*Original Article*

# Long-term Outcomes of Children with Gastroesophageal Reflux Disease Who Underwent Fundoplication: A Single Center Experience

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***Background:*** Fundoplication is indicated in patient with gastroesophageal reflux disease (GERD) who need long-term medication, fail to response to optimal medication therapy, or have life-threatening complication.

***Objective:*** To evaluate the outcome of GERD patients at 12 months after fundoplication.

***Materials and Methods:*** This retrospective study includes children who were diagnosed GERD and underwent fundoplication between January 2006 and December 2018 at King Chulalongkorn Memorial Hospital. Studied outcomes were the need of antireflux medications, prevalence of persistent symptoms, GERD-related hospitalization rate, re-operation rate, and mortality rate at 12 months after fundoplication.

***Results:*** Overall, 59 patients (49% male) were included in the present study. The median age (IQR) at the time of GERD diagnosis and fundoplication was 11 (5 to 48) and 18 (8 to 66) months, respectively. All children had comorbid conditions, the most common of which was neurological impairment (n = 48, 81%). Fifty-seven and 2 patients underwent Nissen and Thal fundoplication, respectively. At 12-month follow-up, 30 (51%) were prescribed antireflux medications and 25 (42%) had persistent GERD symptoms. The median (IQR) hospitalization rate was 2.5 (2 to 3) times/year. Only 1 (1.7%) patient, who had esophageal atresia and tracheoesophageal fistula, underwent reoperation due to fundoplication disruption. There were 9 deaths (15.3%). Causes of death were GERD-related aspiration pneumonia (n = 1), sepsis (n = 5), hospital-acquired pneumonia (n = 2), and recurrent ependymoma (n = 1).

***Conclusion:*** Most patients with GERD who have comorbid conditions have persistent symptoms and need continuing antireflux medications after fundoplication. Therefore, long-term follow-up of GERD patients following fundoplication is essential, particularly those at risk of a high failure rate of fundoplication.

***Keywords:*** Children, Fundoplication, Gastroesophageal reflux disease, GERD, Outcome

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Gastroesophageal reflux (GER), defined as passage of gastric contents into the esophagus with or without regurgitation and vomiting, is a common problem in infancy. The symptom usually resolves without intervention in 95% of infants by age 1 year[1]. Gastroesophageal reflux disease (GERD) occurs when GER leads to troublesome symptoms that affect daily functioning and/or complications, such as esophagitis, hematemesis, malnutrition, feeding or sleeping problems, chronic respiratory disorders, apnea, or brief resolved unexplained event[2,3].

Treatment options of GERD comprise lifestyle modification, antireflux medications, and surgery. Indication for surgical treatment of GERD include acute life-threatening event caused by GERD, chronic aspiration, malnutrition, or persistent symptoms in spite of optimal medication[1]. High risk patients for refractory GERD include those with neurological impairment, obesity, esophageal anatomic disorder, chronic respiratory disorder, and prematurity[1]. Fundoplication is the most common antireflux procedure performed in patients with refractory GERD.

There are numerous reports about the efficacy of antireflux operations in the treatment of GERD in children[4-18]. Most reports showed good results and rather a small number of major complications. One large multicenter study in almost 7,500 children with GERD undergoing fundoplication, with a mean follow-up period of 7.4 years, revealed good to excellent results were achieved in 95% of neurologically normal (NN) and 85% of

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neurologically impaired (NI) patients[18]. In contrast, a retrospective study on 119 children undergoing fundoplication showed that 18% required redo fundoplication and 54% were recommenced on antireflux medications with 42% postoperative complication at 6-month follow-up[11].

The purpose of the present study was to evaluate the clinical outcomes of children with GERD at 12 months after fundoplication.

