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Short-term parent reported recovery following open and laparoscopic fundoplication☆,☆☆

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ABSTRACT

Background: It is assumed that children recover faster after laparoscopic (LF) than after open fundoplication (OF). As this has not been confirmed in any randomized study (RCT), we have in a subsection of a larger RCT compared parent reported recovery of children after LF and OF.
Methods: Postoperative symptoms, use of analgesics, overall well-being, and time to return to school/day-care were recorded in a subsection of children enrolled in a RCT comparing LF and OF. Ethical approval and parental consent were obtained.
Results: Fifty-five children (LF: n = 27, OF: n = 28) of the 88 enrolled in the RCT, were included in the short term follow up on parent reported recovery. Caregivers were interviewed median 28 days [interquartile range (IQR) 22–36] postoperatively. There was no significant difference regarding improvement in overall well-being (LF: 63%, OF: 68%, p = 0.70), new-onset dysphagia (LF: 30%, OF: 18%, p = 0.08), use of analgesics (LF: 15%, OF: 14%, p = 1.00), or time to return to school/day-care (LF: median 7 days [IQR 5–14] vs. OF: 12 days [IQR 7–15], p = 0.35).
Conclusion: We could not demonstrate faster recovery after LF than after OF. Most children had returned to school/day-care after 2 weeks and had improved overall well-being 1 month after surgery.
Type of study: Randomized controlled trial.
Level of evidence: Level II.

Laparoscopic fundoplication (LF) has almost uniformly replaced open fundoplication (OF) in children [1]. Shorter hospital stay, less postoperative pain, and fewer complications are highlighted as the main advantages of LF as compared to OF [2,3]. However, all randomized controlled trials (RCT) comparing LF and OF in children have failed to show these proposed benefits of LF [4–6]. The lack of superiority of LF in children concerning length of hospital stay, pain and complications contrasts what has been found in similar studies in adults [2,3,7–14]. It is, though, possible that previous studies in children have missed possible benefits of LF occurring soon after hospital discharge since no studies have compared such factors in children.

Postoperative recovery is increasingly recognized as an important outcome measure after surgery [15]. So far, there has not been much focus on recovery in the pediatric surgical literature. Recovery is a continuous process that may last for many weeks and is usually not complete when the patient is discharged from hospital [16]. During the recovery period, the process of wound healing and restoration to normal physical functioning occur [17]. Simultaneously, some patients may experience troublesome side effects of the operation or lack of resolution of the symptoms leading to surgery [18]. Because no previous studies have compared recovery after LF and OF in pediatric patients, the main aim of this study was to test the hypothesis that children

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operated by LF have faster recovery than those operated with OF when aspects of recovery such as elimination of gastroesophageal reflux disease (GERD) symptoms, overall well-being, troublesome postoperative symptoms, need for analgesics, and time to return to school or day-care, were compared. In addition, we wanted to obtain general information about the recovery period after fundoplication in order to give parents and patients evidence-based information about what to expect the first few weeks after discharge.

