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Minimally Invasive Repair of Congenital Diaphragmatic Hernia

By the Congenital Diaphragmatic Hernia Study Group*

Abstract

Purpose—Operative approach, including minimally invasive surgery (MIS) in the repair of congenital diaphragmatic hernia (CDH), is variable among institutions. The short-term recurrent hernia rate is not well described. We evaluated the in-hospital recurrence rate of MIS repairs of infants with CDH from the Congenital Diaphragmatic Hernia Registry (CDHR).

Methods—Prospectively collected data from CDH infants were analyzed from the CDHR from January 1995 to January 2010. Recurrent hernia was defined as reoperations during initial hospitalization. Operative approaches included abdominal, thoracic, laparoscopic, and thoracoscopic techniques.

Results—5,480 infants with CDH were identified of which 4,516 (82.4%) were repaired. Operative data was available in 4,390 infants. One hundred fifty-one infants (3.4%) underwent MIS repairs with twelve reported recurrences (7.9%) compared to one hundred fourteen for open techniques (2.7%, $p < 0.05$). MIS demonstrated a significant increased odds for recurrence (OR 3.59, 95% CI:1.92 – 6.71) after adjusting for gestational age, birth weight, patch repair, and ECMO.

Conclusion—Minimally invasive techniques appear to have a significant higher recurrent hernia rate with thoracoscopy being the highest. Although adjusted for patch repair, other factors with regards to disease severity may contribute to differences in outcomes among centers. This study is limited to short-term recurrence during initial hospitalization.

Keywords

congenital diaphragmatic hernia; minimally invasive surgery; thoracoscopy; laparoscopy

INTRODUCTION

The surgical repair of CDH has been traditionally achieved with an open thoracic or abdominal approach. In 1997, the Congenital Diaphragmatic Hernia Study Group (CDHSG) reported that the subcostal laparotomy is the most commonly approach for repair (91%). However, the proliferation of MIS in pediatric surgery has allowed for the laparoscopic and thoracoscopic repair of neonatal CDH to become routine in some institutions. The utilization

Correspondence: KuoJen Tsao, M.D., Assistant Professor, Department of Pediatric Surgery, The University of Texas School of Medicine at Houston, 6431 Fannin St, Suite 5.254, Houston, Texas 77030, 713-500-7305 office, 713-500-7296 fax, kuojen.tsao@uth.tmc.edu.
*This manuscript was prepared by the following investigators, who are part of the writing committee for the Congenital Diaphragmatic Hernia Study Group: KuoJen Tsao, M.D., Pamela A. Lally, M.D., and Kevin P. Lally, M.D., M.S.
From the Departments of Pediatric Surgery and Surgery, The University of Texas School of Medicine at Houston, Houston, Texas, and The Children's Memorial Hermann Hospital, Houston, Texas

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of MIS approaches have been suggested to be advantageous over traditional open surgery including less pain and incisional complications, avoidance of thoracotomy-related sequelae, as well as reduction of surgical stress.

Despite the wide-spread application of MIS, comparative outcomes remain elusive. Current evidence has been limited to case series and meta-analysis. The purpose of this report from the CDHSG is to evaluate the risk-adjusted in-hospital recurrence rate for MIS CDH repair in a large, prospective cohort of neonates with CDH.

METHODS

CDHR

Since 1995, the CDHSG has been evaluating live-born neonates with CDH to allow assessment of therapies and outcome. The CDHR contains data collected from all inborn or transferred infants with CDH during their initial hospitalization. The CDHSG is a voluntary collaboration of international tertiary referral centers providing care for CDH patients who provide data to a central registry (see appendix for participating centers). The CDHR was approved by the University of Texas Medical School at Houston Institutional Review Board (HSC-MS-03-223). Participating centers filed a waiver of consent for data submission or signed a data use agreement for a limited data set. Data include information on delivery and initial hospitalization until death or discharge. Because of the registry nature of the data and evolution of the data collection forms, patients in the CDHR may not have complete data for all variables.