## Materials and Methods

The retrospective study was based on chart review. Study subjects were children aged below 18 years who were diagnosed GERD by clinical suspicion and/or positive diagnostic testing and underwent fundoplication at King Chulalongkorn Memorial Hospital between January 2006 and December 2018. We collected patients from hospital database system using International Classification of Diseases-9 code 44-66, 44-67 for fundoplication and International Statistical Classification of Diseases and Related Health Problems-10 code K21.9 for GERD. We excluded patients who lost to follow-up and those who had cyanotic heart disease, congestive heart failure, or diaphragmatic hernia.

The following information was recorded:

1) Demographic data (age and gender)

2) Comorbidities

3) Preoperative data

3.1) Symptoms of GERD (gastrointestinal manifestations [e.g. vomiting, recurrent regurgitation, hematemesis, dysphagia, recurrent abdominal pain, feeding refusal, and heartburn] and extra-esophageal manifestations [e.g. recurrent pneumonia, stridor, wheezing, chronic cough, apnea, and malnutrition]).

3.2) Investigations (esophageal pH and impedance monitoring, esophagogastroduodenoscopy (EGD), upper GI study, and gastric emptying scintigraphy).

The positive result of tests was defined as follow:

Esophageal pH or combined pH-impedance monitoring: reflux index >10% for infants age <1 year and >4% for children age >1 year)[1].

EGD: presence of reflux esophagitis.

Upper GI study and gastric scintigraphy: presence of reflux from stomach to esophagus.

3.3) Medications.

3.4) GERD-related hospitalization rate.

4) Operative data (age, nutritional status, surgical technique, immediate post-fundoplication complication)

5) Postoperative data at 12-month post fundoplication (nutritional status, symptoms of GERD, investigation, antireflux medications, GERD-related hospitalization rate, re-operation rate, and death)

The study protocol was approved by the Institutional Review Board, Faculty of Medicine, Chulalongkorn University (IRB No. 080/62).

### *Statistical analysis*

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) software for Windows, version 21.0 (SPSS Inc., Chicago, IL). Descriptive statistics were calculated to evaluate the characteristics of the participants. Comparisons between groups were performed using t-test, Wilcoxon signed-rank, Chi-square test, or Fisher's exact test where appropriate. A *p*-value <0.05 was considered to be statistically significant.

## Results

### *Demographic data*

There were 75 children who underwent fundoplication between January 2006 and December 2018, 59 of which met the inclusion criteria. Demographic data and comorbid conditions are shown in Table 1. Thirty (50.8%) patients had more than one comorbid condition in addition to their GERD. The most common comorbid condition was neurological impairment (n = 48, 81.4%), which comprised of brain anomaly, convulsive disorder, and cerebral palsy. Respiratory disease, such as airway anomaly and chronic lung disease, was the second most common comorbid condition among study subjects (n = 23, 39%).

### *Subject characteristics at the time of GERD diagnosis*

Clinical characteristics are shown in Table 1. Recurrent pneumonia was the most common presenting symptoms, followed by regurgitation/vomiting and weight loss/poor weight gain. The median (IQR) preoperative GERD-related hospitalization rate was 3 (1 to 6) times/year.

Fifty-one (86.4%) patients underwent at least one of the diagnostic tests which yielded positive result in 90% of patients (Table 2). Regarding the treatment, all patients received advice about lifestyle modification. Antireflux medications, including proton pump inhibitors, $H_2$ receptor antagonists, and prokinetic agents, were prescribed preoperatively in all patients. The median duration of treatment with antireflux medications prior to operation was 5 (1 to 12) months.

### *Subject characteristics at the time of fundoplication*

The median age (IQR) at the time of fundoplication was 18 (8 to 66) months. The mean (SD) weight for age was 70.3% (18.2). Twenty-nine (49.2%) patients had a gastrostomy placement prior to fundoplication and 27 (45.8%) patients underwent a gastrostomy insertion concurrent with their fundoplication. Among 57 patients who underwent Nissen fundoplication, the technique was open in 54 and laparoscopic in 3 patients. Immediate postoperative complications were reported in 7 (11.9%) patients (4 wound infection/wound dehiscence, 1 urinary tract infection, 1 upper GI bleeding, and 1 esophageal perforation. The median length of stay was 23 (9 to 43) days.

