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ORIGINAL SCIENTIFIC REPORT

Postoperative Small Bowel Obstruction Following Laparoscopic or Open Fundoplication in Children: A Retrospective Analysis Using a Nationwide Database

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Abstract

Background Postoperative small bowel obstruction (SBO) is one of the most serious adverse events resulting in deteriorated quality of life in children. Numerous studies have shown that laparoscopic surgery significantly reduces the occurrence of SBO compared with open surgery in adults. However, evidence of the advantages of laparoscopic surgery over open surgery in terms of reducing SBO is lacking in children. Fundoplication is a common abdominal procedure in children. This study was performed to compare the occurrence of SBO after laparoscopic fundoplication (LF) versus open fundoplication (OF).

Methods Using the Diagnosis Procedure Combination database, a national inpatient database in Japan, we retrospectively identified patients aged 0–18 years who underwent LF or OF from July 2010 to March 2016. Propensity score adjustment was used to compare the occurrence of SBO between the groups.

Results We identified 1838 eligible patients who underwent LF (n = 1362) or OF (n = 476). The median age at surgery was 4.0 and 1.5 years in the LF and OF group, respectively ($P < 0.001$). The median weight at admission was 11.4 and 7.5 kg, respectively ($P < 0.001$). Nineteen (1.4%) patients in the LF group and 13 (2.7%) in the OF group had at least one episode of SBO ($P = 0.11$, log-rank test). In the propensity score-adjusted Cox regression analysis, SBO was significantly less likely to occur in the LF than OF group (hazard ratio, 0.36; 95% confidence interval 0.16–0.82; $P = 0.01$).

Conclusions In this retrospective nationwide study, LF was significantly associated with a reduction in SBO compared with OF in children.

Introduction

Postoperative small bowel obstruction (SBO) is one of the most serious adverse events that deteriorate quality of life for children. A previous study showed that SBO was associated with high mortality rates [1]. The reported incidence of SBO in children varies widely, ranging from 1 to 6% [2–5].

Numerous studies have shown that laparoscopic surgery potentially reduces SBO compared with open surgery in adults [6–9]. However, only a few pediatric studies have assessed the occurrence of SBO between laparoscopic and open surgery, and the results of previous pediatric studies

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are controversial. A meta-analysis and several retrospective cohort studies of intestinal malrotation showed no significant difference in the occurrence of SBO between laparoscopic and open surgery [10, 11]. A previous study suggested that laparoscopic surgery was superior to open surgery in terms of reducing SBO [12]. However, the study failed to adjust for the type of operation, patient demographics, and clinical characteristics. Another study showed that laparoscopic surgery potentially reduced SBO in pediatric appendectomy [13], but the results cannot be generalized to other abdominal operations.

Fundoplication is one of the major surgical procedures performed in children [14]. We therefore conducted a study to compare SBO after pediatric fundoplication between laparoscopic and open surgeries with adjustment for patient backgrounds using a national inpatient database in Japan.

Materials and methods

Data sources

This was a retrospective nationwide cohort study performed using the Diagnosis Procedure Combination database. All 82 university hospitals are obliged to participate in the database, but participation by community hospitals is voluntary. The database includes the following data: unique hospital identifiers; patients' age, body weight, body height, and sex; diagnoses, comorbidities at admission and complications after admission recorded with text data in the Japanese language and the International Classification of Diseases, Tenth Revision (ICD-10) codes [15]; procedures; length of stay; and discharge status. All discharge abstract data for each patient are recorded at discharge by the attending physicians. A previous validation study showed good sensitivity and excellent specificity of diagnoses and procedure records in the database [16].

Because of the anonymity of the patient database, informed consent was waived for the current study. Study approval was obtained from the Institutional Review Board at The University of Tokyo.

Patient selection

We identified pediatric patients (0–18 years old) who underwent primary laparoscopic fundoplication (LF) or open fundoplication (OF) from July 2010 to March 2016. We used the Japanese original procedure codes for these surgeries to identify children who received them. We excluded patients who underwent both LF and OF during the same hospitalization and those who were diagnosed with bowel obstruction before undergoing fundoplication.

