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ORIGINAL ARTICLE

Impact of congenital heart disease on outcomes after primary repair of esophageal atresia: a retrospective observational study using a nationwide database in Japan

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Abstract

Purpose To verify the association between congenital heart disease (CHD) and postoperative complications after primary repair of esophageal atresia in patients from a Japanese nationwide database.

Methods We identified babies in the Diagnosis Procedure Combination database who underwent radical surgery for esophageal atresia from 2010 to 2016. We used multivariable logistic regression analyses to evaluate the occurrence of anastomotic leakage and anastomotic stricture.

Results Among 431 patients who underwent primary anastomosis, 114 patients (27%) had CHD. Anastomotic leakage occurred in 77 patients (17.9%) and stricture in 154 (35.7%). Compared with patients whose anesthetic duration was less than 240 min, those with anesthesia lasting from 240 to 360 min (odds ratio 2.49; 95% confidence interval (CI) 1.17–5.27; $p = 0.02$) or more than 360 min (odds ratio 4.10; 95% CI 1.69–9.96; $p = 0.002$) were more likely to experience anastomotic leakage. Male patients had a lower risk of anastomotic stricture than female patients (odds ratio 0.65; 95% CI 0.43–0.9; $p = 0.04$).

Conclusions CHD was not associated with anastomotic leakage or stricture. The only significant predictor of anastomotic leakage was duration of anesthesia.

Keywords Esophageal atresia · Congenital heart disease · Complications · Anastomotic leak · Anastomotic stricture

Introduction

Esophageal atresia (EA) is often associated with other anomalies, particularly congenital heart disease (CHD). Previous studies have reported that CHD is present in 13 to 42% of EA patients [1–3]. CHD, one factor in Spitz risk classification, increases the risk of mortality and lowers the survival rate after EA repair [4, 5]. However, mortality in high-risk groups has improved with advances in management during the perinatal and perioperative period [6–8]. The survival rate of Group II (bodyweight < 1500 g or CHD) and Group III (bodyweight < 1500 g and CHD) improved from 60 and 18% in 1996 to 82 and 50–67%, respectively. Low birth weight has less effect on mortality now than previously.

Pediatric surgeons focus on performing safe, effective, and minimally invasive procedures for neonates. The reported incidence of complications varies widely, including the incidence of anastomotic leakage (4–27%) and stricture (4–48%) [9–16]. Studies on the impact of CHD on these morbidities after EA repair are scarce.

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The aim of this study was to evaluate the association between CHD and anastomotic leakage and stricture using data from a national inpatient database in Japan.

Materials and methods

Data sources

This retrospective, nationwide cohort study used data from the Diagnosis Procedure Combination database, which has been described in detail elsewhere [17]. All 82 academic hospitals in Japan are required to participate in the database; participation by community hospitals is voluntary. The database includes the following data: unique hospital identifiers; patient's age, body weight, gestational age, and sex; diagnoses, comorbidities at admission, and complications after admission recorded with the codes of the International Classification of Diseases, Tenth Revision (ICD-10) [18] and text data in Japanese; surgical and nonsurgical procedures recorded with the original Japanese coding system; dates of each procedure; dates of administration of drugs, blood products, and device procedures; duration of anesthesia; length of stay; and discharge status. All discharge 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 [19].

Because this study was a secondary analysis of an anonymous patient database, the requirement for informed consent of each patient was not applicable. Study approval was obtained from the institutional review boards of the University of Tokyo.

Patient selection

We identified neonates (≤ 2 days old) who were admitted with a diagnosis of EA (ICD code: Q390, 391) and who underwent primary repair of EA from July 2010 to March 2016.

Outcomes

Outcome measures included: (i) anastomotic leakage and (ii) anastomotic stricture.

We defined anastomotic leakage as both a recorded diagnosis of anastomotic leak after admission and the need for continuous suction drainage for 3 weeks after radical surgery. We defined esophageal anastomotic stricture as the need for dilatation of any type (e.g., balloon dilation, bougienage) after surgery.

Baseline variables

We examined patient's background factors, including sex, age, gestational age (in weeks), body weight (at birth or admission), birth asphyxia, CHD, other associated malformations, duration of anesthesia, gastrostomy placement, and hospital volume.