1. Material and methods

1.1. Inclusion and data collection

This is a substudy of a two-center, randomized, non-blinded, parallel-group study where the primary endpoint was to compare recurrence rate of GERD after LF and OF in children under 15 years [4,19]. One hundred five patients referred to tertiary university hospitals Rikshospitalet and Ullevål were eligible for inclusion in the RCT. Inclusion criteria were age < 15 years and GERD confirmed by 24-h pH monitoring and/or upper gastrointestinal contrast study. Exclusion criteria were parents not speaking Norwegian, multiple previous laparotomies hindering laparoscopy, and comorbidity deemed incompatible with laparoscopy. Patients were randomized in blocks of 10 (1:1 allocation ratio) using opaque envelopes prepared by the two senior authors (KB, RE). To reduce the risk of selection bias towards the end of each block, 10 additional markers were added to the envelope when only 3 markers remained. Randomization was performed the day before surgery. Demographics and preoperative symptoms were recorded in all patients as described in previous publications [4,19]. The operative procedure was identical except for abdominal access by laparoscopy or laparotomy, and has been described previously [4]. Based on feedback from parents during the early stages of the RCT, a semi-structured telephone interview with caregivers of patients to assess postoperative recovery were included in the protocol for patients operated from 2005. The interview was scheduled 1 month after surgery. The interviewer (CKK) had not been involved in the treatment of the patients. During the interview, elimination of GERD symptoms, dysphagia, retching, abdominal discomfort, use of analgesics, overall well-being, and time to return to school or day-care were documented. Elimination of GERD symptoms (vomiting, regurgitation and heartburn) was recorded as yes (1) or no (0). The caregivers were also asked to rate if the child's overall well-being was worse (0), unaltered (1) or better (2) compared to preoperatively. If the caregivers were unable to provide an answer, this was recorded as uncertain (3). The caregivers were also asked to list reasons for any change in overall well-being, and if uncertain, why. All answers were written down in free text and later categorized into the following categories: New-onset or worsened dysphagia, retching, pain, general discomfort, respiratory symptoms, reduced food intake, and poor sleep. Each patient could have more than one reason. New-onset dysphagia was defined as swallowing difficulties not present before the operation and was recorded as none (0), having to avoid certain types of food (1), only able to eat soft foods (2), only able to drink (3), or not applicable because the child was exclusively tube fed (4). Retching was categorized as either absent (0), new-onset (1), or persisting (2). Furthermore, persistent retching was recorded as decreased (1), unchanged (2), or increased (3) compared to preoperatively. Postoperative new-onset abdominal discomfort was recorded as none (0), mild (1), moderate (2), severe (3), or not able to assess (4). Use of analgesics was recorded as using (1) or not using (0). The type of analgesic, if used, was also recorded. Time to return to school or day-care was defined as the number of postoperative days spent at the hospital and at home after discharge. The caregivers were asked about reasons for time spent at home before resuming school or day-care. All answers were written down in free text and later categorized into the following categories; new-onset or worsened general discomfort, fatigue or dysphagia. More than one reason could be listed for each patient.

Neurological impairment (NI) was defined as a static or progressive, central or peripheral neurological condition associated with intellectual disability and/or functional impairment [20]. Postoperative complications were registered according to the Clavien-Dindo classification, and the comprehensive complication index (CCI) was calculated using www.assessurgery.com/calculator/ [21,22].

1.2. Ethics

The study was approved by the regional ethical committee for medical research, and participation was voluntary. Written and oral information about the study was given, and written consent obtained. The trial is registered at ClinicalTrials.gov, number NCT01551134.

1.3. Statistical analysis

Sample size was calculated for the primary outcome of detecting a difference in recurrence of GERD after LF and OF [19], and not for the secondary outcomes presented in this paper. Categorical data were compared using Pearson's X^2 test or Fisher exact test as appropriate and expressed by risk ratio (RR) and a 95% confidence interval, in addition to a p-value. Age, length of hospital stay, days to follow-up, CCI score, days until return to school or day-care, and days spent at home were not normally distributed and, therefore, analyzed by Mann Whitney U-test and expressed as median and interquartile range (IQR). To reduce the probability for false positives involved with performing multiple statistical tests, we did not analyze the different subgroups of postoperative complications or symptoms between LF/OF or Non-NI/NI. All statistical analyses were performed with IBM SPSS Statistics for Windows, version 25.0 (IBM, Armonk, NY). A p-value <0.05 was considered statistically significant.

2. Results

2.1. Patients and perioperative data

Inclusion of patients for the RCT started in 2003 and ended in 2009 (Fig. 1). Twenty patients had already been operated when the substudy on recovery was initiated in 2005. Two eligible patients were not included because a competent laparoscopic surgeon was not present at the time of randomization. In addition, 9 patients were excluded (parents did not speak Norwegian n = 1, comorbidity incompatible with laparoscopy n = 4, multiple previous laparotomies n = 4). One patient randomized to OF underwent fundoplication as part of a congenital hiatal hernia repair and was therefore excluded from analysis. Twelve caregivers were not interviewed either because they could not be reached by telephone or because the interviewer was not available to make the call. Hence, the caregivers of 55 patients (LF: 27 patients, OF: 28 patients) were successfully interviewed median 28 days [IQR: 22–36] postoperatively (LF: 30 days [IQR: 24–39] vs. OF: 25 days [IQR: 21–33], p = 0.09).

