



# Assessment of quality of life after laparoscopic GERD surgery in children: a prospective study

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## Abstract

The purpose of this study is to assess quality of life (QoL) after laparoscopic anti-reflux surgery (LARS) in children with gastroesophageal reflux disease (GERD) and to evaluate GERD symptoms and their impact on daily life and school. From June 2016 to June 2019, all children with GERD from 2 to 16 years of age, without neurologic impairment or malformation-related reflux, were prospectively included in a monocentric study. Patients (or their parents according to the age of the child) answered the Pediatric Questionnaire on Gastroesophageal Symptoms and QoL (PGSQ) before surgery and 3 and 12 months after surgery. Variables were compared by paired, bilateral Student *t*-test. Twenty-eight children (16 boys) were included. The median age at surgery was 77 months (*IQR*: 59.2–137) with median weight of 22 kg (*IQR*: 19.8–42.3). All had a laparoscopic Toupet fundoplication. Median duration of follow-up was 14.7 months (*IQR*: 12.3–22.5). One patient (4%) had a recurrence of GERD symptoms without abnormalities on follow-up examinations. Preoperative total PGSQ score was 1.42 ( $\pm 0.7$ ) and decreased significantly 3 months ( $0.56 \pm 0.6$ ;  $p < 0.001$ ) and 12 months after surgery ( $0.34 \pm 0.4$ ;  $p < 0.001$ ). PGSQ subscale analysis revealed a significant decrease at 3 and 12 months for GERD symptoms ( $p < 0.001$ ), impact on daily life ( $p < 0.001$ ), and impact on school ( $p = 0.03$ ).

**Conclusion:** There was a significant improvement in symptoms and their frequency after LARS in children, as well as an improvement of QoL, in the short and medium term. The impact of GERD should be taken into consideration in the treatment decision, given that surgery clearly improves the QoL.

## What is Known:

- Laparoscopic anti-reflux surgery (LARS) is an established and effective treatment option in pediatric patients with severe GERD refractory to medical treatment.
- Effect of LARS on the quality of life (QoL) has been mainly investigated in the adult population but there is very little data on the effect of LARS on the QoL in pediatric patients.

## What is New:

- Our prospective study was the first to analyze the effect of LARS on QoL in pediatric patients without neurologic impairment using validated questionnaires at two postoperative time points with a significant improvement in postoperative QoL at 3 and 12 months.
- Our study emphasizes the importance of evaluating QoL and impact of GERD on all the aspects of daily life and of taking these into consideration in the treatment decision.

**Keywords** Gastroesophageal reflux · Laparoscopic fundoplication · Children · Quality of life · PGSQ · GERD surgery

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## Abbreviations

GER	Gastroesophageal reflux
GERD	Gastroesophageal reflux disease
HRQoL	Health-related quality of life
LARS	Laparoscopic anti-reflux surgery
PGSQ	Pediatric Questionnaire on Gastroesophageal Reflux Disease Symptom and Quality of life
QoL	Quality of life

## Introduction

Gastroesophageal reflux (GER) is defined as retrograde passage of gastric content into the esophagus with or without regurgitation/vomiting. GER is a physiologic process occurring frequently in infants and children, as opposed to GERD (gastroesophageal reflux disease) which is one of the most common foregut disorders, defined by the joint recommendations from the European and North American Pediatric Gastroenterology Societies [1] as “GER leading to troublesome symptoms that affect daily functioning and/or complications such as esophagitis or stricturing,” impacting 7–20% of the pediatric population [2, 3].

Fundoplication is one of the most commonly performed upper gastrointestinal procedures in pediatric patients. Laparoscopic anti-reflux surgery (LARS) is an established and effective treatment option in pediatric patients with severe GERD refractory to medical treatment [4]. Nissen fundoplication is the standard laparoscopic surgical procedure for the management of GERD in children. Partial fundoplications such as Toupet’s procedure seem to be associated with a lower incidence of postoperative dysphagia and thus a better quality of life for patients without neurological impairment [5].