Outcomes

The primary outcome was the occurrence of SBO, which was recorded with the ICD-10 codes K565 (intestinal adhesions with obstruction), K566 (other and unspecified intestinal obstruction), or K913 (postprocedural intestinal obstruction). We first identified all children who underwent fundoplication and then searched for a subsequent hospitalization with SBO in the same hospital.

Baseline variables

We examined patient background factors including sex, age, body weight, body height, the number of complex chronic comorbidities, concurrent gastrostomy, year of operation, and the proportion of LFs among all fundoplications at each hospital. Age was categorized into the following four groups: 0 years (neonates/infants), 1–5 years (young children), 6–12 years (older children), and 13–18 years (adolescents). Body weight was categorized into the following four groups: $\leq$5.0, 5.1 to 10.0, 10.1 to 30.0, and $\geq$30.1 kg. We categorized body height into quintiles so that the number of patients in each group was almost equal (<60, 60–75, 76–91, 92–116, and $\geq$117 cm). The number of complex chronic comorbidities was counted using the Pediatric Complex Chronic Conditions Classification System version 2 [17]. The number of complex chronic comorbidities was classified as 0, 1, 2, or $\geq$3.

Statistical analyses

We used Fisher's exact test and the Chi-square test to compare proportions of categorical variables (such as sex), and we used the *t* test and Mann–Whitney *U* test to compare averages of continuous variables (such as age). We performed a log-rank test to compare the occurrence of SBO between the LF and OF groups.

An unadjusted comparison using observational data is often affected by confounding bias. Propensity score analyses are generally applied to control for measured confounding factors. We performed propensity score-adjusted Cox regression analysis to compare the occurrence of SBO to adjust for differences in the patient demographic characteristics and hospital characteristics between the LF and OF groups [18]. Propensity scores for undergoing LF were calculated using a logistic regression model. The predictor variables included age, sex, body weight, body height, number of complex chronic conditions, concurrent gastrostomy, year of operation, and proportion of LFs among all fundoplications at each hospital. We calculated the C-statistic to evaluate the goodness of fit.

The independent variables were the performance of LF or OF and the propensity scores. The absence of a violation of the proportional hazard assumption was determined using Schoenfeld residuals, which showed no violation of the proportional hazard assumption.

We also compared the occurrence of SBO between patients who underwent fundoplication with and without gastrostomy using Fisher's exact test. We used a significance level of $P < 0.05$ for all statistical tests, and all reported P values are two-sided. All statistical analyses were conducted using Stata/MP 14.0 (Stata Corp., College Station, TX, USA).

Results

We identified 1853 patients who underwent primary LF and OF during the study period. We excluded patients who underwent revision surgery for fundoplication because of recurrence ($n = 7$), those who underwent both LF and OF during the same hospitalization ($n = 1$), and those who were diagnosed with bowel obstruction before fundoplication ($n = 7$). We thus identified 1838 eligible patients (1362 who underwent LF and 476 who underwent OF).

Table 1 shows the patient demographics. Overall, there was no significant difference between the proportions of

Table 1 Demographics of the patients in the laparoscopic fundoplication and the open fundoplication groups