Demographics, preoperative symptoms, length of hospital stay, and postoperative complications occurring within 30 postoperative days were similar among those operated by laparotomy and laparoscopy (Table 1). Apart from more boys among the included patients, there were no significant differences included and non-included patients with regards to age, diagnosis, surgical access, or having a gastrostomy (Table 2).

2.2. Overall well-being, postoperative gastrointestinal symptoms, and use of analgesics

Sixty-six percent of the caregivers reported improved overall well-being of the child as compared to preoperatively. There were no significant differences between those who had an open or a laparoscopic operation or between non-NI and NI patients (Table 3). In

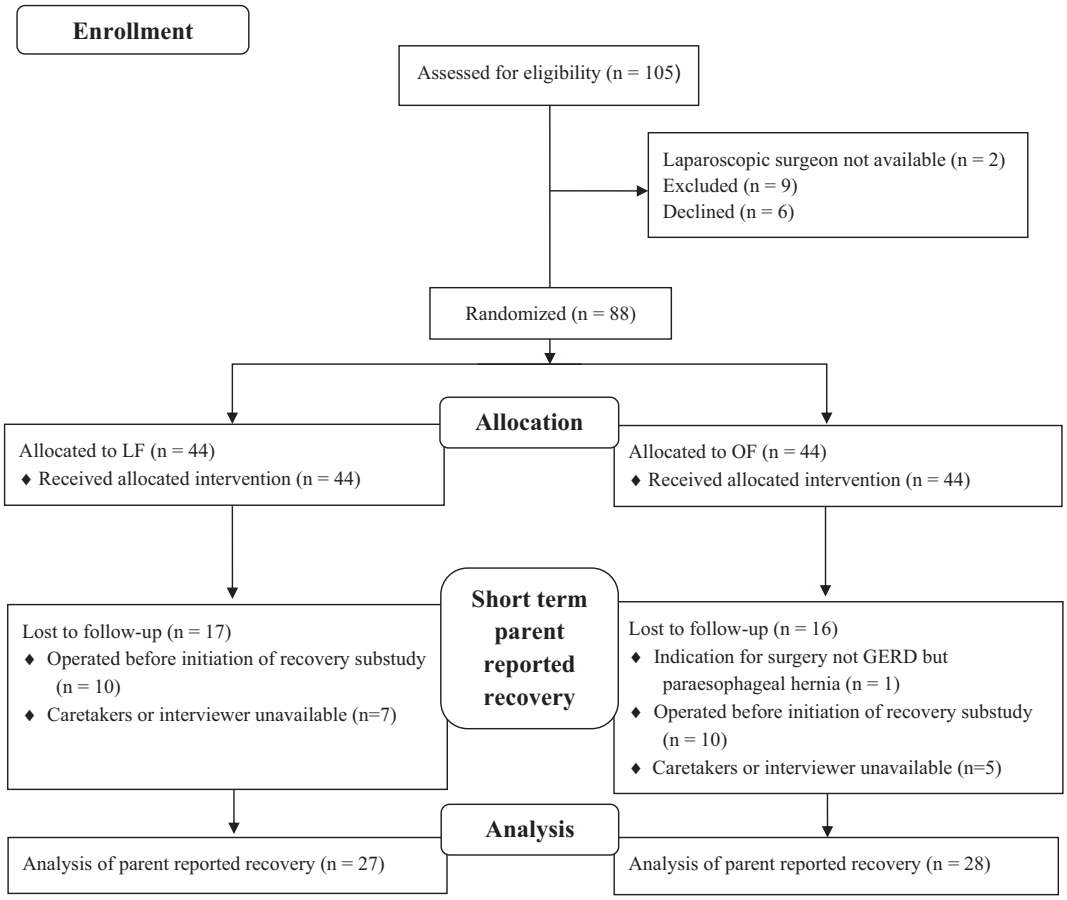

Fig. 1. CONSORT flow diagram for pediatric patients randomized to laparoscopic (LF) and open fundoplication (OF). GERD: Gastroesophageal reflux disease.

