Quality-of-life assessments in evaluation of laparoscopic Rosetti fundoplication

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Received: 19 April 1994/Accepted: 26 August 1994

Abstract. It has recently been suggested that quality-of-life investigations should be included in the evaluation of new medical and surgical regimens. We present the quality-of-life evaluations for the first 40 consecutive patients undergoing laparoscopic antireflux surgery at our department. Two well-established and validated questionnaires, the Psychological General Well Being (PGWB) Index, and the Gastrointestinal Symptom Rating Scale (GSRS), were used. The PGWB gives a general measure of patients' well-being while the GSRS concentrates on gastrointestinal complaints. In untreated reflux esophagitis patients, the PGWB score is very low. We found normal PBWB scores preoperatively during optimal medical treatment with potent acid inhibition. The average score became significantly better (than on medical treatment, \( P < 0.05 \)) 1 month postoperatively, after which it fell off to normal values 3 and 12 months after operation. The GSRS scores were good in all subgroups postoperatively, especially regarding reflux syndrome, where scores were significantly \( (P < 0.05) \) better than on medical treatment.

In conclusion: After laparoscopic antireflux surgery, patients had good quality-of-life scores, better than untreated patients and as good as or better than on optimal medical treatment. Different treatment regimens could be discriminated by adding the patients' view of the treatment effect. We suggest that quality-of-life effects should be included when evaluating new regimens in laparoscopic surgery.

Key words: Esophagitis — Fundoplication — Gastroesophageal reflux — General well-being — Laparoscopy — Quality of life

With the introduction of laparoscopic cholecystectomy, laparoscopic surgical procedures have gained enormous interest and recognition [20, 23]. New potential areas for these procedures, like hernia, appendectomy, bowel resections and antireflux surgery, are presently being evaluated in clinical trials. Fundoplication for gastroesophageal reflux disease seems to be an ideal procedure for laparoscopy since it does not involve opening of the intestine and laparoscopy gives a better view of the operative field than is possible with open surgery.

If surgical procedures are to be generally accepted it is important to make a proper evaluation of these procedures. This has to include postoperative results, safety, cost, and Quality of Life (QoL) evaluations [10].

At the Department of Surgery, NAL, Trollhättan, Sweden, we have since May 1992 operated upon 95 consecutive patients laparoscopically, of which nine have been converted to open surgery. This study presents our early experiences with QoL evaluations in the first 40 consecutive patients operated upon with this procedure.

Materials and methods

Forty consecutive patients were treated with the laparoscopic 360° Rosetti fundoplication. All patients had a long history of symptomatic erosive esophagitis demanding continuous acid reduction with omeprazole 20–60 mg daily (or high H2-receptor-blocking doses in patients allergic to omeprazole). All patients were ‘responders’ to acid reduction—i.e., the treatment relieved them of most or all of their reflux symptoms. Preoperative investigations included evaluation of gastroesophageal reflux symptoms, QoL, upper GI endoscopy, 24-h esophageal manometry, and pH monitoring.

Operative technique

the laparoscopic 360° Rosetti fundoplication is performed as identically as possible compared to conventional open surgery. The crura and distal esophagus are first dissected free under strict visual guidance. The short gastric vessels are normally not divided. A posterior hiatal repair is performed with a nonabsorbable suture. The 360°
Table 1. Dimensions in the GSRS questionnaire

<table>
<thead>
<tr>
<th>Syndrome</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea syndrome</td>
<td>Increased passage of stools, Loose stools, Urgent need for defecation</td>
</tr>
<tr>
<td>Indigestion syndrome</td>
<td>Borborygmus, Abdominal distension, Eructation, Increased flatus</td>
</tr>
<tr>
<td>Constipation syndrome</td>
<td>Decreased passage of stools, Hard stools, Feeling of incomplete evacuation</td>
</tr>
<tr>
<td>Abdominal pain syndrome</td>
<td>Abdominal pain, Sucking sensations, Nausea</td>
</tr>
<tr>
<td>Reflux syndrome</td>
<td>Heartburn, Acid regurgitation</td>
</tr>
</tbody>
</table>

fundoplication is performed by pulling part of the fundus behind the esophagus. The fundoplication is completed when the fundus, pulled behind the esophagus, is connected to the major curvature high on the corpus/fundus with three nonabsorbable sutures. During the operation, a 36F tube is inserted in the esophagus and we make sure there is plenty of space beside the esophagus with the tube inserted both in the hiatus and the fundoplication. The result is a floppy fundoplication 1.5–2 cm long.