	Laparoscopic fundoplication (N = 1362)		Open fundoplication (N = 476)		Total (N = 1838)		P value
	n	%	*n*	%	*n*	%	
Sex							0.32
Male	797	58.5	266	55.9	1063	57.8	
Female	565	41.5	210	44.1	775	42.2	
Age (yr), median (IQR)	4.0 (1.5–9.4)		1.5 (0.6–4.8)		3.1 (1.2–8.6)		<0.001
							<0.001
Neonate/infant (<1 year)	214	15.7	180	37.8	394	21.4	
Early child (1–5 years)	564	41.4	181	38.0	745	40.5	
Late child (6–12 years)	368	27.0	73	15.3	441	24.0	
Adolescent (13–18 years)	216	15.9	42	8.8	258	14.0	
Body weight (kg), median (IQR)	11.4 (7.8–17.1)		7.5 (3.3–12)		10.3 (6.8–16)		<0.001
							<0.001
≤5.0 kg	128	9.4	160	33.6	288	15.7	
5.1–10.0 kg	432	31.7	166	34.9	598	32.5	
10.1–30.0 kg	742	54.5	142	29.8	884	48.1	
>30.1 kg	60	4.4	8	1.7	68	3.7	
Body height (cm), mean (SD)	91.7 (48.6)		72.1 (33.8)		86.6 (46.1)		<0.001
							<0.001
<60 cm	183	13.4	172	36.1	355	19.3	
60–75 cm	271	19.9	104	21.8	375	20.4	
76–91 cm	277	20.3	83	17.4	360	19.6	
92–116 cm	315	23.1	58	12.2	373	20.3	
≥117 cm	316	23.2	59	12.4	375	20.4	
Number of complex chronic conditions							<0.001
0	234	17.2	36	7.6	270	14.7	
1	452	33.2	113	23.7	565	30.7	
2	333	24.4	137	28.8	470	25.6	
≥3	343	25.2	190	39.9	533	29.0	
Concurrent gastrostomy	674	49.5	215	45.2	889	48.4	0.10
Proportion of LF among all fundoplications at each hospital							<0.001
Favors LF (≥30%)	1347	98.9	289	60.7	1636	89.0	
Favors OF (<30%)	15	1.1	187	39.3	202	11.0	
Follow-up period (days), median (IQR)	1030 (533–1511)		1264 (661–1699)		1109 (561–1582)		<0.001

IQR interquartile range, *LF* laparoscopic fundoplication, *OF* open fundoplication

Table 2 Number of patients with zero, one, or more episodes of postoperative intestinal obstruction

Number of episodes	All episodes				Episodes requiring surgery			
	Laparoscopic fundoplication(n = 1362)		Open fundoplication(n = 476)		Laparoscopic fundoplication(n = 1362)		Open fundoplication(n = 476)	
	n	%	n	%	n	%	n	%
0	1343	98.6	463	97.3	1358	99.7	470	98.7
1	15	1.1	11	2.3	3	0.2	6	1.3
2	3	0.2	1	0.2	1	0.1	0	0.0
≥3	1	0.1	1	0.2	0	0.0	0	0.0
All	19	1.4	13	2.7	4	0.3	6	1.3

Table 3 Propensity score-adjusted Cox proportional hazard model for postoperative intestinal obstruction in the laparoscopic fundoplication and the open fundoplication groups

	Hazard ratio	95% confidence interval	P value
Fundoplication			
Open surgery	Reference		
Laparoscopy surgery	0.36	0.16–0.82	0.01

male and female patients. The median (interquartile range) age at the time of the operation was 4.0 (1.5–9.4) years in the LF group and 1.5 (0.6–4.8) years in the OS group. The median follow-up period was 1030 (533–1511) days in the LF group and 1264 (661–1699) days in the OF group. The median body weight at admission was 11.4 (7.8–17.1) kg in the LF group and 7.5 (3.3–12) kg in the OF group ($P < 0.001$). The OF group had more patients with complex chronic conditions than the LF group. About 50% of the patients underwent gastrostomy with fundoplication in the LF group, and 45% of the patients underwent concurrent gastrostomy in the OF group.

Fifteen (1.1%) patients in the LF group and 11 (2.3%) in the OF group had one episode of SBO. Four (0.3%) patients in the LF group and two (0.4%) in the OF group had more than one episode of SBO. Four (0.3%) patients in the LF group and six (1.3%) in the OF group had an episode of SBO requiring surgery (Table 2). The cumulative percentages of patients with at least one episode of SBO were 1.4 and 2.7% in the LF and OF group, respectively ($P = 0.11$, log-rank test).

Table 3 shows the results of the propensity score-adjusted Cox regression. The C-statistic indicated that the goodness of fit of the propensity score model was 0.85. There was a significant difference in the proportion of SBO between the LF and OF groups (hazard ratio, 0.36; 95% confidence interval, 0.16–0.82; $P = 0.01$).