those nine patients who were reported to have impaired or uncertain overall well-being, the caregivers reported the following conditions to contribute; dysphagia (5 patients), unwillingness to eat (3 patients), retching and nausea (2 patients), general discomfort (2 patients), fatigue (1 patient), poor sleep (1 patient), and respiratory symptoms (1 patient).

Table 1
Demographics, preoperative symptoms, length of hospital stay, and postoperative complications occurring the first 30 days after Nissen fundoplication. Postoperative complications are graded according to the Clavien-Dindo classification (CD) and comprehensive complication index (CCI). The total number of complications is higher than the number of patients with complications because some patients had more than one complication.

	All (n = 55)	LF (n = 27)	OF (n = 28)	Non-NI (n = 26)	NI (n = 29)
Age at surgery, years, median [IQR]	4.3 [2.1–9.3]	4.6 [2.1–10.9]	4.0 [2.1–8.8][a]	4.8 [2.0–11.3]	3.6 [2.3–8.5][m]
Male/female, n/n	41/14	19/8	22/6[b]	22/4	19/10[n]
NI, n (%)	29 (53)	16 (59)	13 (46)[c]	N/A	N/A
Esophageal atresia, n (%)	3 (5)	2 (7)	1 (4)[d]	3 (12)	0 (0)[o]
Preoperative vomiting or regurgitation, n (%)	53 (96)	27 (100)	26 (93)[e]	25 (96)	28 (97)[p]
Preoperative dysphagia, n (%)	8 (15)	4 (15)	4 (14)[f]	4 (16)	4 (14)[q]
Not able to assess[¤], n (%)	20 (36)	9 (33)	11 (39)	1 (4)	19 (66)
Preoperative retching, n (%)	15 (27)	10 (37)	5 (18)[g]	3 (12)	12 (41)[r†]
New gastrostomy established during NF, n (%)	6 (11)	4 (15)	2 (7)[h]	2 (8)	4 (14)[s]
Gastrostomy present postoperatively, n (%)	32 (58)	17 (63)	15 (54)[i]	5 (19)	27 (93)[t†]
Length of hospital stay, days, median [IQR]	7.0 [4.0–12.0]	7.0 [4.0–11.0]	7.0 [4.0–12.8][j]	4.0 [4.0–6.3]	11.0 [7.0–14.0][u†]
Patients with complications, n (%)	31 (56)	16 (59)	15 (54)[k]	14 (54)	17 (59)[v]
CD grade I[*] complications, n (%)	15 (27)	8 (30)	7 (25)	10 (38)	5 (17)
CD grade II[#] complications, n (%)	20 (36)	11 (41)	9 (32)	4 (15)	16 (55)
CD grade IIIb[$] complications, n (%)	3 (6)	2 (7)	1 (4)	2 (8)	1 (3)
CCI, median [IQR]	8.7 [0.0–20.9]	8.7 [0.0–20.9]	8.7 [0.0–20.9][l]	8.7 [0.0–9.6]	20.9 [0.0–20.9][w]