Postoperatively patients have strict routines. They start taking fluids the day after surgery and are recommended to stay on fluid nutrition 2–4 weeks postoperatively. After this, they start eating solid food, chewed carefully.

QoL evaluations

For QoL evaluations two well-validated self-administered questionnaires were used.

Psychological General Well Being (PGWB) Index. This index was initially developed to provide an instrument that could be used for measuring subjective well-being or distress [6]. It is extensively documented with respect to reliability and validity. It has been used in several clinical studies [4–6, 8, 11] and has well-documented values in normal populations. The PGWB protocol includes 22 items, divided into six dimensions: anxiety (nervousness, tension, anxiety, relaxedness, stress), depressed mood (depressed, downhearted, sad), positive well-being (general spirits, happy, interested in daily life, cheerful), self-control (firm control, afraid of losing control, emotionally stable), general health (bothered by illness, healthy enough to do things, concerned about health), vitality (energy, wakes feeling rested, vigorous, tiredness). Each dimension comprises three to five items (see above) using a six-point Likert scale, which gives a maximum score of 132 and a minimum of 22. The highest the value, the better the patient. The mean scores in the reference population are 101 for females and 103 for males.

Gastrointestinal Symptom Rating Scale (GSRS). The GSRS is designed to evaluate a wide range of gastrointestinal symptoms [4, 5, 24]. The questionnaire includes 15 items and uses a seven-point Likert scale. The items are grouped into five dimensions (syndromes): diarrhea syndrome, indigestion syndrome, obstipation syndrome, abdominal pain syndrome, and reflux syndrome (Table 1). The highest score, 7, denotes the most pronounced symptoms and 1 indicates no symptoms.

The questionnaires were given to the patients at clinical visits before the decision concerning surgery was made, at 1 and 3 months after surgery, and finally after 8–12 months postoperatively together with other questions concerning the effect of the operation. The distribution and collection of questionnaires was administered by an assistant nurse with extensive experience in such matters at our department. She checked the questionnaires and contacted the patients if needed for completion and if the questionnaires were missing. This person is also responsible for collection of data concerning adverse postoperative events (such as infection, thrombosis, etc.), which have been followed for 1 month for all inhouse operations at our clinic for 4 years.

The QoL values were also compared with earlier investigated patients with untreated reflux esophagitis (n = 192), with our patients during medical treatment (n = 52), and with a group of patients primarily treated with open fundoplication using the Nissen 360° (n = 32) or Rosetti 360° (n = 30) fundoplication.

Statistics

For comparisons between the groups of patients, a 95% confidence interval was constructed by using the mean square error in the ANOVA table together with quartiles from the Student t distribution.

Results

Preoperative patient characteristics

The first 40 consecutive patients with completed laparoscopic fundoplication were investigated. The mean age was 48 years, the mean weight was 83 kilos, 75% were males, the mean LES pressure was 4.2 cm H2O, and the mean % pH < 4 was 14%. Six patients had Barret’s esophagus. The primary symptom complex in all patients was heartburn, demanding omeprazole or very high doses of H2 blockers (in patients allergic to omeprazole) for symptom relief for at least 12 months prior to operation.

Postoperative results

Peroperative complications were very few. One patient had subcutaneous emphysema and one a postoperative pneumonia. Minor problems with local pain in trocar holes were also noted in some patients.

Postoperatively all patients have been followed for 12 months with symptom control. Thirty-nine patients were completely cured of their heartburn. One additional patient was initially cured but had a relapse of heartburn after 4 months. Dysphagia to some degree was found in all patients at 1–3 months if they were asked specifically. At 12 months 14 patients (35%) had dysphagia, 10 mild and 4 moderate, but none had daily symptoms. In the patients’ overall assessment 37 of 40 were satisfied with the operative result. Three patients were not completely satisfied.

QoL evaluations

The mean PGWB score preoperatively, during optimal medical treatment, was 101.0 (compared to 85 for untreated patients before reflux esophagitis diagnosis [11]). One month postoperatively the mean score increased significantly to 114.1 (P < 0.05). At 3 and 8–12 months the scores were 103.1 and 103.1 (n.s., compared to medical treatment) (Fig. 1). The GSRS was administered preoperatively and after 1 month, 3