Improving health-related quality of life (HRQoL) is increasingly recognized as an essential part of patient care. Effect of LARS on the HRQoL has been mainly investigated in the adult population [6, 7], but there is very little data on the effect of LARS on the QoL in pediatric patients.

The aim of our study was to assess QoL after laparoscopic anti-reflux surgery in children with GERD (3 and 12 months after surgery), using a validated questionnaire evaluating GERD symptoms and their impact on daily life and school.

## Materials and methods

### Study design

From June 2016 to June 2019, all children with GERD from 2 to 16 years of age, without neurologic impairment or malformation-related reflux, referred for GERD surgery in the pediatric surgery department of Caen University Hospital, were prospectively included in a monocentric study. Before study procedures, informed consent was obtained from the patients’ caregivers and children. All patients had been referred for anti-reflux surgery by a pediatrician/pediatric gastroenterologist because of therapy-resistant gastroesophageal reflux symptoms (well-conducted PPI therapy by omeprazole 1–4 mg/kg/day or esomeprazole 10 mg/day if weight < 20 kg or 20 mg/day if weight > 20 kg, sometimes combined with sodium alginate during at least 8 weeks as

recommended by Rosen et al. [1], with symptoms despite PPI). All patients underwent a preoperative workup (esophageal pH monitoring, endoscopy, or upper gastrointestinal series), and all had well-documented GERD.

### Surgical procedures

All patients were operated with the same protocol. An open laparoscopic approach to the abdominal cavity was done, with opening of the umbilicus and introduction of a 5-mm optical trocar. Three operating trocars of 3 mm were used, one at the subxiphoid level to expose the hiatal region and two at the right and left flank level. Partial fundoplication laparoscopy according to Toupet (270° posterior wrap) was performed without dividing the short gastric vessels. All procedures were performed by a single pediatric surgeon (TP) with > 20 years of experience in pediatric laparoscopic surgery. The position of the trocars and the dissection phase were similar in all the procedures.

### Clinical assessment

Patients (or their parents according to the age of the child) answered the Pediatric Questionnaire on Gastroesophageal Reflux Disease Symptom and Quality of life (PGSQ) [8] before surgery and at 3 and 12 months after laparoscopic anti-reflux surgery, during postoperative appointments. All patients underwent a postoperative upper gastrointestinal series, performed at 3 and 12 months postoperatively, as part of the usual follow-up after this type of operation in our center, in order to verify the surgical setup.

### GERD and quality of life questionnaire

The PGSQ [8] is a reliable and valid tool for parental and child’s self-report on QoL. The PGSQ was developed in 2 age-stratified versions to assess pediatric GERD. These include the PGSQ-Cp (for children aged 2 to 8 years, parent/caregiver report) and the PGSQ-A (for adolescents aged 9–17 years). For the purpose of this study, the PGSQs were translated from English to French using the forward translation/backward translation process followed by a preliminary pilot testing. The PGSQ provides subscales for symptom burden, impact on everyday life, school impact (if applicable), and a total score, with 36 items for the PGSQ-Cp (for children aged 2 to 8 years, parent/caregiver report) and 34 items for the PGSQ-A (for adolescents aged 9–17 years) (Table 1). For each item, respondents are asked to evaluate the frequency of events over the past 7 days on a 5-point Likert scale from 0 to 4 (never, almost never, sometimes, almost always, always). Scores are then averaged for each domain: symptoms score, everyday life impact score, and school score. Higher PGSQ subscale scores

**Table 1** Description of the different categories making up the PGSQ. QoL: quality of life

PGSQ — sections	PGSQ-Cp	PGSQ-A	Score
Symptoms score	17 items	15 items	0–4
Everyday life impact score	13 items	13 items	0–4
School score	6 items	6 items	0–4
<b>Total</b>	<b>36 items</b>	<b>34 items</b>	

represent more frequent symptoms and more severe impact on QoL. The total PGSQ score is calculated as the sum of the symptoms and everyday life impact subscales divided by the number of items for these sections. School impact was not included in the total score, since not all patients in the study were of school age. Higher total PGSQ scores are indicative of worse QoL. This self-report questionnaire can be completed in 10 min and, therefore, fulfills the goal of brevity sought in clinical research.

