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Long-term surgical outcomes in congenital diaphragmatic hernia: observations from a single institution

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Abstract

Background/Purpose: Surgical complications are common in survivors of congenital diaphragmatic hernia (CDH), but little is known about long-term incidence patterns and associated predictors.

Methods: A cohort of 99 CDH survivors was prospectively followed at a single-institution multidisciplinary clinic. Data were gathered regarding the adverse surgical outcomes of hernia recurrence, chest and spinal deformity, and operative small bowel obstruction (SBO), and then were retrospectively analyzed in relation to perinatal and perioperative markers of disease severity to determine significant predictors. Statistical methods used included univariate and multivariate regression analysis, hazard modeling, and Kaplan-Meier analysis.

Results: At a median cohort age of 4.7 (range, 0.2-10.6) years, 46% of patients with patch repairs and 10% of those with primary repairs had a hernia recurrence at a median time of 0.9 (range, 0.1-7.3) years after repair. Chest deformity was detected in 47%. Small bowel obstruction and scoliosis occurred in 13%. Recurrence and chest deformity were significantly more common with patch repair, liver herniation, age at neonatal extubation greater than 16 days, oxygen requirement at discharge, and prematurity. The strongest predictor of SBO was patch repair. Multivariate analysis showed that patch repair was independently predictive of recurrence and early chest deformity (odds ratios of 5.0 and 4.8, confidence intervals of 1-24 and 1-21, $P < .05$). Use of an absorbable patch was associated with the highest risk of surgical complications.

Conclusions: For long-term survivors of CDH, specific perinatal and operative variables, particularly patch repair, are associated with subsequent adverse surgical outcomes.

The survival of newborns with congenital diaphragmatic hernia (CDH) has increased along with improvements in pulmonary management [1,2]. A corresponding rise in the number of survivors with significant chronic medical and surgical morbidity must be anticipated. To improve short- and long-term management of these infants, further studies are necessary to clarify the prevalence of and risk factors for specific surgical complications.

The most common adverse surgical outcomes in infants with CDH include diaphragmatic hernia recurrence, chest wall and spinal deformities, small bowel obstruction (SBO),

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hernia incarceration, and midgut volvulus [3-5]. Prosthetic patch repair is associated with subsequent hernia recurrence in up to half of patients by 3 years of age, with many patients having multiple recurrences [3]. The prevalence of chest deformity also approaches 50%; and the incidence of scoliosis has been reported in up to 27% of CDH survivors, although large studies are lacking [6-8]. Literature is also sparse regarding the incidence and causes of intestinal obstruction after CDH repair, but this has been reported to occur in 4% to 21% of patients [4,5].

We prospectively followed a cohort of CDH survivors at a single-center multidisciplinary clinic and documented surgical outcomes. The purpose of this study was to describe the patterns and frequency of surgical complications in this population and then retrospectively examine perinatal clinical and operative data to identify significant risk factors for specific adverse surgical outcomes.

1. Methods

Permission for this study was obtained from the Committee on Human Research of the University of California, San Francisco (UCSF), H11258-30536-01.

1.1. Study cohort

Ninety-nine CDH patients that survived to discharge and were seen at the UCSF multidisciplinary clinic between 2000 and 2008 were prospectively followed. We documented perinatal and perioperative variables that could serve as potential predictors of adverse outcomes, including prenatal anatomical evaluations with determination of the presence of liver herniation into the thorax by ultrasound [9] and the lung-to-head ratio (LHR) [10,11]; fetal intervention, if any, including tracheal occlusion; birth age and weight; operative procedures and findings (type of hernia repair, patch type, and presence of liver herniation); need for fundoplication or gastrostomy tube; duration of intubation and mode of ventilation; and oxygen requirements at neonatal discharge.

At follow-up, patients were examined and chest x-rays were performed. Degree of chest deformity or scoliosis was noted. Neurodevelopmental, audiometric, pulmonary, and growth and nutritional characteristics were evaluated. Any surgical procedures and intraoperative findings were documented, along with measurement of time intervals from first repair until operation for hernia recurrence or bowel obstruction.

1.2. Operative repair

All liveborn CDH patients were medically stabilized before surgical closure of the hernia. Primary repair was attempted if possible. For patients who required a patch repair from 1998 to 2006, the type of patch used was either polytetrafluoroethylene (Gore-Tex [GTX]; Gore Medical, Flagstaff, AZ) or small intestinal submucosa (Surgisis [small intestinal submucosal patch, SIS]; Cook Biotech, West Lafayette, IN). Current practice at UCSF since 2006 has been to use a custom-layered combination patch of Gore-Tex and Surgisis (SIS + GTX).