Body weight was categorized into the following two groups: < 1500 g and ≥ 1500 g. Gestational age was categorized into two groups: < 37 weeks (preterm) and ≥ 37 weeks. Hospital volume was defined as the average annual number of radical operations for EA performed at each hospital and was categorized as high volume (≥ 4 cases) or low volume (< 4 cases). We categorized the duration of anesthesia for radical surgery as < 240 min, 240–359 min, or ≥ 360 min.

We identified the following associated malformations according to ICD-10 codes: any anomaly (Q0-Q99), respiratory system (Q30–34), digestive system (Q38–45), trisomy 21 (Q90), trisomy 18 (Q91.0–3), and trisomy 13 (Q91.4–7). We defined CHD according to ICD-10 code (Q20–26). We identified major CHD as CHD except for patent ductus arteriosus without operation [2].

Statistical analyses

We used Fisher's exact tests and chi-squared tests to compare the proportions for categorical variables and used *t* tests or Mann–Whitney *U* tests to compare averages or medians for continuous variables. We analyzed the occurrence of leakage and stricture only in patients who underwent radical surgery.

We performed multivariable logistic regression analysis to compare postoperative leakage between patients with versus without major CHD, with adjustment for the following items: patient sex, body weight, gestational age, and congenital anomaly (trisomy 18); duration of anesthesia for radical surgery; and hospital volume. We performed logistic regression analysis to compare the occurrence of anastomotic stricture between the 2 groups, with adjustment for the following items: patient sex, body weight, gestational age, leakage at radical surgery, duration of anesthesia for radical surgery, and hospital volume. We chose all covariates that were shown to be associated with the outcomes and that can be potential confounders from the clinical perspective [2, 16, 20–22]. We also adjusted for clustering within the hospitals using generalized estimating equations. We excluded patients with trisomy 18 because patients with trisomy 18 generally cannot ingest orally and are not likely to need intervention for stricture.

There were some missing values for gestational age and duration of anesthesia for radical surgery. We conducted a multiple imputation method for the multivariable analyses. We applied 20 imputed datasets, using the multivariate imputation by chained equations technique for missing data and the "mi impute chained" command in Stata. We combined the estimates from the 20 imputed datasets using Rubin's rules to obtain combined imputation estimates and standard errors with the Stata command "mi estimate: xtgee" for the analysis of anastomotic leak and anastomotic stricture [23]. We used a significance level of $p < 0.05$ for all statistical tests; all reported p values were two-sided. All statistical analyses were conducted with Stata/MP 15.0 (Stata Corp., College Station, TX, USA).

Results

We identified a total of 431 patients who underwent primary repair of EA and analyzed their data to identify risk factors for anastomotic leak and anastomotic stricture. Table 1 shows patients' characteristics. Additional anomalies were present in 257 patients (59.6%); 114 patients (26.4%) had major CHD. Only 54 patients (12.5%) underwent primary repair of EA at hospitals whose annual number of EA cases was 4 or more.

Table 2 shows a comparison of outcomes between patients with versus without major CHD. Anastomotic leakage occurred in 77 patients (17.9%); anastomotic stricture

Table 1 Characteristics of patients with primary repair of esophageal atresia

	Total ($n=431$)	Patients without major congenital heart disease ($n=317$)	Patients with major congenital heart disease ($n=114$)	p value
Patient characteristics				
Sex				
Male, n (%)	234 (54.3)	172 (54.3)	62 (54.4)	0.98
Body weight at admission, n (%)				
< 1500 g	22 (5.1)	18 (5.7)	4 (3.5)	0.37
≥ 1500 g	407 (94.4)	298 (94.0)	109 (95.6)	
Missing	2 (0.5)	1 (0.3)	1 (0.9)	
Gestational age, n (%)				0.29
Preterm (< 37 weeks)	136 (31.6)	99 (31.2)	37 (32.5)	
Term (≥ 37 weeks)	250 (58.0)	189 (59.6)	61 (53.5)	
Missing	45 (10.4)	29 (9.1)	16 (14.0)	
Severe birth asphyxia, n (%)	29 (6.7)	20 (6.3)	9 (7.9)	0.56
Congenital malformation, n (%)				
Any anomaly other than esophageal atresia	257 (59.6)	143 (45.1)	114 (100.0)	< 0.001
Heart disease	137 (31.8)	23 (7.3)	114 (100.0)	< 0.001
Respiratory system	43 (10.0)	27 (8.5)	16 (14.0)	0.09
Digestive system	134 (31.1)	93 (29.3)	41 (36.0)	0.19
Any chromosomal abnormality	21 (4.9)	9 (2.8)	12 (10.5)	0.001
Trisomy 21	7 (1.6)	3 (0.9)	4 (3.5)	0.08
Trisomy 13	0 (0.0)	0 (0.0)	0 (0.0)	–
Trisomy 18	11 (2.6)	4 (1.3)	7 (6.1)	0.01
Treatment				
Age at radical surgery (median [IQR])	0 (0–1)	0 (0–1)	0 (0–1)	0.76
< 31 days	422 (97.9)	311 (98.1)	111 (97.4)	0.70
≥ 31 days	9 (2.1)	6 (1.9)	3 (2.6)	
Gastrostomy (before or at time of radical surgery), n (%)	63 (14.6)	37 (11.7)	26 (22.8)	0.004
Catecholamine use, n (%)	263 (61.0)	173 (54.6)	90 (78.9)	< 0.001
Blood transfusion, n (%)	297 (68.9)	200 (63.1)	97 (85.1)	< 0.001
Annual hospital volume for esophageal atresia, n (%)				
≥ 4 cases	54 (12.5)	36 (11.4)	18 (15.8)	0.22
Follow-up period(days), median (IQR)	1081 (510–1627)	1102 (553–1556)	1002 (328–1757)	0.48