### *Outcomes post-fundoplication*

At 12-month follow-up, 25 (42.4%) patients had persistent GERD symptoms. Thirty (50.8%) patients remained taking antireflux medications (Table 3), twenty-five patients had persistent symptoms at 12 months, and

five patients had no symptom at 12 months but during a decreasing dose of proton pump inhibitor. Eighteen (30.5%) patients underwent at least one of the follow-up tests (esophageal pH or combined impedance-pH monitoring, esophagogastroduodenoscopy, and gastric scintigraphy), which tested positive result in 5 of 18 (27.8%) patients. The median GERD-related hospitalization rate was 2.5 (2 to 3) times/year. Only 1 patient, who had esophageal atresia and tracheoesophageal fistula, underwent reoperation due to fundoplication disruption. Time to re-fundoplication after the first operation was 1 month. There were 9 deaths (15.3%). Causes of death were GERD-related aspiration pneumonia (n = 1), sepsis (n = 5), hospital-acquired pneumonia (n = 2), and recurrent ependymoma (n = 1).

Among 48 children with neurological impairment, 25 (52.1%) patients remained taking antireflux medications, and 21 (43.8%) patients had persistent GERD symptoms. There was no statistically significant difference of every studied outcome between neurologically impaired and neurologically normal patients (data not shown).

**Table 1.** Patient's characteristics at the time of GERD diagnosis

| Characteristics | Value |
|---|---|
| Median (IQR) age (month) | 11 (5 to 48) |
| Gender | |
| Male | 29 (49) |
| Comorbid conditions | |
| Neurological diseases | 30 (50.8) |
| Respiratory diseases | 7 (11.9) |
| Both neurological and respiratory diseases | 18 (30.5) |
| Esophageal atresia with tracheoesophageal fistula | 3 (5.1) |
| Pfeiffer syndrome | 1 (1.7) |
| Clinical presentations | |
| Regurgitation/vomiting | 49 (83.1) |
| Hematemesis | 12 (20.3) |
| Feeding refusal | 11 (18.6) |
| Wheezing | 8 (13.6) |
| Recurrent pneumonia | 51 (86.4) |
| Chronic cough | 3 (5.1) |
| Stridor/hoarseness | 11 (18.6) |
| Apnea | 6 (10.2) |
| Malnutrition | 45 (76.3) |
| Antireflux medications | |
| Proton pump inhibitors | 58 (98.3) |
| $H_2$ receptor antagonists | 2 (3.4) |
| Prokinetic agents | 57 (96.6) |

Data are expressed as number (%) unless specified

### *Comparison between pre- and post-fundoplication characteristics*

Subject characteristics at pre- and post-fundoplication are shown in Table 4. Although weight for age significantly increased after fundoplication, the prevalence of malnutrition (defined as weight for age of <90%) was not statistically different. GERD-related hospitalization rate tended to decline following fundoplication. There was no significant reduction of GERD symptoms after fundoplication.

### *Outcome of pediatric GERD patients undergoing fundoplication*

The comparison of post-fundoplication outcome among children with GERD is shown in Table 5.

## Discussion

Fundoplication has become an increasingly common procedure in children with GERD. It is the definitive therapy for persistently symptomatic GERD in infants and children refractory to optimal medical therapy. Since proton pump inhibitors have side effects especially when given for prolonged periods, fundoplication is also indicated in patients who need long-term PPIs[19,20]. The most frequent indications for fundoplication in the present study were respiratory symptoms regurgitation/vomiting, and malnutrition which were quite similar to a large multicenter study[18].

Patients with GERD who have underlying disorders, including neurological impairment and esophageal atresia are at risk of fundoplication failure. Esposito et al reported that all neurologically normal children with GERD were free of symptoms and only 3.7% patients required antireflux medications at over 5-year post-fundoplication[21].