Data

The current study used prospectively collected data from the CDHR from January 1995 to January 2010 from 93 international institutions. Patient characteristics such as demographics, birth weight, estimated gestational age (EGA), Apgar scores, associated anomalies, side of defect, and defect size were collected. Associated anomalies included major cardiac defects, chromosomal anomalies, and syndromes. Major cardiac anomalies were defined as all cardiac anomalies except patent ductus arteriosus, isolated atrial septal defect, and isolated ventricular septal defects. According to the CDHR, standardized defect size has only been recently collected. For the purposes of this study, primary or patch repair was used as a surrogate marker of defect size. Hospital course data included need and timing of extracorporeal membrane oxygenation (ECMO), treatment details (including surgical timing/approach, need for patch, ventilator management), survival, morbidity (such as gastroesophageal reflux disease, feeding approach, and need for oxygen at 30 days), and hospital length of stay were collected. Operative approaches included laparotomy, thoracotomy, laparoscopy, or thoracoscopy. Conversions from MIS to open operations were not able to be identified from registry data. Recurrent hernia was defined as reoperation during initial hospitalization. Survival was defined as alive at hospital discharge or transfer.

Statistical analysis

Clinical variables are reported as percentages and means ± standard deviation. Variables of proportions were evaluated using χ^2 analysis with $p < 0.05$ as statistically significant. Logistic regression was used to evaluate association among significant variables and CDH recurrence before hospital discharge. Odds ratios (OR) were calculated and 95% CIs were generated. The analysis was conducted using STATA10 (Stata Corp., College Station, TX).

A univariable analysis was performed initially to evaluate the association of each predictor variable with the primary outcome of recurrence. All independent variables were analyzed, which included patient demographics, status at delivery, treatment and operative data, and

associated comorbidities. Statistically significant variables were used in a multivariable logistic regression analysis. These variables were evaluated for their influence on the primary outcome (recurrence) independently as well as in combination for interaction and confounding.

RESULTS

Overall

Query of the CDHR for the study period identified 5,480 infants with CDH. Operative repair was performed in 4,516 (82.4%) infants. However, complete operative data including surgical approach was only available in 4,390 (80.1%) patients. The study cohort consisted of only those records that included complete operative approach and outcomes. Mean birth weight of repaired infants was 3.18 kg ± 0.60 kg with median estimated gestational age of 38 weeks (range 23 – 44 weeks).

Centers utilizing MIS

Only 20 CDHSG centers (21.5%) performed laparoscopic and/or thoracoscopic repairs of CDH. The median percentage of cases utilizing MIS techniques was 6.5% (range 1.2 – 24.8%). Ten institutions (10.7%) had only performed thoracoscopy. Within centers that reported both thoracoscopic and laparoscopic techniques, only two centers (2.2%) had performed more laparoscopic operations.

Operative Approach

Within the study cohort, 4,239 infants (96.5%) with CDH underwent traditional open repair. A MIS approach was achieved in 151 infants (3.5%). Five operative approaches were identified: laparotomy (91.4%), thoracotomy (3.1%), laparotomy and thoracotomy (1.4%), laparoscopy (0.6%), and thoracoscopy (2.8%). Patient characteristics were compared (Table 1). The mean EGA and birth weight were significantly smaller in the open group compared to the MIS infants. The open cohort had a higher proportion of major cardiac anomalies (5.2% vs. 2.6%) and chromosomal abnormalities (2.7% vs. 1.3%), but this did not reach statistical significance. Specific parameters describing severity of pulmonary hypertension and hypoplasia was not analyzed. Instead, need for ECMO was used as a marker for overall disease severity and need for patch repair as a surrogate for defect size. Both were significantly higher in the open cohort. However, the timing of ECMO in relation to the repair of CDH (before, on, or after) was not evaluated. Delayed repair and preoperative stabilization appeared to be practiced in both groups (6.9 days open vs. 5.4 days MIS, $p = 0.15$).

Recurrence of CDH

The overall recurrence rate for the entire cohort was 2.9% (126 of 4390). The highest rate of recurrence occurred in patients that underwent thoracoscopic repair (8.8%) (Table 2). An unadjusted comparison of open to MIS repairs demonstrated a significantly higher proportion of in-hospital recurrence in the MIS group (7.9% vs. 2.6%, $p < 0.05$). Although the difference did not meet statistical significance ($p = 0.16$) average time to recurrence occurred sooner in the MIS groups compared to open repairs (105.2 days open vs. 68.4 days MIS).