LF, Laparoscopic Nissen fundoplication; OF, Open Nissen fundoplication; NF, Nissen fundoplication; NI, Neurological impairment; IQR, Interquartile range; N/A, Not applicable.
Risk ratio (95% Confidence interval) for categorical data and p values for each comparison between LF vs. OF: [a] p = 0.55, [b] RR: 0.90 (0.66–1.22), p = 0.46, [c] RR: 1.28 (0.77–2.12), p = 0.34, [d] RR: 2.01 (0.20–21.56), p = 0.61, [e] RR: 1.07 (0.97–1.19), p = 0.49, [f] RR: 0.94 (0.28–3.19), p = 1.00, [g] RR: 2.07 (0.82–5.28), p = 0.11, [h] RR: 2.07 (0.41–10.41), p = 0.42 [i] RR: 1.18 (0.75–1.84), p = 0.48, [j] p = 0.74, [k] RR: 1.11 (0.69–1.76), p = 0.67, [l] p = 0.48.
Risk ratio (95% Confidence interval) for categorical data and p values for each comparison between NI vs. Non-NI: [m] p = 0.95, [n] RR: 0.77 (0.57–1.06), p = 0.11, [o] RR: 1.13 (0.98–1.30), p = 0.10, [p] RR: 1.00 (0.91–1.11), p = 1.00, [q] RR: 2.5 (0.77–8.10), p = 0.19, [r] RR: 3.59 (1.14–11.32), p = 0.01, [s] RR: 1.79 (0.36–9.00), p = 0.67, [t] RR: 4.84 (2.19–10.71), p = <0.01, [u] p = <0.01, [v] RR: 1.09 (0.68–1.74), p = 0.72, [w] p = 0.24.
[¤] Because the child was exclusively tube-fed [*]Gastroenteritis, hematoma, wound infection, or feeding problems [#]Airway infections, gastrostomy infections, or blood transfusion [$]Food impaction requiring endoscopy, port site hernia, or leakage requiring redo gastrostomy [†]p < 0.05.

Table 2
Dropout analysis of patients not interviewed after randomization to laparoscopic (LF) or open (OF) Nissen fundoplication.

	Interviewed (n = 55)	Not interviewed (n = 33)	p
Age at surgery, years, median [IQR]	4.3 [2.1–9.3]	4.4 [1.5–7.6]	0.16
Male, n (%)	41 (75)	14 (45)	0.01
Neurological impairment, n (%)	28 (51)	15 (55)	0.74
Gastrostomy present postoperatively, n (%)	32 (58)	16 (48)	0.54
Esophageal atresia, n (%)	3 (6)	1 (1)	1.00
Laparoscopic Nissen fundoplication, n (%)	27 (49)	17 (52)	0.83

IQR, Interquartile range.

Table 3
Caregivers' assessment of their child's overall well-being after Nissen fundoplication compared to preoperatively.

	All (n = 55)	LF (n = 27)	OF (n = 28)	Non-NI (n = 26)	NI (n = 29)
Better, n (%)	36 (66)	17 (63)	19 (68)[a]	16 (61)	20 (69)[e]
Unchanged, n (%)	10 (18)	6 (22)	4 (14)[b]	4 (15)	6 (21)[f]
Impaired, n (%)	5 (9)	3 (11)	2 (7)[c]	3 (12)	2 (7)[g]
Uncertain, n (%)	4 (7)	1 (4)	3 (11)[d]	3 (12)	1 (3)[h]

LF, Laparoscopic Nissen fundoplication; OF, Open Nissen fundoplication; NI, Neurological impairment.
Risk ratio (95% Confidence interval) and p values for each comparison between LF vs. OF; [a] RR: 0.93 (0.63–1.36), p = 0.70, [b] RR: 1.56 (0.49–4.91), p = 0.50, [c] RR: 1.56 (0.28–8.60), p = 0.67, [d] RR: 0.35 (0.38–3.12), p = 0.61.
Risk ratio (95% Confidence interval) and p values for each comparison between NI vs. Non-NI; [e] RR: 1.12 (0.76–1.66), p = 0.56, [f] RR: 1.35 (0.43–4.24), p = 0.73, [g] RR: 0.60 (0.11–3.30), p = 0.66, [h] RR: 0.30 (0.03–2.70), p = 0.36.

All, but two patients were completely free from GERD symptoms at the time of the telephone interview (Table 4). One of these two patients did not experience relief of GERD symptoms after the operation, and later pH-monitoring showed a pathological reflux-index. The second patient had no symptoms, used no antacids and had a normal pH-monitoring at the scheduled follow-up 6 months postoperatively. There were no significant differences in new-onset abdominal discomfort, dysphagia, retching, or use of analgesics after LF and OF (Table 4). No children used opioid analgesics at follow-up. Apart from persisting retching (all grades) among NI children, there were no significant differences regarding postoperative gastrointestinal symptoms when comparing NI and non-NI patients (Table 4).