1.3. Statistical analysis

Tabulated data were analyzed to determine which prenatal and postnatal patient characteristics or operative variables were significantly associated with the surgical complications of hernia recurrence, chest deformity, scoliosis, and operative SBO. Univariate analysis was performing using the Pearson χ^2 and Fisher's Exact tests for categorical variables, and the Student's t test and the Wilcoxon's rank sum test for continuous variables. Odds ratios (ORs) and positive and negative predictive values were generated to evaluate the usefulness of variables as predictors of adverse outcomes. Because hernia recurrence is a time-dependent outcome, we calculated hazard ratios for different repair types and used Kaplan-Meier survival curves using the log-rank test for equality of survivor functions. To determine predictor independence, multivariate regression analysis was performed when appropriate with manual selection of relevant predictors.

2. Results

2.1. Cohort characteristics

General cohort characteristics are presented in Table 1. There was 1 postdischarge death occurring in a 21-month-old boy owing to delayed transfer to UCSF for management of volvulus. For the purposes of statistical analysis, perinatal predictors of adverse surgical outcomes were given the following binary classifications: patch vs primary repair, liver herniation vs no herniation, age at extubation greater or less than 16 days (cohort median), neonatal discharge with or without oxygen supplementation, prenatal intervention (tracheal occlusion, n = 8) or no prenatal intervention, premature birth (<36 weeks) or term birth (≥36 weeks), LHR less than or greater than 1.0, and use or no use of extracorporeal membrane oxygenation (ECMO) therapy (n = 8).

2.2. CDH recurrence

Thirty patients (31%) have had a hernia recurrence at a median time of 0.9 (range, 0.1-7) years after initial repair. Of patients who developed recurrence, 26 had an initial patch repair and 4 had a primary repair. Thus, 46% of patch repairs and 10% of primary repairs have recurred, although follow-up times vary (Table 2). Of the 30 patients with recurrence,

Table 1 Cohort characteristics (N = 99)

Variable	Data point (% or range)
Demographic data	
Male sex	60 (61%)
Median current age	4.7 (0.2-10.6) y
Mortality after discharge	1 (1%)
Physiologic data	
Left-sided CDH	80 (82%)
Liver herniation	54 (56%)
Median gestational age at delivery	38 (28-41) wk
Treatment data	
Prenatal intervention	8 (9%)
Median age at repair [a]	5 (0-540) d
Initial nonprimary hernia repair	57 (58%)
GTX	16 (17%)
SIS	23 (24%)
SIS + GTX composite	15 (16%)
Muscular flap	1 (1%)
Other patch [b]	2 (2%)
Minimally invasive repair	5 (5%)
ECMO	8 (8%)
Median age at final extubation	16 (0-55) d
Discharge with oxygen supplementation	28 (32%)
Fundoplication	25 (25%)
Gastrostomy tube	31 (31%)

[a] Three patients were diagnosed with CDH well outside the neonatal period.

[b] Two patients were referred for management after repair with an unknown type of patch.

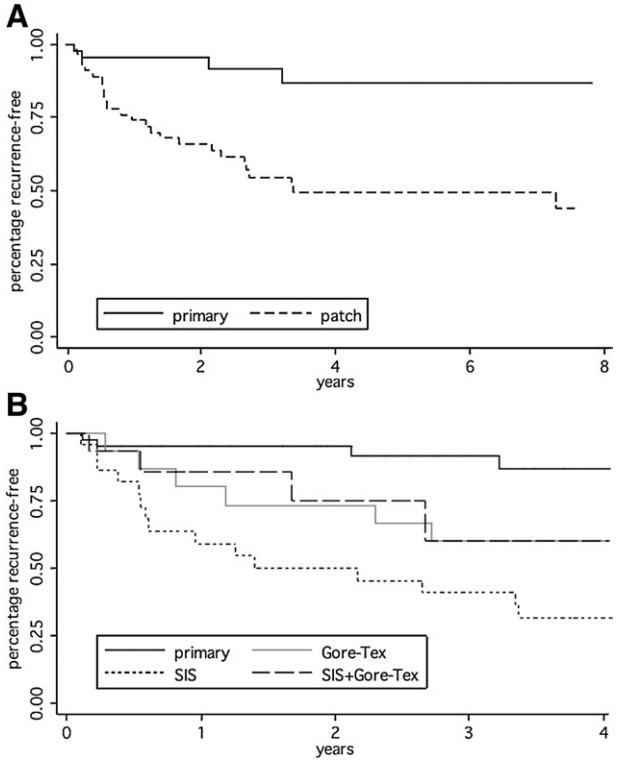

Fig. 1 Kaplan-Meier analysis of recurrence-free intervals, stratified by repair type. A, Proportion of cohort without a recurrence measured over 8 years: primary vs patch repair. B, Proportion of cohort without a recurrence measured over 4 years, stratified by repair subtype: primary, GTX, SIS, and SIS + GTX composite patch.