**Table 2.** Preoperative tests and results

| | Total (%) | Positive (%) |
|---|---|---|
| Esophageal pH or combined impedance-pH monitoring | 28 (47.5) | 18 (64.2) |
| Esophagogastroduodenoscopy | 10 (16.9) | 7 (70.0) |
| Gastric scintigraphy | 17 (28.8) | 13 (76.5) |
| Upper GI study | 25 (42.4) | 19 (76.0) |

Koivusalo et al reported symptom control of GERD was achieved in 87% of patients (26% neurologically impaired) after fundoplication[17]. A prospective study in children with GERD (20% neurologically impaired) revealed the reduction of the use of acid-suppressive medication from 100% to 16%. Only 12% of patients had persistent/recurrent reflux symptoms at 3 months after fundoplication[12]. The efficacy of fundoplication in the present study was not as good as those reported in previous studies. Over 40% of patients still had persistent either esophageal or extra-esophageal GERD symptoms and around 50% remained taking antireflux medications in our study. This difference might be attributable to the higher prevalence of neurologically impaired in our study (81.4%) compared to those studies[12,17,21]. Furthermore, all patients in our study had at least 1 comorbid condition whereas 22% of enrolled subjects in the study reported by Koivusalo et al was healthy[17]. In contrast, a study on 119 children undergoing fundoplication reported that those who had comorbidity did not have a significantly higher need for redo fundoplication or need to recommence antireflux medications at 6-month follow-up[11]. A number of studies demonstrated excellent outcomes of fundoplication among neurologically impaired children.

**Table 3.** Outcomes at 12 months after fundoplication

| Characteristics | Value |
|---|---|
| Mean (SD) weight for age | 82.0% (22.8) |
| Symptoms | |
| Regurgitation | 8 (13.6) |
| Recurrent pneumonia | 11 (18.6) |
| Malnutrition | 16 (27.1) |
| The need of antireflux medications | |
| Proton pump inhibitors | 30 (50.8) |
| Prokinetic agents | 25 (42.4) |
| Median (IQR) hospitalization rate (time/year) | 2.5 (2 to 3) |
| Reoperation rate | 1 (1.7) |
| GERD-related mortality rate | 1 (1.7) |

Data are expressed as number (%) unless specified

Capito et al also reported 12% rate of recurrence GERD in children with neurological impairment[13]. A study in children age <2 years (59% developmental delay) showed that the resolution of GERD symptoms was achieved in 87.7% of patients[14].

When considering redo fundoplication as the outcome, there was only 1 child undergoing redo operation due to fundoplication disruption in the present study. This result is quite different from previous reports. The rate of redo fundoplication has been reported to be around 4 to 18% with a higher rate in neurologically impaired patients[11,15,18]. The low rate of redo fundoplication in spite of persistent GERD symptoms in our study may be explained by a short-term follow-up period and a high rate of continuing antireflux medications.

Although there was no significant reduction of GERD symptoms and hospitalization rate after fundoplication, our study demonstrated that the nutritional status of study subjects significantly improved. The substantial improvement of nutritional status in the present study was observed only among patients who underwent gastrostomy placement concurrent with fundoplication. Thus the better nutritional status might not be due to fundoplication per se. In contrast, a retrospective study on 76 neurologically impaired patients reported that nutritional status at 1-year after fundoplication significantly improved regardless of concomitant gastrostomy tube placement[22]. Nevertheless, gastrostomy placement concurrent with fundoplication was reported to be associated with a higher risk of being back on antireflux medications at 6-month follow-up[11].

Our study has some limitations. First of all, it was a retrospective study and thus the diagnosis of GERD was based on the presenting symptoms without confirmation by novel diagnostic tests such as combined esophageal multichannel intraluminal impedance and pH monitoring (MII-pH). Nevertheless, no gold standard exists for the diagnosis of GERD so far. The follow-up period after fundoplication in this study was only 12 months and thus delayed complications may be missing from the evaluation. In addition, there was no record about the adverse effects of long-term use of antireflux medications. Another limitation of this retrospective study was that it was unclear why antireflux medications was prescribed to some patients without GERD symptoms.