2.3. Return to school or day-care

Twenty-seven patients (LF: 12, OF: 15) attended school or day-care preoperatively. 83% (10/12 patients) and 100% (15/15 patients) of children operated by LF and OF, respectively, had resumed attending school or day-care at the time of the interview (RR: 0.83 (0.65–1.07), p = 0.19). Time to return to school or day-care was median 7.0 days [IQR: 5–14] after LF and 12.0 days [IQR: 7–15] after OF (p = 0.35). Six children were able to resume school or day-care the day after hospital discharge (LF: 2/12 patients vs. OF: 4/15 patients, RR: 0.63 (0.14–2.85), p = 0.66). Time spent at home after discharge before return to school or day-care was median 3.0 days [IQR: 1–10] (LF: 2.0 days [IQR: 1–10] vs. OF: 7.0 days [IQR: 0–10], p = 0.66).

The most common reason for needing time to recover at home after hospital discharge was dysphagia. New-onset or worsened dysphagia was more common for those operated laparoscopically (8/10 patients) than for those having OF (3/11 patients, RR: 2.93 (1.07–8.08), p = 0.03). General discomfort (LF: 2/10 patients vs. OF: 5/11 patients, RR: 0.44 (0.11–1.78), p = 0.36) and fatigue (LF: 1/10 patient vs. OF: 5/11 patients, RR: 0.22 (0.03–1.58), p = 0.15) were other reasons, with no significant differences between the groups.

3. Discussion

The main finding of this RCT subsection comparing LF and OF is that troublesome symptoms were common, but well-being had

Table 4
Gastrointestinal symptoms in children one month after Nissen fundoplication.

	All (n = 55)	LF (n = 27)	OF (n = 28)	Non-NI (n = 26)	NI (n = 29)
Elimination of GERD symptoms[¤], n (%)	53 (96)	26 (96)	27 (96)[a]	24 (92)	29 (100)[i]
Use of analgesics[*], n (%)	8 (15)	4 (15)	4 (14)[b]	3 (12)	5 (17)[j]
Abdominal discomfort, n (%)					
None	42 (76)	21 (78)	21 (75)[c]	20 (77)	22 (76)[k]
Mild	6 (11)	3 (11)	3 (11)	4 (15)	2 (7)
Moderate	1 (2)	1 (4)	0 (0)	0 (0)	1 (3)
Severe	2 (4)	0 (0)	2 (7)	2 (8)	0 (0)
Not able to assess	4 (7)	2 (7)	2 (7)	0 (0)	4 (14)
New-onset dysphagia, n (%)					
None	17 (31)	5 (18)	12 (43)[d]	12 (46)	5 (17)[l]
Avoid certain types of food	10 (18)	6 (22)	4 (14)	9 (34)	1 (3)
Only soft foods	1 (2)	1 (4)	0 (0)	1 (4)	0 (0)
Only liquids	2 (4)	1 (4)	1 (4)	2 (8)	2 (0)
Exclusively tube fed	25 (45)	14 (52)	11 (39)	2 (8)	23 (80)
Retching, n (%)					
None	29 (53)	12 (44)	17 (61)[e]	19 (73)	10 (34)[m†]
New-onset	14 (25)	8 (30)	6 (21)[f]	5 (19)	9 (32)[n]
Persisting	12 (22)	7 (26)	5 (18)[g]	2 (8)	10 (34)[o†]
Increased	5 (9)	4 (15)	1 (4)	1 (4)	4 (14)
Unchanged	4 (7)	2 (7)	2 (7)	1 (4)	3 (10)
Decreased	3 (6)	1 (4)	2 (7)	0 (0)	3 (10)
New-onset/worsened symptom, n (%)	32 (58)	18 (67)	14 (50)[h]	17 (65)	15 (52)[p]

