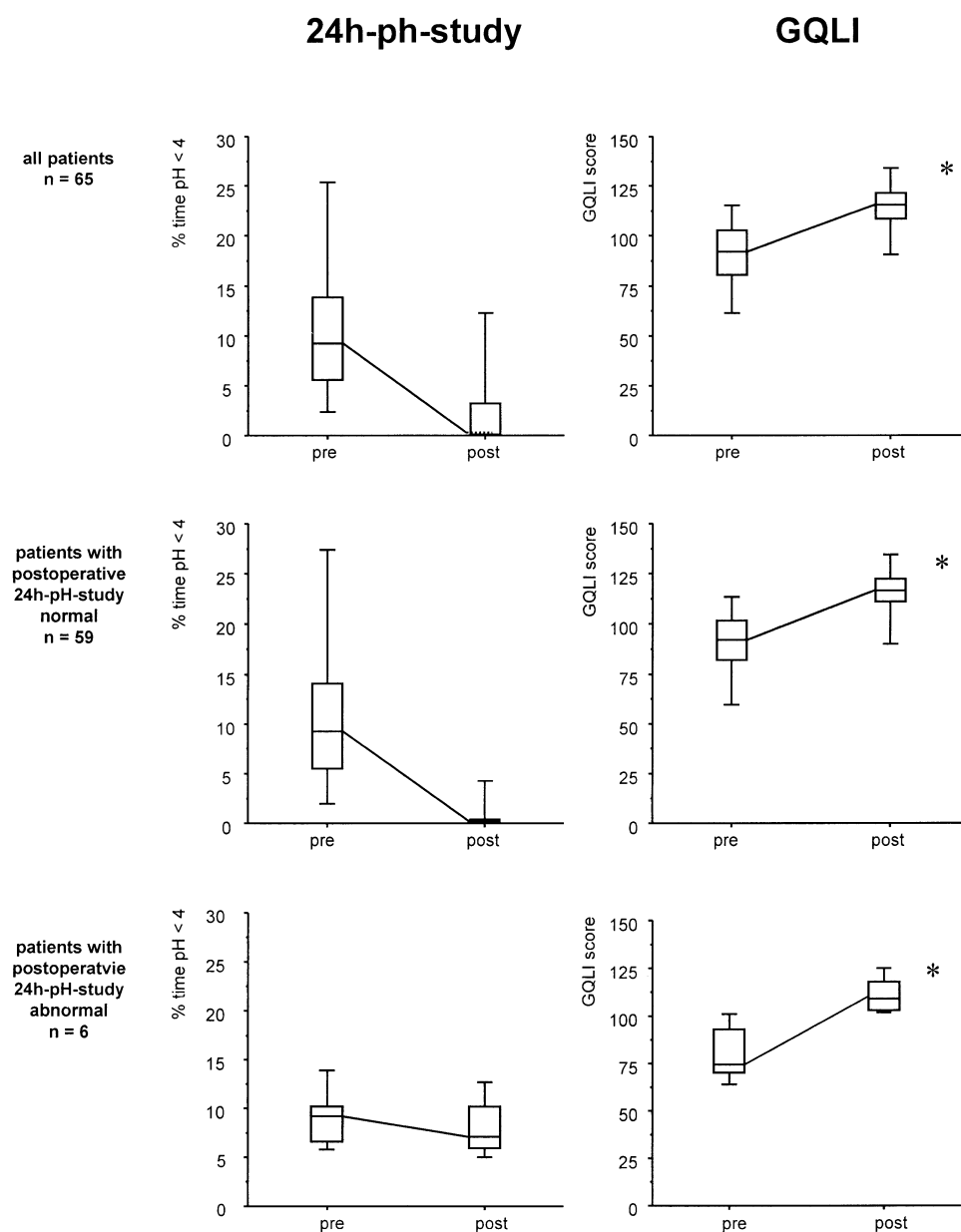


Fig. 1. Graphs showing results of 24-h pH studies and GQLI scores for all patients, patients with normal postoperative pH studies and patients with persistent reflux. Data are presented in box and whisker plots representing the median with the 25/75th resp. the 5/95th percentile. The asterisk(*) indicates that the improvement of post- to preoperative GQLI was statistically significant ($p < 0.05$).

was cured in all other patients within 3–6 months postoperatively.

The patients were subsequently divided into two subgroups (group 1, postop. pH study normal; group 2, pH study abnormal). As shown in Fig. 1, the GQLI showed postoperative improvement in both groups from 88.5 ± 19.3 to 112 ± 16.7 in group 1 and from 79.5 ± 12.2 to 111.7 ± 8.3 in group 2. The improvement in total quality-of-life score was due to a homogeneous increase for all five domains in both groups.