11 (37%) have had more than 1 recurrence. Using Kaplan-Meier analysis, the recurrence-free interval over 8 years for the entire cohort is shown in Fig. 1A, which demonstrates that, by 4 years postoperatively, 50% of patch repairs failed (log-rank test for equality $P < .001$).

To estimate relative risk of recurrence over time based on patch repair type, hazard ratios were calculated. Compared with a primary hernia closure, an SIS repair had the highest hazard ratio for recurrence at 8.6 ($P < .001$), whereas an SIS + GTX repair had the lowest hazard ratio of 3.8 ($P = .06$, Table 2). Fig. 1B shows the proportion of patients without recurrence over 4 years stratified by patch type; the recurrence-free interval was shortest in those with an SIS repair vs a GTX or SIS + GTX repair (log-rank test for equality, $P < .001$).

Because follow-up time is unequal between repair types, we also examined the risk of early recurrence based on repair type. Early recurrence was considered present when it occurred less than 6 months after initial repair. Only an SIS repair was significantly associated with early recurrence, with an OR of 5.1 (confidence interval [CI], 2-17; $P = .009$). Seven of 23 SIS repairs (30%) failed in less than 6 months, vs 2 GTX repairs (12%), 2 SIS + GTX repairs (13%), and 2 primary repairs (5%). Of the 11 patients with multiple recurrences, 10 (91%) had an initial SIS repair and 1 had an initial SIS + GTX repair.

Multiple perinatal markers of CDH severity were significantly associated with hernia recurrence by univariate analysis (Table 3). Multivariate regression analysis showed

Table 2 Estimates of recurrence risk

Repair type	Number with recurrence (%)	Median time to recur (range), y	Mean follow-up time (SD), y	Recurrence hazard ratio (95% CI)	*P*
Primary repair	4 (10%)	1.2 (0.1)	3.5 (2)	1.0 (reference)	–
Patch repair	26 (46%)	0.9 (0.1)	5.6 (3)	5.4 (2-16)	.002
GTX	7 (44%)	1.2 (0.3)	7.5 (3)	4.3 (1-15)	.02
SIS	15 (68%)	0.6 (0.1)	6.4 (1)	8.6 (3-26)	<.001
SIS + GTX	4 (27%)	1.1 (0.2)	2.2 (1)	3.8 (1-15)	.06

Table 3 Predictors of surgical complications

Variable	Hernia recurrence, 30 affected (31%)		Chest deformity, 47 affected (47%)		Bowel obstruction, 13 affected (13%)	
	OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*
Patch repair	8.2 (3-26)	<.001	7.5 (3-20)	<.001	11.2 (1-90)	.02
Liver herniation	5.1 (2-14)	.002	3.5 (1-9)	.006	5.4 (1-26)	.04
Oxygen at discharge	5.5 (2-14)	<.0001	5.5 (2-17)	.002	3.1 (1-10)	.06
Extubation age >16 d	3.0 (1-7)	.02	3.7 (1-9)	.005	0.9 (0-3)	.8
Premature birth (<36 wk)	3.4 (1-9)	.02	0.9 (0-3)	.8	4 (1-14)	.03
Hernia recurrence			4.1 (1-12)	.008	6.9 (2-25)	.003

that only patch repair was independently predictive of subsequent recurrence, with an OR of 5.0 (CI, 1-24; $P < .05$).

Variables not listed in Table 3, including ECMO therapy, low birth weight, CDH laterality, prenatal intervention, and LHR less than 1.0, were not significant predictors of recurrence or any other adverse surgical outcomes.

2.3. Chest deformity

Significant chest deformity, usually in the form of an asymmetric pectus excavatum or chest wall hypoplasia, was identified in 47 patients (47%). Nine patients with an initial primary repair (21%) and 38 with a patch repair (67%) developed chest deformity. By univariate analysis, patients with a history of patch repair, liver herniation, oxygen requirement at neonatal discharge, prolonged intubation, and hernia recurrence had significantly increased odds of chest deformity ($P < .05$, Table 3). On multivariate analysis, no variable was an independent predictor of overall chest deformity, although patch repair was independently predictive of early chest deformity occurring during the first year postrepair (OR, 4.8; CI, 1-21; $P = .04$). An SIS repair was the only patch repair type significantly associated with the development of early chest deformity (OR, 3.0; CI, 1-8; $P = .02$).