IQR interquartile range

Table 2 Comparison of outcomes in patients without versus with major congenital heart disease

	Total (*n* = 431)	Patients without major congenital heart disease (*n* = 317)	Patients with major congenital heart disease (*n* = 114)	*p* value
Outcome				
Duration of anesthesia, *n* (%)				0.24
< 240 min	103 (23.9)	78 (24.6)	25 (21.9)	
240–360 min	201 (46.6)	154 (48.6)	47 (41.2)	
> 360 min	78 (18.1)	53 (16.7)	25 (21.9)	
Missing	49 (11.4)	32 (10.1)	17 (14.9)	
Length of stay (days), median (IQR)	52 (34–96)	46 (31–78)	79 (41–150)	< 0.001
Length of ICU stay, *n* (%)				
< 2 weeks	108 (25.1)	84 (26.5)	24 (21.1)	0.49
2–4 weeks	198 (45.9)	144 (45.4)	54 (47.4)	
≥ 4 weeks	125 (29.0)	89 (28.1)	36 (31.6)	
Anastomotic leak, *n* (%)	77 (17.9)	54 (17.0)	23 (20.2)	0.45
Anastomotic stricture requiring intervention, *n* (%)	154 (35.7)	124 (39.1)	30 (26.3)	0.01
In-hospital death, *n* (%)	24 (5.6)	7 (2.2)	17 (14.9)	< 0.001

requiring intervention occurred in 154 patients (35.7%). Patients without major CHD had a longer stay. However, no significant differences were detected between patients with versus without major CHD in duration of anesthesia or length of intensive care unit stay.

Table 3 shows univariate analysis for anastomotic leakage. Duration of anesthesia was associated with anastomotic leakage (incidence of 9.7% in < 240 min group, 20.4% in 240–360 min group, and 30.8% in > 360 min group; $p < 0.002$). There was no significant difference between patients with versus without major CHD in the occurrence of anastomotic leakage (20.2% vs. 17.0%, $p = 0.45$).

Table 4 shows multivariable logistic regression analysis for anastomotic leakage. Only duration of anesthesia was significantly associated with occurrence of anastomotic leakage. With duration of anesthesia less than 240 min as a reference, anesthetic duration from 240 to 360 min (odds ratio 2.49; 95% CI 1.17–5.27, $p = 0.02$) and duration longer than 360 min (odds ratio 4.10; 95% CI 1.69–9.96, $p = 0.002$) were associated with a greater risk of anastomotic leakage. The presence of major CHD, sex, body weight at admission, gestational age, trisomy 18, and annual hospital volume for EA were not significant risk factors for anastomotic leakage.

Table 5 shows univariate analysis for anastomotic stricture requiring intervention. We excluded 11 patients with trisomy 18. Female patients developed anastomotic stricture more often than male patients (41.9% vs. 31.9%, $p = 0.03$). Patients *with* major CHD were less likely to develop anastomotic stricture than those *without* CHD (27.1% vs. 39.6%, $p = 0.02$).