LF, Laparoscopic Nissen fundoplication; OF, Open Nissen fundoplication; NI, Neurological impairment.
Risk ratio (95% Confidence interval) and p values for each comparison between LF vs. OF; [a] RR: 1.00 (0.90–1.11), p = 1.00, [b] RR: 1.04 (0.29–3.73), p = 1.00, [c] RR: 1.04 (0.81–1.34), p = 1.00, [d] RR: 0.55 (0.26–1.16), p = 0.08, [e] RR: 0.73 (0.44–1.22), p = 0.23, [f] RR: 1.38 (0.55–3.46), p = 0.46, [g] RR: 1.45 (0.52–4.02), p = 0.47, [h] RR: 1.33 (0.85–2.11), p = 0.21.
Risk ratio (95% Confidence interval) and p values for each comparison between NI vs. Non-NI; [i] RR: 1.02 (0.97–1-21), p = 0.22, [j] RR: 1.49 (0.40–5.65), p = 0.71, [k] RR: 1.14 (0.89–1.50), p = 0.47, [l] RR: 1.67 (0.97–2.86), p = 0.20, [m] RR: 0.47 (0.27–0.82), p = <0.01, [n] RR: 1.61 (0.62–4.20), p = 0.32, [o] RR: 4.48 (1.08–18.60), p = 0.02, [p] RR: 0.79 (0.51–1.24), p = 0.31.
[¤] Vomiting, regurgitation, and/or heartburn [*]Non-Steroid Anti Inflammatory Drugs or Paracetamol [†]p < 0.05.

improved in most children after 1 month regardless of operative approach. Furthermore, nearly all patients who attended school or day-care, were back at school or day-care by the first 2 weeks. Dysphagia was a common reason for having to stay at home after discharge and was the most common contributor to a decline in postoperative overall well-being. We did not demonstrate any difference in recovery after LF and OF.

The overall well-being of the children 1 month after the fundoplication did not seem to be influenced by the operative approach. Overall well-being incorporates the main contributors to recovery after fundoplication, including disappearance of GERD symptoms, resolution of pain, and lack of new troublesome symptoms related to the surgery and restoration of normal activity. Similar overall well-being after LF and OF has also been found in adults studies [2,3,23], but results from pediatric populations are lacking. Postoperative complications are a significant predictor of postoperative well-being [24], and the similar incidence of complications after LF and OF may partly explain similar overall well-being after LF and OF in this cohort. Furthermore, most of the caregivers in our study reported that their child's overall well-being had improved after the fundoplication even though symptoms related to the operation were common. This suggests that relief of GERD symptoms outweighs discomfort related to the surgical treatment.

Postoperative dysphagia was the most frequently reported reason for hindering children to attend school or day-care, as well as the most important contributor to impaired postoperative overall well-being. We did not find a statistical difference in the rate of postoperative dysphagia, although there was a trend towards more dysphagia after LF. Whether LF is associated with more or less dysphagia compared to OF is debated [25]. Increased incidence of dysphagia during the first 4 weeks after OF compared to LF was found in one pediatric cohort [26], whereas two RCTs in adult patients found more dysphagia after LF [11,12]. No definite explanation has been given to why laparoscopy may cause more postoperative dysphagia than OF, although the creation of a floppy wrap has been suggested to be more difficult when done laparoscopically [11]. To improve postoperative well-being, caregivers and patients should receive information on how adequate food intake may be facilitated as well as how discomfort related to dysphagia may be reduced.

We did not find any difference in new-onset or persistent retching after LF and OF. Long-term studies comparing retching after LF and OF exist, but results are conflicting [5,19]. We have not been able to identify any studies comparing the incidence of retching after LF and OF during the first few weeks after fundoplication. Children with NI had more preoperative retching than non-NI children, and this difference was also found postoperatively. However, the incidence of new-onset retching was not different between NI and non-NI patients. Retching has been found to be more frequent in the NI population before and after fundoplication [27,28], possibly because of hyperactive vagal reflexes [29]. We prescribed ondansetron liberally, encouraged caregivers to use small and frequent meals, and to frequently ventilate the gastrostomy if the child had one. These measures may have reduced the frequency of postoperative new-onset retching regardless of neurological status, and should be part of the preoperative information given to caregivers.