### Statistical analysis

Continuous variables were described by mean (standard deviation) or median (interquartile range) according to their distribution. Qualitative variables were described by numbers (percentage). Variables were compared by a paired, bilateral Student *t*-test for quantitative variables, and chi-squared test for qualitative variables. We compared the quality-of-life score at different time intervals to M0 (Student's *t*-test for paired series) in the entire population and by age group, then by sections, and by age group for each score. Differences with a *p* value < 0.05 were considered statistically significant. Statistical analysis was performed using R 3.4.3 (R Foundation for Statistical Computing).

### Ethics committee approval

The study protocol was approved by the Ethics Committee of the French Pediatric Society (*CER\_SFP\_2018\_089*).

## Results

### Clinical data

Between June 2016 and June 2019, 28 children underwent laparoscopic anti-reflux surgery in our center, and all accepted to participate in the study. There was no drop-out during follow-up. Sixteen were boys (57%). Twenty patients (71%) were younger than 8 years old. Seven patients (25%) had a congenital anomaly allowing their inclusion (2 interatrial communications, 1 mitral regurgitation, 1 solitary kidney, 1 Scimitar syndrome, 1 cystic fibrosis, 1 infant skull fracture).

### Preoperative time

Twenty-five patients (89%) had a clinical history of neonatal GERD and 4 patients (14%) a history of esophagitis. Medical background and clinical history are described in Table 2. Digestive and extra-digestive symptoms are described in Table 3. At preoperative workup, 27 patients (96%) had an upper gastrointestinal series, 11 (39%) had pH monitoring, and 16 (57%) had an endoscopy. The results of preoperative workup are indicated in Table 4.

### Postoperative time

Median age at inclusion was 77 months (*IQR*: 59.3–137) and median weight was 22 kg (*IQR*: 19.8–42.3). No surgical conversion was necessary. Median operative time was 73 min (*IQR*: 60–77.5). No perioperative complications were observed. Median duration of hospital stay was 3 days (*IQR*: 2–3), including the operative day. Median duration of follow-up was 14.7 months (*IQR*: 12.3–22.5). At 3 months, 4 patients had symptoms of dysphagia, 3 had retching, 5 had abdominal pain, and one suggesting dumping. At 12 months, only one patient had dysphagia, one had abdominal pain, and one had dumping. All upper gastrointestinal series, performed at 3 and 12 months postoperatively, showed the absence of gastroesophageal reflux.

Only one patient (4%) had a recurrence of GERD symptoms without abnormalities on follow-up examinations

**Table 2** Baseline characteristics of the patients

	Median ( <i>IQR</i> )
<b>Age at the time of operation (months)</b>	77 (59.3–137)
<b>Weight at the time of operation (kg)</b>	22 (19.8–42.3)
<b>Duration of hospital stay (days)</b>	3 (2–3)
	<i>n</i> (%)
<b>Male gender</b>	16 (57)
<b>Toupet fundoplication</b>	28 (100)
<b>Congenital anomalies</b>	7 (25)
<b>Past medical history, comorbidities</b>	
Neonatal GERD	25 (89)
Esophagitis	4 (14)
Asthma	5 (18)
Pulmonary (other than asthma)	16 (57)
ENT	18 (64)
Allergies	4 (14)
Dermatological	3 (11)
Ophthalmological	2 (7)
Renal	2 (7)
Cardiological	3 (11)
Past surgery	11 (39)

**Table 3** Digestive and extra-digestive symptoms before gastroesophageal reflux surgery

Symptoms	n (%)
<b>Digestive symptoms</b>	
Heartburn	15 (54)
Regurgitation	14 (50)
Abdominal/epigastric pain	9 (32)
Halitosis	7 (25)
Feeding refusal/failure to thrive	7 (25)
Nausea	5 (18)
Dysphagia	2 (7)
<b>Extra-digestive symptoms</b>	
Bronchitis/wheezing	13 (46)
Recurrent otitis	12 (43)
Laryngitis	8 (29)
Chronic cough	7 (25)
Pneumonia	6 (21)
Sleeping troubles	3 (11)
Dental erosion	2 (7)

(esophageal pH monitoring and upper gastrointestinal series). None of the patients required redo-surgery.