Multivariable logistic regression analysis for stricture showed that the only significant risk factor for anastomotic stricture was patient sex. Boys had a lower risk of anastomotic stricture than girls (odds ratio 0.65; 95% CI 0.43–0.97, $p = 0.04$) (Table 6).

Discussion

This nationwide retrospective cohort study investigated the association between CHD and postoperative complications after EA repair. CHD was not significantly associated with anastomotic leakage or stricture. A longer duration of anesthesia was a predictive risk factor for the occurrence of anastomotic leakage. To our knowledge, the present study had the largest sample size among studies on this issue in the literature. This is the first study to use a nationwide database to identify predictive risk factors for morbidity after EA repair.

We defined anastomotic leakage as both the presence of a recorded diagnosis of anastomotic leak after admission and the need for continuous suction drainage for 3 weeks after radical surgery. Data extraction using only a diagnosis of anastomotic leakage has the possibility of underestimation. The estimated incidence of anastomotic leakage was 17.9% in our study, which is comparable to that in previous studies (4–27%) [9–16]. Consequently, our definition seemed to be reasonable.

In risk-adjusted analyses of patients in a database of 49 tertiary children's hospitals across the US, neither surgeon nor hospital volume affected mortality, reoperation, or dilatation within 1 year [21]. Our study showed that hospital volume was not associated with anastomotic leakage or stricture, but that duration of anesthesia was a predictive risk factor for anastomotic leakage. Longer duration of anesthesia

Table 3 Univariate analysis of anastomotic leakage

	n	Leakage	%	*p* value
Major congenital heart disease				
Yes	114	23	20.2	0.45
No	317	54	17.0	
Sex				
Male	234	40	17.1	0.65
Female	197	37	18.8	
Body weight at admission				
< 1500 g	22	7	31.8	0.08
≥ 1500 g	407	70	17.2	
Gestational age				
Preterm (< 37 weeks)	136	27	19.9	0.52
Term (≥ 37 weeks)	250	43	17.2	
Severe birth asphyxia				
Yes	29	7	24.1	0.36
No	402	70	17.4	
Trisomy				
Trisomy 13	0	0	0.0	–
Trisomy 18	11	3	27.3	0.42
Trisomy 21	7	0	0.0	0.36
Gastrostomy (before or at time of radical surgery)				
Yes	63	16	25.4	0.09
No	368	61	16.6	
Annual hospital volume of EA surgery				
Low (< 4)	377	69	18.3	0.53
High (≥ 4)	54	8	14.8	
Duration of anesthesia (min)				
< 240	103	10	9.7	0.002
240–360	201	41	20.4	
> 360	78	24	30.8	

EA esophageal atresia

Table 4 Multivariable logistic regression analysis using a generalized estimation equation for leakage

	Leakage		
	Odds ratio	95% CI	*p* value
Major congenital heart disease			
Yes	1.23	0.65–2.32	0.52
No	Ref		
Sex			
Female	Ref		
Male	0.88	0.49–1.56	0.66
Body weight at admission			
< 1500 g	1.70	0.55–5.28	0.36
≥ 1500 g	Ref		
Gestational age			
Preterm (< 37 weeks)	1.18	0.66–2.14	0.57
Term (≥ 37 weeks)	Ref		
Trisomy 18			0.37
Yes	2.07	0.43–10.02	
No	Ref		
Annual hospital volume for EA			
Low (< 4)	Ref		
High (≥ 4)	0.81	0.41–1.58	0.53
Duration of anesthesia			
< 240 min	Ref		
240–360 min	2.49	1.17–5.27	0.02
> 360 min	4.10	1.69–9.96	0.002

CI confidence interval, *Ref* reference, *EA* esophageal atresia

was associated with an increased risk of leakage. Generally, experienced surgeons complete the procedure quickly [24]. Therefore, these data suggest that the surgeon's skills did affect the incidence of anastomotic leakage, our finding inconsistent with the aforementioned US study [21]. Therefore, a further study is needed to validate this controversial issue.