Table 4 shows the occurrence of SBO between fundoplication with and without gastrostomy in the LF and OF groups. In the LF group, there was a significant difference in the proportion of SBO between patients with and without gastrostomy (0.6 vs. 2.8%, respectively; $P < 0.001$). In the OF group, there was no significant difference in the proportion of SBO between patients with and without gastrostomy (1.9 vs. 3.4%, respectively; $P = 0.40$).

Discussion

This study compared SBO between children undergoing LF and OF using a large nationwide database, with adjustment for the patients' demographic and hospitals' characteristics. The propensity score-adjusted analysis showed that SBO was significantly less likely to occur in the LF than OF group.

Our results showed significant differences in the baseline characteristics between the groups, including age, body weight, body height, and number of complex chronic conditions. It is inappropriate to directly compare the crude proportions of SBO between the groups. Therefore, to control for confounding bias, we used propensity score-adjusted Cox regression analysis to compare the occurrence of SBO between the groups.

Several meta-analyses of SBO after colorectal surgery in adults have shown that the laparoscopic approach significantly reduced the occurrence of SBO and subsequent surgery for SBO compared with the open approach [6, 7]. Another study that adjusted for the type of operation and the patients' demographic and clinical characteristics reported the same result [9]. However, few reports comparing the incidence of SBO after laparoscopic versus open surgery exist in the literature, and even fewer such reports focus on pediatric patients. The advantage of laparoscopic surgery in reducing SBO in children remains controversial. Prior studies on intestinal malrotation showed no significant difference in the occurrence of postoperative SBO between laparoscopic and open surgery [10, 11]. Conversely, one retrospective cohort study showed that laparoscopic surgery was associated with a reduction in

Table 4 Postoperative small bowel obstruction between patients with and without gastrostomy in the laparoscopic and open fundoplication groups

Variables	Fundoplication with gastrostomy		Fundoplication without gastrostomy		P value
	n	%	*n*	%	
Laparoscopic fundoplication	1/674	0.1	18/688	2.6	<0.001
Open fundoplication	4/215	1.9	9/261	3.4	0.40
All	5/889	0.6	27/949	2.8	<0.001

SBO [12]. However, the outcomes of the study were not adjusted for the type of operation or the patients' demographic and clinical characteristics. In the present study, there were substantial discrepancies in the patients' demographic and complex chronic conditions between the LF and OF groups. Our propensity-adjusted comparison successfully adjusted for these conditions.

Previous studies of both adult and pediatric surgery have reported that the laparoscopic approach decreased postoperative pain, the duration of hospitalization, and postoperative complications and offered better esthetic results compared with open surgery [19–21]. The present study is the first to show that SBO is less likely to occur after LF than OF in children.

This study also showed that concurrent gastrostomy with fundoplication was significantly associated with a lower incidence of SBO. This may be plausible because gastrostomy confines the upper abdominal cavity, preventing both intestinal volvulus and adhesion between the upper abdominal skin incision and bowel.

Several limitations of this study should be acknowledged. First, we were not able to follow up patients across different hospitals in this database. Thus, we may have underestimated the occurrence of postoperative SBO. In Japan, however, most patients are hospitalized in the same hospital where the operation was performed. Second, we were unable to account for intraoperative conversion from the laparoscopic to open approach. However, a prior study reported that the conversion rate was very low [22]. Third, both LF and OF included various fundoplication techniques, but we could not confirm the details of the techniques used because of a lack of data. Fourth, fundoplication requires little intestinal manipulation. Future studies are needed to explore the occurrence of SBO after operations that require more intestinal manipulation (e.g., treatment of choledochal cysts, biliary atresia, and duplication of the alimentary tract).

Conclusion

In this retrospective nationwide study, LF was associated with a significantly lower incidence of SBO than was OF in children after adjustment for patient backgrounds. Our results provide new information for selective methods of fundoplication in the pediatric population.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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