**Quality-of-life analysis**

Twenty-eight patients answered PGSQ questionnaire at baseline (M0), 27 patients at 3 months (M3), and 26 patients

**Table 4** Results of preoperative workup

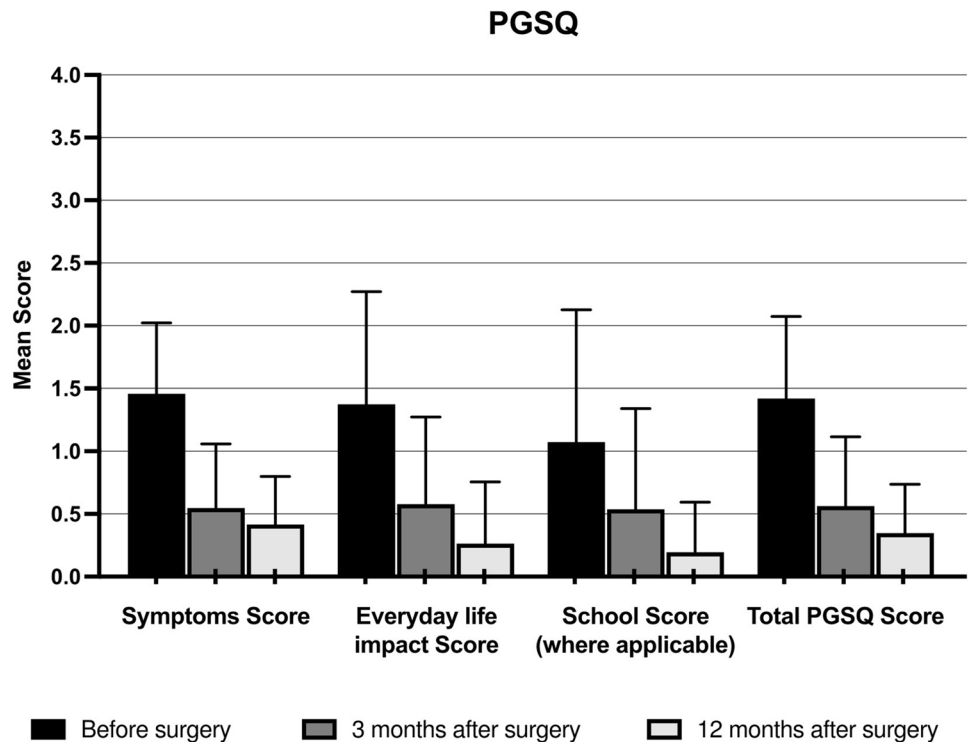
Preoperative workup	n = 28 (%)
<b>pH monitoring</b>	11 (39)
<b>Upper gastrointestinal series</b>	27 (96)
GERD	24 (86)
• Anatomical abnormality	17 (61)
• Angle of His anomalies	12 (43)
• Loose cardia	7 (25)
• Hiatal hernia	4 (14)
<b>Endoscopy</b>	16 (57)
• Esophagitis	9 (32)
• Esophagitis and gastritis	5 (18)
• Loose cardia only	2 (7)

at 12 months (M12). The median duration of follow-up was 14.7 months (IQR: 12.3–22.5).