**Table 4.** The comparison between pre- and post-fundoplication characteristics

| Characteristics | Pre-fundoplication | Post-fundoplication | *p*-value |
|---|---|---|---|
| Mean (SD) weight for age | 73.2% (17.6) | 82.0% (22.6) | 0.005 |
| Prevalence of symptom, n (%) | | | |
| Regurgitation/vomiting | 49 (83.1) | 8 (13.6) | 0.17 |
| Recurrent pneumonia | 51 (86.4) | 11 (18.6) | 0.15 |
| Malnutrition | 45 (76.3) | 16 (27.1) | 0.40 |
| Median (IQR) hospitalization rate (time/year) | 3 (1 to 6) | 2.5 (2 to 3) | 0.06 |

**Table 5.** Outcome of pediatric GERD patients undergoing fundoplication: review of the literature

| | Pascoe (2016) | Mauritz (2017) | Gilger (2004) | Esposito (2006) | Rossi (2016) | Rosales (2018) | Koivusalo (2018) | Present study |
|---|---|---|---|---|---|---|---|---|
| Patients (n) | 119 | 25 | 176 | 238 | 162 | 106 | 277 | 59 |
| Neurological impairment (%) | 16.8 | 20 | 70 | 0 | 73 | 0 | 72 | 81.4 |
| Type of fundoplication (%) | | | | | | | | |
| Open/laparoscopic | 7.6/92.4 | 0/100 | 100/0 | 0/100 | 7/93 | 0/100 | 74/26 | 95/5 |
| Complete/partial* | 100/0 | 28/72 | 53/47 | 38/62 | 100/0 | 100/0 | 47/63 | 97/3 |
| Follow-up (months) | 6 | 3 to 4 | 2 | 60 | 7 to 101 | 24 | 12 | 12 |
| Outcome post fundoplication (%) | | | | | | | | |
| The need of antireflux medication | 53.8 | 16 | 63 | 3.7 | 40 | Not specified | 29 | 50.8 |
| Persistent GERD symptoms | 48 | 12 | 63 | 3.7 | 34.2 | 12.3 | 13 | 42.4 |
| Reoperation rate | 17.6 | 4 | 18 | 2.6 | 14 | 1 | 7 | 1.7 |
| Mortality rate | Not specified | Not specified | 1.5 | 0 | 4 | 4.7 | 0.3 | 15.3 |

* Complete fundoplication: Nissen technique; partial fundoplication: Thal, Toupet and Boix Ochoa technique

## Conclusion

Although patients with GERD who have comorbid conditions have persistent symptoms and need continuing antireflux medications after fundoplication, they tend to have improved nutritional status and decreased hospitalization. Long-term follow-up of GERD patients following fundoplication is essential, particularly those at risk of a high failure rate of fundoplication.

## What is already known on this topic?

High risk children for refractory GERD include those with neurological impairment, chronic respiratory disorder, esophageal anatomic disorder, and prematurity. Fundoplication is the most common antireflux procedure performed in children with refractory GERD.

## What this study adds?

The outcome following fundoplication in pediatric patients with GERD who have neurological impairment and chronic respiratory disease shows conflicting results. The present study emphasizes the high failure rate of fundoplication among patients with GERD who have these comorbid conditions. Most of them have persistent symptoms and need continuing antireflux medications after fundoplication.