Children operated by laparotomy did not have more abdominal discomfort and did not use more analgesics than those operated by laparoscopy at the time of follow-up. This is in line with results from RCTs on LF and OF in adults finding no significant difference in abdominal or wound pain 1 month after surgery [2,30]. The majority of the children had no abdominal discomfort 1 month after the fundoplication. This contrasts findings in adults where abdominal discomfort after LF and OF was much more common [31]. It is, though, important to bear in mind that caregivers may have underreported abdominal discomfort [32]. Furthermore, it is possible that wound and visceral pain was more prevalent during the earlier stages of recovery and that recording of abdominal discomfort earlier in the postoperative period would have shown a difference between the two operative approaches [31].

Children operated by LF did not return significantly faster to school or day-care than those operated by OF. No comparable studies have been performed in children following fundoplication. A RCT comparing open and laparoscopic appendectomy in children did not find faster return to school after laparoscopy [33], contrasting studies in adults which show that those undergoing laparoscopic appendectomy have shorter sick leave [34]. In contrast to our data, adults undergoing LF needed 1 week shorter sick leave than those undergoing OF [35]. Apart from type 2 error, we can only speculate why LF and laparoscopic appendectomy did not result in faster return to school or day-care [33]. Since children need smaller laparotomy incisions than adults due to their size, they may have less postoperative pain than adults undergoing a similar operation and thereby recover faster [36]. The similar incidence of postoperative symptoms and complications may also be a reason for LF not having faster recovery than OF in our study.

The main strengths of this study are its randomized design, and that a person not involved in the treatment of patients, conducted the interviews. Furthermore, the different aspects of recovery were recorded simultaneously, which is important as patients may have recovered in some, but not all areas at the time of follow-up [18]. The most important limitation of this study is the small sample size, and the study may therefore be underpowered to detect significant differences in outcomes such as return to school or day-care, symptoms or well-being. Therefore, this study should be viewed as hypothesis generating, and not proof that there is no difference in recovery after LF and OF. Another limitation is the use of return to school or day-care as the only measure for duration of recovery. Since many of our patients were either permanently cared for at home or institutionalized, the duration of recovery for this important subgroup was not evaluated. Furthermore, as the caregivers were asked to remember the number of days the child was home from school or day-care, the answers are only as accurate as the parents' memories. As many NI children were exclusively tube fed and/or lacked the means to communicate, we lack data on dysphagia and abdominal discomfort for many in this subgroup. We were unfortunately not able to interview all patients that were randomized during the study period, and this may have introduced bias. However, the patients were missed at random, and apart form more males among those interviewed, no significant differences were found when comparing those interviewed with those who were not. Using a validated tool to assess postoperative symptoms and well-being would have strengthened the study. Unfortunately, no such tool has been validated for the age group 0–15 years, with and without NI, in Norwegian. However, a single-item scale for overall well-being has been shown to exhibit good responsiveness to change over time when the respondent is used as its own control, and has been used previously to assess recovery after pediatric surgical procedures [37,38].

In addition to compare recovery after LF and OF, this study gives surgeons detailed data on the postoperative course after Nissen fundoplication in children, both for neurologically normal and impaired patients. Consequently, these data may be used to give evidence-based preoperative information to both patients and caregivers. This is important as proper preoperative information ensures that caregivers and patients are prepared for the postoperative period. Preoperative information has the potential to alleviate both postoperative pain and anxiety and thereby improve postoperative recovery [39–41]. Although troublesome symptoms are common after fundoplication, caregivers may be assured that most children experience improved overall well-being 1 month after surgery. Furthermore, parents should be informed that many patients will need additional time to recover at home after discharge, and they should make plans to stay at home with their child. When conveying that some patients might not be fully recovered after 1 month, emphasis should be given on the fact that close to 100% seem better after 1 year [19].

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