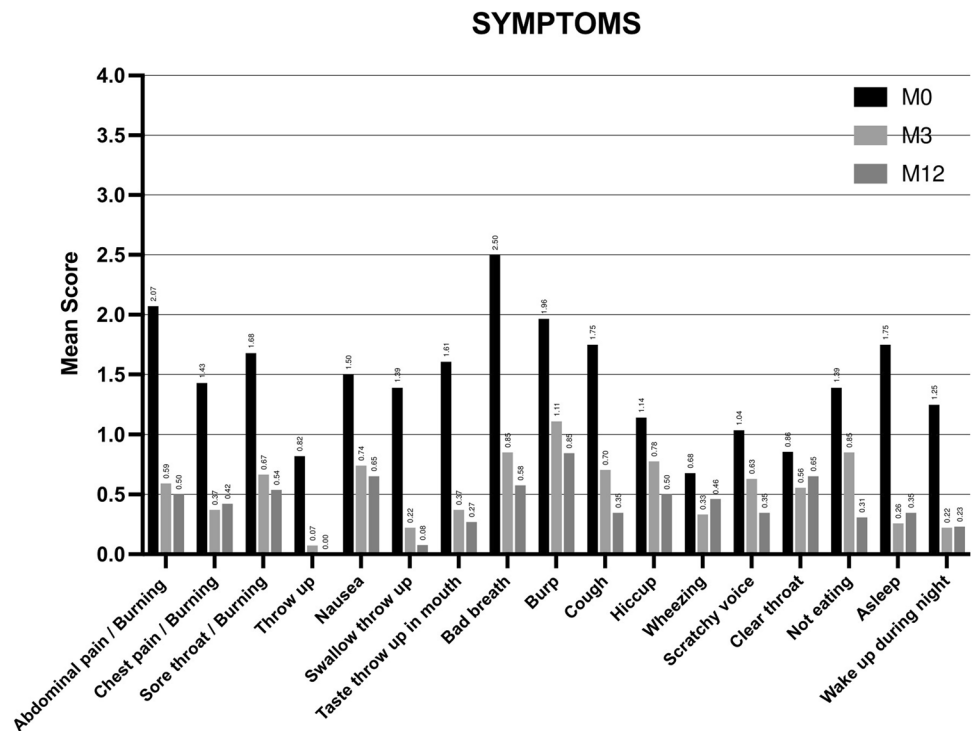
Preoperative total PGSQ score was 1.42 (±0.7) and decreased significantly to 0.56 (±0.6; *p* < 0.001) at 3 months after surgery and to 0.34 (±0.4; *p* < 0.001) at 12 months after surgery.

PGSQ subscale analysis revealed a significant decrease at 3 months and 12 months (Fig. 1). Preoperative symptoms score was 1.46 (±0.6) and decreased significantly to 0.55 (±0.5; *p* < 0.001) at 3 months after surgery and to 0.42 (±0.4; *p* < 0.001) at 12 months after surgery. The symptoms items of the PGSQ are described in Fig. 2. Preoperative everyday life impact score was 1.38 (±0.9) and decreased significantly to 0.58 (±0.7; *p* < 0.001) at 3 months after surgery

**Fig. 1** Comparison of quality of life (QOL) measures before surgery and at 3 and 12 months after laparoscopic anti-reflux surgery. Mean scores (± standard deviation) are shown for total and subscores of the Pediatric Gastroesophageal Symptom and Quality of Life Questionnaire (PGSQ)



**Fig. 2** Description of *symptoms* before surgery and at 3 and 12 months after laparoscopic anti-reflux surgery. Mean scores are shown for each symptoms item of the Pediatric Gastroesophageal Symptom and Quality of Life Questionnaire (PGSQ)



and to 0.26 ( $\pm 0.5$ ;  $p < 0.001$ ) at 12 months after surgery. When it was applicable, preoperative school impact score was 1.08 ( $\pm 1.1$ ) and decreased significantly to 0.54 ( $\pm 0.8$ ;  $p = 0.02$ ) at 3 months after surgery and to 0.20 ( $\pm 0.4$ ;  $p = 0.003$ ) at 12 months after surgery (Table 5 and Fig. 1).