To evaluate whether the outcome of antireflux surgery differs in patients with or without Barrett's esophagus, the pH studies and quality of life of the two groups were compared. The quality of life in patients without Barrett's esophagus improved from 88.5 ± 16.3 to 114.2 ± 16.4 ; in patients with Barrett's esophagus, it increased from 94.2 ± 17.4 to 113 ± 9.3 . Thus, there was no statistically significant difference between the two groups.

Discussion

Since the introduction of LNF, the application of this procedure has increased exponentially [3]. Although most physicians agree on a standardized preoperative workup that includes esophageal manometry, endoscopy, and/ or 24-h pH study, evaluation of the effectiveness of surgery is a more controversial area [8]. Relief of symptoms combined with a normal endoscopy and/ or a normalized 24-h pH study are the accepted criteria for a successful LNF. Quality-of-life surveys have added a new dimension to the validation of outcomes, but it is still uncertain how precisely they reflect the effectiveness of antireflux surgery.

Glise et al. [6] and Rattner [15] reported on the improved quality of life following LNF using different scoring systems. However, neither of them correlated their data with objective parameters, such as endoscopy or pH study.

We might ask whether we can rely on symptom relief or

24h-ph-study

GQLI

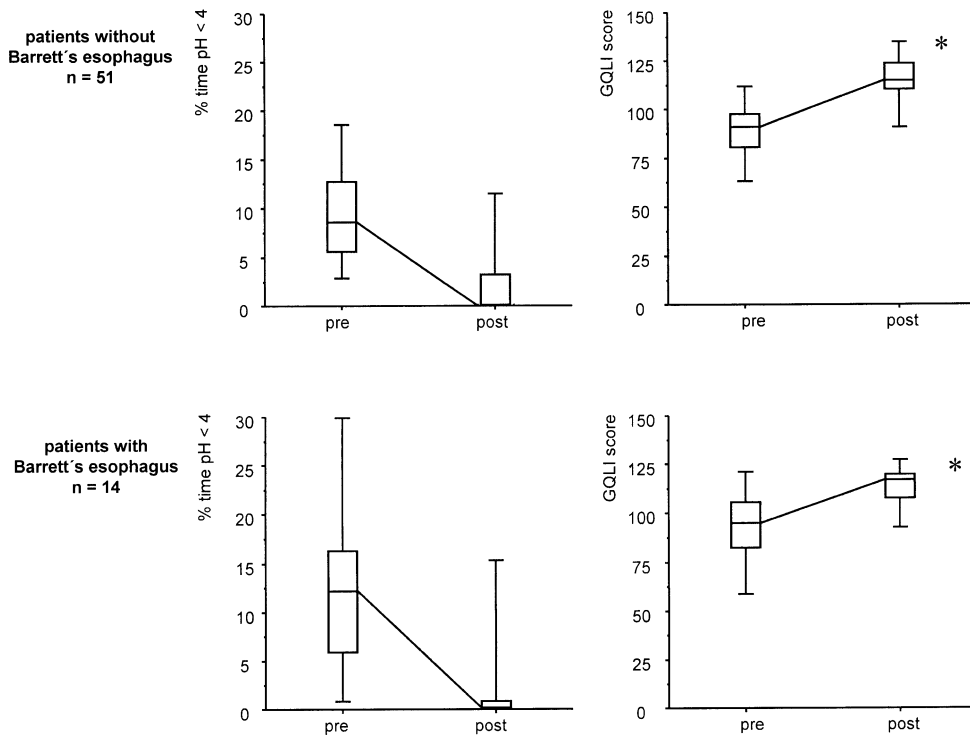


Fig. 2. Graphs showing results of 24-h pH studies and GQLI scores for patients without and with Barrett's esophagus. Data are presented in box and whisker plots representing the median with the 25/75th resp. the 5/95th percentile. The asterisk(*) indicates that the improvement of post- to preoperative GQLI was statistically significant ($p < 0.05$).

Table 2. Gastrointestinal Quality of Life Index before and after laparoscopic Nissen fundoplication normal and abnormal postoperative pH studies

Domain	Normal (n = 59)		Abnormal (n = 6)	
	Pre	Post	Pre	Post
Gastrointestinal symptoms	47.2 ± 9.7	58.9 ± 8.3	42.0 ± 6.2	56.0 ± 5.1
Emotional status	9.5 ± 3.6	14.4 ± 3.1	8.7 ± 2.5	13.7 ± 1.3
Physical function	17.1 ± 5.7	21.1 ± 4.7	15.1 ± 4.3	21.0 ± 3.8
Social function	12.3 ± 3.3	14.2 ± 3.1	10.7 ± 3.1	14.5 ± 1.5
Treatment outcome	2.7 ± 1.2	3.5 ± 0.9	2.8 ± 0.8	4.0 ± 0.0
Total score	88.5 ± 19.3	112.0 ± 16.7 ^a	79.5 ± 12.2	111.7 ± 8.3 ^a

Data presented as mean ± standard deviation (SD). A total score of 122.6 has been assessed as indicative of a normal healthy population.