A diagnosis of chest deformity occurred during the first 2 years postrepair in the vast majority of affected patients (74%). Eleven patients with chest deformity (23%) demonstrated improvement or resolution of the deformity without intervention. Two patients of 5 (40%) who had a thoracoscopic primary repair developed mild chest deformity.

2.4. Bowel obstruction

Thirteen patients (13%) have undergone laparotomy for SBO at a median interval of 1.2 (range, 0.1-3.6) years postrepair. The cause of the obstruction was adhesions in 7 cases (54%), reherniation in 5 cases (39%), and midgut volvulus in 1 case (8%). The patient with volvulus had a contemporaneous hernia recurrence that was nonobstructing. In most cases of adhesive SBO, interloop or incisional adhesions were responsible for the obstruction, rather than patch adherence. Significant univariate predictors of SBO included a history of patch repair, liver herniation, prematurity, and hernia recurrence (Table 3). Multivariate analysis yielded no significant independent predictors of SBO.

Of the patients with operative SBO, 8 had an initial SIS repair, 1 had a GTX repair, 3 had an SIS + GTX repair, and 1 had a primary repair. By univariate logistic regression and Fisher's Exact test, the only repair subtype significantly associated with SBO was SIS, with an OR of 8.1 (CI, 2-28; $P = .001$).

2.5. Scoliosis

Thirteen patients (13%) have been identified as having a significant spinal curvature on physical examination (approximately >10°-20° curvature). Eleven of these patients had a patch repair (85%), and 2 (15%) had an initial primary repair. By univariate analysis, although patients with several perinatal markers of disease severity were significantly more likely to have scoliosis, the CI ranges obtained from this analysis were too broad to reliably identify predictors of this adverse outcome (data not shown).

3. Discussion

Surgical complications are common among CDH survivors, but data are limited regarding long-term incidence patterns and associated risk factors [4,5,7,8,12-16]. As with the adverse medical outcomes of neurodevelopmental delay, hearing loss, pulmonary insufficiency, and growth and nutritional failure, adverse surgical outcomes seem to be most frequent in those patients with a large CDH defect requiring patch repair. In keeping with existing reports, in our cohort of 99 patients with a mean age of nearly 5 years, we found that 31% had hernia recurrence, 47% developed chest deformity, and 13% had SBO and scoliosis. Of all clinical predictors, we found a history of patch repair to be the most strongly and independently predictive of subsequent surgical complications, which correlates with the observation in other reports that large hernia size—for which patch repair is a surrogate marker—strongly reduces overall survival as well as increases the risk of multiple adverse outcomes [14,17].

In contrast with our previous study [5], these longer-term data have revealed that use of a bioabsorbable patch that promotes native tissue ingrowth (SIS) without the presence of a permanent material such as polytetrafluoroethylene (GTX) predisposes patients to earlier hernia recurrence and multiple recurrences. Existing reports supporting the use of SIS for CDH repair do not examine results beyond 1 to 2 years of age [5,18,19]. Although the recurrence rate in our cohort was high among all patch types as compared with primary hernia closure, nearly a third of patients who had an SIS repair had a recurrence within 6 months, which was strikingly higher than the incidence for other repair types. In addition, an SIS-only repair was significantly associated with a higher frequency of early chest deformity and operative bowel obstruction. The reasons for these latter increased risks with SIS repair are unclear but may be related to disease severity or hernia recurrence requiring repeat laparotomies and patch repairs. Some reports have shown that the material does not always provide durable defect repair in other settings and may be proinflammatory [20-22]. In response to these findings, our group no longer performs SIS-only repairs. In addition, patients never received an SIS-only patch as a repair for a recurrence; these were managed using GTX or in some cases a muscular flap. Because no difference was found with GTX + SIS repairs over GTX in terms of adverse surgical outcomes, further study is required to ascertain whether a composite repair is advantageous.

The risk of surgical complications was higher in patients with severe disease as indicated by other perinatal clinical markers besides patch repair, in particular liver herniation through the defect, age at extubation greater than 16 days, and oxygen supplementation required at neonatal discharge. We found these same variables to be strongly predictive of nonsurgical adverse outcomes in this cohort as well. Patients without these clinical characteristics had a very low likelihood of developing surgical complications; and thus, these markers are perhaps most useful as negative predictors of adverse outcomes. Based on predictive values data from our cohort of children with a range of CDH severity, for patients with a primary repair, no liver herniation, short duration of intubation, and no oxygen dependence at discharge, families may be counseled that the risk of hernia recurrence is less than 10%, risk of chest deformity is less than 25%, and risk of bowel obstruction is less than 5% over the first 5 years of life.