**Discussion**

GERD is frequent, impacting 7–20% of the pediatric population [2, 3]. In most infants and children, symptoms will resolve spontaneously with growth, with an estimated prevalence of GERD in infants 0 to 23 months of 2.2 to 12.6%, compared to 0.6 to 4.1% for children 2 to 11 years old, and 0.8% to 7.6% for adolescents 12 to 17 years old [9]. However, some patients will require surgical treatment due to persisting symptoms or complications of GERD. According to guidelines, anti-reflux surgery may be considered in children when GERD is refractory to optimal medical management [1]. LARS for the treatment of GERD in children was first described in the early 1990s and has become the gold

standard procedure as surgical treatment of children with GERD, with a low rate of recurrence and low morbidity [10]. Several studies showed laparoscopic surgery to be a safe and effective treatment for GERD with good results on symptom resolution and a low failure rate, ranging from 4 to 20% [11, 12]. However, the evidence regarding the efficacy of this procedure is controversial and limited with a lack of standardized means to measure outcomes. Results of GERD laparoscopic surgery in children are mainly based on retrospective series in which diagnosis of GERD, preoperative workup, and indication are often missing. Patient’s groups are heterogeneous, incomparable from one study to another, with variable proportions of neurological patients and children with malformative GERD, which can influence indication and patient outcomes. Our patient population is very homogenous, involving non-neurological patients without malformative GERD, in a prospective study, which is rare in the current literature. It was important for the outcomes, thus making it possible to compare patients. Our study confirms the good results of laparoscopic GERD surgery. We reported a very low reflux recurrence rate with only one patient with

**Table 5** Mean value of section scores PGSQ ( $\pm$  SD\*) = ( $\pm$  standard deviation)

PGSQ — Sections	Mean M0 $\pm$ SD	Mean M3 $\pm$ SD	p value	Mean M12 $\pm$ SD	p value
Symptoms score	1.46 $\pm$ 0.6	0.55 $\pm$ 0.5	<0.001	0.42 $\pm$ 0.4	<0.001
Everyday life impact score	1.38 $\pm$ 0.9	0.58 $\pm$ 0.7	<0.001	0.26 $\pm$ 0.5	<0.001
School score	1.08 $\pm$ 1.1	0.54 $\pm$ 0.8	0.02	0.20 $\pm$ 0.4	0.003
Total PGSQ score	1.42 $\pm$ 0.7	0.56 $\pm$ 0.6	<0.001	0.34 $\pm$ 0.4	<0.001

clinical symptoms without paraclinical abnormality (4%) without surgical revision.

This study was not designed to compare the effects of surgical techniques, i.e., Nissen or Toupet. The choice of partial or complete wrap remains controversial, and to date, evidence does not demonstrate superiority of one or the other technique [13, 14]. Laparoscopic Toupet fundoplication has been said to reduce troublesome dysphagia and gas-related symptoms. Recently, Broeders et al. demonstrated that laparoscopic Toupet fundoplication in adult reduces postoperative dysphagia and dilatation for dysphagia compared with laparoscopic Nissen fundoplication [15]. Reoperation rate and prevalence of gas-related symptoms were lower after Toupet fundoplication, with similar reflux control [15]. The practice of our center is to limit Nissen fundoplication indications to patients requiring concomitant gastrectomy, in order to insure complete reflux control. In children without neurological impairment, including those in our study, a laparoscopic Toupet fundoplication is carried out in order to reduce postoperative dysphagia.

The effectiveness of surgery for GERD and improvement of HRQoL is essential for a functional surgery. In adults, most longitudinal studies have observed a lasting effect of LARS on long-term QoL, with an approximate 95% satisfaction rate in patients with chronic GERD [1, 16]. Marlais et al. have shown a significantly reduced QoL in children and adolescents with GERD compared with both healthy children and children with inflammatory bowel disease [17].

Prospective pediatric studies of LARS are scarce, and concern the long-term efficacy without assessment of QoL. To our knowledge there are currently very few data on the improvement of HRQoL after GERD surgery in pediatric patients. According to Cullis et al., seven studies reported assessment of validated QoL measures before and after anti-reflux surgery in 148 children [18]. In children, only a few studies observed an improvement in QoL, with an assessment between 1 and 6 months after laparoscopic GERD surgery [19–21]. Our study is one of the few to analyze prospectively the effect of laparoscopic GERD surgery on QoL in children using validated questionnaires, with a significant improvement in postoperative QoL at 3 months and 12 months. A medium-term assessment, at 1 year after surgery, is one of the strengths of our study compared to others currently available. Stellato et al. demonstrated that although laparoscopic fundoplication is an effective therapy in terms of reflux symptom control in children over 2 and 5 years old, the positive effect on QoL may decrease over time [22, 23]. In these studies, with the same patients, they confirm that reflux symptoms are still improved after surgery but with a decline in symptom-free patients over time. The initial increase in QoL shortly after LARS appears to decline over time. However, their study included patients with and without neurologic impairment, and neurologic impairment was