Anastomotic stricture occurred in 35.7% of patients, a level comparable to other studies (4–48%) [9–16]. The association between major CHD and anastomotic stricture did not reach statistical significance in multivariable logistic regression analysis. The association between CHD and the development of anastomotic strictures is controversial [16, 25]. Hypo-oxygenation of the anastomotic site resulting from CHD might affect the development of anastomotic stricture. In addition, a longer gap results in greater tension on the anastomosis, which can lead to gastroesophageal reflux and ischemia. These factors also might increase the risk of stricture [22]. We assumed that anastomotic stricture can be seen more often in patients who suffered from anastomotic leakage. However, anastomotic leakage was not significantly associated with anastomotic stricture in the present study. Surprisingly, this study showed gender difference in the occurrence of anastomotic stricture. This result is not consistent with those in previous studies. This cannot be explained from the clinical perspective, and we believe that this may have happened by chance.

In this study, the duration of anesthesia was not significantly associated with the occurrence of anastomotic stricture. However, a previous study reported that surgeon's skill was a crucial factor in avoiding anastomotic stricture [24].

This study has a few limitations. First, the database does not have data on arterial oxygen saturation measured with pulse oximetry nor cardiac function. We defined CHD according to ICD-10 codes and could not classify patients with CHD by disease severity, i.e. whether cyanosis and/or heart failure were present or not. Second, the database does not have data on procedure time; instead, we used data on duration of anesthesia as an alternative variable. Third, the database does not include information on type of EA (Gross classification) or length of gap. To simplify analysis,

Table 5 Univariate analysis of anastomotic stricture requiring intervention

	n	Stricture	%	*p* value
Major congenital heart disease				
Yes	107	29	27.1	0.02
No	313	124	39.6	
Sex				
Male	229	73	31.9	0.03
Female	191	80	41.9	
Body weight at admission				
< 1500 g	19	9	47.4	0.31
≥ 1500 g	399	143	35.8	
Gestational age				
Preterm (< 37 weeks)	134	46	34.3	0.43
Term (≥ 37 weeks)	242	93	38.4	
Severe birth asphyxia				
Yes	26	13	50.0	0.14
No	394	140	35.5	
Trisomy 21				
Yes	7	2	28.6	1.00
No	413	151	36.6	
Gastrostomy (before or at time of radical surgery)				
Yes	57	21	36.8	0.94
No	363	132	36.4	
Leakage at surgery				
Yes	74	34	45.9	0.06
No	346	119	34.4	
Annual hospital volume for EA				
Low (< 4)	367	136	37.1	0.48
High (≥ 4)	53	17	32.1	
Duration of anesthesia				
< 240 min	98	29	29.6	0.09
240–360 min	196	70	35.7	
> 360 min	77	35	45.5	

Patients with trisomy 18 were excluded from this analysis because these patients are generally unable to ingest orally and are not likely to need intervention for stricture

EA esophageal atresia

we therefore focused on patients who underwent primary anastomosis. Fourth, we were not able to follow-up patients across different hospitals in this database. Thus, we may have underestimated the occurrence of anastomotic stricture. In Japan, however, most patients are re-hospitalized in the same hospital, where the operation was performed. Finally, we did not know the details of the procedures, such as suture material used for anastomosis, the number of sutures for anastomosis, quality of the surgeon, or surgical approach (thoracotomy or thoracoscopy; however, almost all procedures were performed through thoracotomy during the study period in Japan [unpublished data]). These issues could have resulted in bias in our data and findings.

Table 6 Multivariable logistic regression analysis using a generalized estimating equation for stricture

	Stricture		
	Hazard ratio	95% CI	*p* value
Congenital major heart disease			
Yes	0.57	0.32–1.01	0.06
No	Ref		
Sex			
Female	Ref		
Male	0.65	0.43–0.97	0.04
Body weight at admission			
< 1500 g	1.46	0.41–5.17	0.55
≥ 1500 g	Ref		
Gestational age			
Preterm (< 37 weeks)	0.83	0.50–1.38	0.48
Term (≥ 37 weeks)	Ref		
Leakage at operation			0.13
Yes	1.59	0.88–2.89	
No	Ref		
Annual hospital volume for EA			
Low (< 4)	Ref		
High (≥ 4)	0.91	0.62–1.34	0.64
Duration of anesthesia			
< 240 min	Ref		
240–360 min	1.24	0.71–2.18	0.45
> 360 min	1.61	0.80–3.23	0.18

CI confidence interval, *Ref* reference, *EA* esophageal atresia

Despite these limitations, the current study showed that CHD was not a risk factor for anastomotic leakage or stricture in patients after surgery for EA. Only the duration of anesthesia was identified as a predictive risk factor for anastomotic leakage, suggesting that surgery performed by skilled surgeons could have a lower risk of anastomotic leakage.

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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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