^a $p < 0.05$ post- to preoperative score

Table 3. Patient self-assessment of outcome

	n	Improved or cured	Satisfied with operative result	Postop. well-being	Would undergo surgery again
Total	65	96%	95%	93%	95%
Non-Barrett	51	97%	95%	92%	97%
Barrett	14	93%	93%	93%	93%

quality-of-life data as a basis for deciding which patients need further medical treatment or further endoscopic controls. In a study comparing Nissen and Toupet fundoplication, Kamolz et al. [11] also presented data on pre- and postoperative pH study. However, in contrast to our results,

they stated that quality of life correlated well with the degree of esophageal mucosal damage. In their series, 2.8% of patients with LNF had persistent increased esophageal acid exposure. If the correlation was as good as they reported, these patients would not have exhibited an improvement in

quality of life. Unfortunately, these data were not explicitly shown.

In a study designed to measure GERD, Velanovich and Karmy-Jones examined the relationship between the health-related quality-of-life score and such physiological parameters as endoscopy and 24-h pH monitoring [18]. All of their patients were evaluated prior to surgery only. Using regression analysis, they found that the total quality-of-life score correlated well with the degree of mucosal damage but not with the 24-h pH monitoring score. The lack of correlation was surprising to the authors, especially given that both life-quality assessment and 24-h pH monitoring correlated well with the grade of esophagitis. In contrast to our own results, they suspected that this finding was due to there being so much statistical variation in their data that significance was not reached.

In our patients, pH study correlated well with endoscopy but not necessarily with the quality-of-life data. Six patients with persistent reflux had an improved quality-of-life score, yet two others obtained only a slight improvement in their quality of life despite having normal pH studies with no evidence of dysphagia or other complications. Endoscopy of these six patients revealed that the fundoplication was relatively wide in three cases and regular in the three other cases. The GQLI score improved in all patients, regardless of whether their postoperative pH study was normal or abnormal. One might expect that patients with a persistent abnormal pH study would not show an increase in quality-of-life score in the domain of symptoms, which would then be compensated for by a greater increase in the other domains. But this was not the case. A comparison of the GQLI scores of both groups showed a homogeneous increase in all five domains.

One might argue that the patients' quality of life should have been re-evaluated 1 year after surgery, on grounds that the clinical picture could have changed. However, when Kamolz et al. [11] assessed quality of life at 6 weeks, 3 months, and 1 year after LNF, they found that there is a minor difference between 6 weeks and 3 months but no difference at all between 3 months and 1 year after surgery.

In our series of 65 patients, the quality of life improved for all but one patient. Although acid exposure in the esophagus of this patient decreased from 20% to 0.5% time pH <4, endoscopy revealed that there was no esophagitis following surgery (prior to grade 1). It was decided retrospectively that this patient was a poor candidate for LNF owing to a moderate esophageal motility disorder that had been detected by manometry. In terms of outcome of surgery and complications, our series was otherwise comparable with previous reports [5, 7, 9, 14, 16, 19]. In particular, the relatively high rate of persistent reflux (9.2%) has been reported previously; for example, Hinder et al. reported a rate of 14% (3-24 months) and Hunter et al. found rates of 13% (3 months) and 9.2% (2 months after LNF), respectively [7, 9].

However, six patients who complained of persistent reflux also reported that their quality of life had improved to a level that was similar to that of the patients who had undergone antireflux surgery successfully. The same phenomenon is sometimes seen preoperatively when patients who show severe acid reflux on pH study do not necessarily present with an equivalent severity of symptoms [10]. For

example, Hunter et al. [9] reported that patients in their volunteer population with abnormal pH test results had no reflux symptoms and that 50% of the patients re-evaluated for chest symptoms did not have reflux. Six weeks after surgery, seven of their 55 patients had abnormal pH studies, yet only one patient was symptomatic (this was a patient with severe gastric dysfunction). Abnormal pH studies were found in 9% of patients 1 year after surgery. Two of these patients were asymptomatic. Combining our data with those of other reports, we must conclude that neither the relief of symptoms nor improvement in the quality of life following LNF is an adequate measure of the effectiveness of antireflux surgery.

The surgical approach to GERD has two objectives. First, we aim to improve the quality of life of patients who are suffering the symptoms of chronic reflux disease. Second, we want to prevent the early and late postoperative complications of GERD, such as esophagitis, stricture, or the development of Barrett's esophagus, which eventually results in adenocarcinoma of the esophagus [12, 13]. Caution should therefore be taken when interpreting the results of quality-of-life assessment. We believe that postoperative endoscopy and/or pH study is mandatory to prove the success of LNF and to decide whether further treatment is needed.

With respect to quality of life, there was no difference between patients with Barrett's esophagus and those without it. Because the disease is not necessarily cured by LNF, we expected only a minor improvement in the quality of life of patients who presented with a diagnosis of Barrett's esophagus. Nevertheless, all of them improved postoperatively—those with as well as those without Barrett's esophagus.

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