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## ผลลัพธ์ระยะยาวของการผ่าตัด fundoplication ในผู้ป่วยเด็กโรคกรดไหลย้อน: ประสบการณ์จากหนึ่งสถาบัน

สุภาวดี สวัสดิ์แก้ว, ไพศาล เวชชพิพัฒน์, กตเวที เดชอรัญ, วรนุช จงศรีสวัสดิ์

***ภูมิหลัง:*** Fundoplication เป็นการผ่าตัดที่ใช้รักษาผู้ป่วยโรคกรดไหลย้อนที่จำเป็นต้องรับประทานยารักษาเป็นระยะเวลานาน ผู้ที่ไม่ตอบสนองต่อการรักษาด้วยยา หรือผู้ที่มีภาวะแทรกซ้อนที่คุกคามชีวิต

***วัตถุประสงค์:*** เพื่อประเมินผลลัพธ์ของการผ่าตัด fundoplication ในผู้ป่วยโรคกรดไหลย้อนที่ 12 เดือนหลังการผ่าตัด

***วัสดุและวิธีการ:*** การศึกษานี้เป็นการศึกษาย้อนหลังในผู้ป่วยเด็กที่เป็นโรคกรดไหลย้อนที่รักษาด้วยการผ่าตัด fundoplication ระหว่างเดือนมกราคม พ.ศ. 2549 ถึงเดือนธันวาคม พ.ศ. 2561 ที่โรงพยาบาลจุฬาลงกรณ์ ผลลัพธ์ของการผ่าตัดที่นำมาวิเคราะห์ประกอบด้วยการรับประทานยารักษาโรคกรดไหลย้อน ความชุกของอาการของโรคกรดไหลย้อน อัตราการนอนโรงพยาบาลที่สัมพันธ์กับโรคกรดไหลย้อน อัตราการผ่าตัดซ้ำ และอัตราตายที่ 12 เดือนหลังการผ่าตัด

***ผลการศึกษา:*** มีผู้ป่วยที่นำมาศึกษารวม 59 ราย (เพศชายร้อยละ 49) ค่ามัธยฐาน [พิสัยระหว่างควอร์ไทล์] ของอายุที่ได้รับการวินิจฉัยโรคกรดไหลย้อนและรักษาด้วยการผ่าตัด fundoplication เท่ากับ 11 (5 ถึง 48) และ 18 (8 ถึง 66) เดือนตามลำดับ ผู้ป่วยทุกคนมีโรคร่วมโดยพบความผิดปกติของระบบประสาทมากที่สุด (จำนวน 48 คน, ร้อยละ 81) ผู้ป่วยจำนวน 57 คนและ 2 คน ได้รับการผ่าตัด fundoplication ด้วยวิธี Nissen และ Thal ตามลำดับ เมื่อติดตามผลการรักษาไปที่ 12 เดือนหลังการผ่าตัด พบว่าผู้ป่วยจำนวน 30 คน (ร้อยละ 51) ยังรับประทานยารักษาโรคกรดไหลย้อน และจำนวน 25 คน (ร้อยละ 42) ยังคงมีอาการของโรคกรดไหลย้อน อัตราการนอนโรงพยาบาลเท่ากับ 2.5 (2 ถึง 3) ครั้งต่อปี มีผู้ป่วยเพียง 1 คน (ร้อยละ 1.7) ซึ่งมีโรคร่วมเป็น esophageal atresia และ tracheoesophageal fistula ที่ต้องได้รับการผ่าตัดซ้ำเนื่องจาก fundoplication disruption มีผู้ป่วยจำนวน 9 คน (ร้อยละ 15) เสียชีวิต สาเหตุการตายแบ่งเป็นติดเชื้อในกระแสเลือดจำนวน 5 คน ปอดอักเสบจำนวน 3 คน และ recurrent ependymoma จำนวน 1 คน

***สรุป:*** ส่วนใหญ่ผู้ป่วยเด็กโรคกรดไหลย้อนที่มีโรคร่วมยังมีอาการของโรคกรดไหลย้อนและจำเป็นต้องได้รับยารักษาโรคกรดไหลย้อนภายหลังการผ่าตัด fundoplication ดังนั้นการติดตามอาการผู้ป่วยโรคกรดไหลย้อนในระยะยาวภายหลังการผ่าตัดจึงมีความสำคัญ โดยเฉพาะอย่างยิ่งในผู้ป่วยที่มีโอกาสสูงที่จะมีผลการรักษาไม่ดีหลังการผ่าตัด fundoplication