Long-term skeletal deformity has been noted in CDH survivors and tends to be most severe in those who had large defects [8]. Congenital diaphragmatic hernia–associated chest deformity is particularly troublesome, as it tends to be asymmetric and progressive. In our cohort, chest deformity was most common after patch repair; but a significant proportion of patients with an initial primary repair still developed this problem (21%). Multisystem disease severity, particularly pulmonary failure as assessed by oxygen dependence at discharge, seems to increase the risk of chest deformity, although all CDH survivors should have close surveillance of their chest wall during childhood. No patient in the cohort has had repair of a chest deformity.

Moderate scoliosis was also frequently noted in our cohort; but onset tended to be later in childhood, and no patients have yet undergone surgical correction. We could not identify significant independent risk factors for this condition, but patients with a patch repair tended to be more likely to develop scoliosis.

Bowel obstruction after CDH repair may occur at any time. In addition, the typically unfixed, nonrotated intestine in CDH patients is a potential risk factor for volvulus; but we observed only 1 case in our cohort. We found that SBO most commonly occurred because of adhesive disease (54%), but hernia recurrence was responsible for 5 obstructions (39%). The most significant perinatal predictors of subsequent SBO were not markers of severe pulmonary insufficiency but rather the anatomical markers of CDH severity: patch repair, liver herniation, and hernia recurrence. Although SIS repairs were significantly associated with SBO, this observation may be related to length of follow-up time or to the fact that this was the most common type of patch repair in the cohort.

Our study is limited by missing data points for some patients not seen consistently in clinic or who were lost to follow-up. However, in clinic, we saw nearly 80% of all CDH patients who survived to discharge; so the cohort data are likely representative of the general CDH population. It should be emphasized that the cohort consisted only of patients who survived to discharge and were seen at clinic, and there was a significant predischarge mortality (25%); this partly explains the apparently low prevalence in the cohort of patients with ECMO and with a low LHR, who had increased perinatal mortality. The low prevalence of these conditions may have reduced their significance as predictors.

In summary, we have confirmed a high frequency of surgical complications in a large cohort of CDH survivors and found that, although a history of patch repair is the most significant predictor of adverse surgical outcomes, patients with other perinatal markers of disease severity are also at risk for hernia recurrence, chest deformity, and bowel obstruction.

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Discussion

Priscilla Chiu, MD (Toronto, Ontario): That is a wonderful cohort, but you have left out the thoracoscopic or laparoscopic repair patients. I want you to comment on the recurrence rate there.

Tim Jancelewicz, MD (response): This cohort consists of 5 patients who had a thoracoscopic repair, and that particular variable was not significantly associated with an adverse outcome.

Charles Stolar, MD (New York City, NY): I congratulate you for following this very important group of patients because as more survive we are learning what they look like as they grow up. I am particularly interested in those patients who have an emerging incidence of scoliosis and chest wall deformity, because it is not ordinarily seen in boys but because it is becoming more common. I think you recorded 14% at 4.7 years. I would say that the relationship to the patch calls into question the causality issue because diaphragmatic hernia is a field defect. The whole side of the chest grows more slowly than the contralateral side; and because the chest grows asymmetrically, they are going to get bent over that way. It is not that they are tethered by the patch, at least that is how we think about it.

My question—because you have an ongoing CDH clinic, could you describe your protocol for following and managing the axial skeletal abnormality?

Dr Jancelewicz (response): We think scoliosis is a late-onset phenomenon; so we do not specifically formally measure spinal curvature in clinic in about the first 5 years of life, at least in the patients that I have seen. We suspect that the incidence of scoliosis will become more common beyond age 5 and a little bit older. There is actually at present no formal measurement in clinic; but if we do see something obvious, then we initiate referrals to appropriate physicians.

Unidentified speaker: Yesterday we heard some data that suggest the possibility that autologous flap repairs may have a lower incidence of recurrence. Has the incidence of recurrence with patch repairs caused you to change your approach or think about other approaches for these patients?

Dr Jancelewicz: There is definitely individual surgeon preference in our practice. I think that flap repairs are reserved in our practice, and I will defer to the surgeons to comment on this on their own; but the flap repair is reserved for multiply recurrent patients.