the only factor that was significantly related to QoL: children without neurologic impairment scored 28.8 points higher in their study. Our prospective study was the first to analyze the effect of LARS on QoL in pediatric population without neurologic impairment using validated questionnaires at two postoperative time points.

Indeed, there is another study showing satisfactory results of anti-reflux surgery in non-neurological patients, with a comparison to a group of control patients, however this study concerning a retrospective evaluation, using a non-specific GERD questionnaire, the PedsQL [24].

Most of our patients were in school, allowing a more objective QoL assessment as well as the daily impact of GERD, including on school. Two other studies with longer follow-up found a sustained improvement but did not use validated questionnaires [14, 25]. There is currently no or few standardized instruments for children and parents' assessment of QoL, with variation in postsurgical outcomes in both children and parents, as suggested by Pilli et al. [26]. We chose the PGSQ instrument for few reasons: both age-stratified versions of the PGSQ are able to identify and quantify important GERD symptoms and their effects on children's lives and, critical to application in clinical trials, demonstrated responsiveness to changes in clinical status. Younger children are generally more suggestible, so queries from parents or clinicians regarding a specific symptom may be biased toward affirmative responses, thereby decreasing the reliability of the symptoms that are reported by the child with GERD. Validated symptom questionnaires that are related to specific age groups are needed for achieving reliability [27]. Our no refusal rate suggested that parents are very interested in participating in this type of research. The absence of missing data showed that the instrument is user-friendly and easy to complete.

Our study emphasizes the importance of evaluating QoL and impact of GERD on all the aspects of daily life, and of taking these into consideration in the treatment decision. Quality of life is mainly linked to the symptoms, regardless of the acid index on the pH-impedance study. This parameter adds to the debate that anti-reflux surgery can be indicated not only for esophageal complications (esophagitis, etc.) but also in case of disabling symptoms. This should be taken into consideration in the treatment decision, especially since surgery appears to clearly improve the QoL.

There are, however, several limitations of our study. First, it is a study in a single center, with small size, it could be considered as a limiting factor. Most studies on effects of LARS, especially those in children, are quite small. Likewise, there are several missing data on items concerning school. Some children were not in school (age < 3 years) or completed the questionnaire during vacation period, thus reducing the number of responses for these items. To limit these, we excluded these data from the total score to homogenize our results.

Finally, we do not yet have long-term data for our study and a 5-year evaluation seems necessary.

All these results show a significant improvement in symptoms and their frequency after laparoscopic anti-reflux surgery in children, as well as an improvement of quality of life, in the short and medium term. The effectiveness of surgery for GERD and GERD-related QoL is essential for a functional surgery. We confirm this benefit with our study. We recommend that the impact of GERD on all the aspects of daily life should be taken into consideration in the treatment decision, especially since surgery appears to clearly improve the QoL. Long-term assessment seems necessary to confirm this observed benefit and is ongoing in our center, with a further evaluation planned at 5 years from surgery.

**Supplementary Information** The online version contains supplementary material available at <https://doi.org/10.1007/s00431-023-04897-2>.

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**Authors' contributions** Dr Haffreingue conceptualized and designed the study, collected data, drafted the initial manuscript, and reviewed and revised the manuscript. Dr Dolet carried out the initial analyses and reviewed and revised the manuscript. Drs Dupont-Lucas, Marret, Petit, and Rod conceptualized and designed the study, coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content. All the authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

**Data availability** The data that support the findings of this study are available from the corresponding author (AH), upon reasonable request.

## Declarations

**Competing interests** The authors declare no competing interests.

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