As expected, infants that required a patch repair had a significantly higher recurrence rate (3.8% primary vs. 2.0% patch, $p < 0.05$). MIS repairs that used a patch had the highest recurrence rate at 8.8% (Table 3). Surprisingly, the lowest recurrence rate was seen in open patch repairs (1.6%). In comparison of all open operations, primary repairs demonstrated a significantly higher recurrence rate ($p < 0.05$). MIS repairs demonstrated similarly higher

but not significantly different recurrence rates with regards to patch utilization (8.8% patch vs. 6.1% primary, $p = 0.75$).

A univariate analysis of all variables including patient characteristics, markers for disease severity, and operative technique was performed for association with recurrence. Mean EGA, birth weight, need for ECMO, need for patch repair, and surgical approach were identified as variables that highly correlated with recurrent CDH. These significant variables were utilized in a multiple logistic regression analysis to identify significant factors related to recurrence and surgical approach. After adjustment, only need for patch repair remained a significant covariate to type of surgical technique. The risk-adjusted OR for recurrence based on operative approach was 3.59 (95% CI: 1.92–6.71) in favor of open operations.

Survival

Although the overall survival was high in both groups, MIS patients had statistically improved mortality (82.9% open vs. 98.7% MIS, $p < 0.05$). Known significant variables for overall survival were utilized to determine the overall risk-adjusted survival. A logistic regression model demonstrated a significant increased odds of survival for infants undergoing MIS repairs (OR 5.57; 95% CI: 1.34 – 23.14) after adjusting for gestational age, birth weight, need for ECMO, and patch repairs.

DISCUSSION

The surgical approach to repair the CDH remains variable despite the overwhelming utilization of laparotomy. Since Silen reported the first MIS repair of an adolescent Bochdalek-type CDH in 1995, MIS approaches have gained in popularity. In a recent review of the CDHR, prospectively collected operative data on over 4,000 live, inborn infants with CDH suggest that the operative approach included open abdominal and thoracic approaches as well as laparoscopic and thoracoscopic strategies. Although several centers have reported their success with laparoscopic and thoracoscopic modalities for the repair of the neonatal CDH, current evidence comparing the outcomes open to MIS repairs of CDH have been limited to retrospective reviews and case series. Landsale *et al* recently published a systematic review and meta-analysis of neonatal endosurgical repairs of CDH. Studies were only eligible if they directly compared open and endosurgical neonatal CDH repair and included survival, CDH recurrence, prosthetic patch use, and operative time. Only 3 studies met inclusion criteria. The cumulative risk ratio for death was 0.33 (95% CI: 0.10 – 1.13) in favor of endosurgical repairs and recurrence was 3.21 (95% CI: 1.11 – 9.29) in favor of open repairs.

Survival

The overall survival for CDH according to the CDHR has been reported as 68.7%. For the purposes of this study, those patients that never survived to repair were excluded in order to only compare operative techniques. As a result, the overall survival in both groups was extraordinarily high (82.9% open and 98.7% MIS) with the MIS patients demonstrating a significantly higher survival rate. The risk-adjusted OR of survival for MIS repairs was 5.57 (95% CI: 1.34 – 23.14). Such results would suggest a tremendous survival advantage to MIS approaches as a treatment modality for CDH even after risk-adjustment. However, concluding that the MIS approach would have such an impact on overall survival on a complex disease such as CDH seems highly implausible. More likely, the data suffers from selection bias based on surgeon preference. Patients with less severe disease that have better survival were better candidates for MIS.

Surgical approach

With advances in MIS technology and increasing surgeon experience, patient characteristics and disease severity become less prohibitive to MIS approaches for CDH repair, where initial MIS operations were reserved for the stable infants with anticipated small defects. Although laparotomy remains the most popular operative approach (91.4%) for the repair of neonatal CDH, thoracoscopy was the preferred MIS technique. Surgeon preference and determinant for operative selection were unable to be elucidated from the CDHR data. Despite its prospective nature, the lack of blinding and randomization renders this study to selection bias in which perceived higher-risk infants may undergo open repairs. Although its influence of surgeon preference cannot be determined, this may be reflected in the overall higher survival rate in the MIS cohort compared to open repairs.

In addition, there remains tremendous heterogeneity within centers. MIS approaches were used in 20% of CDHSG institutions. Of those, half of the centers performed laparoscopy in addition to thoracoscopy. Although clinical preference for MIS approaches may have migrated to thoracoscopy over time, this general trend was not analyzed in this study.

Recurrence of CDH

The reported recurrence rates for MIS repair of CDH range from 5% to 23.1%. This study demonstrated an overall recurrence of 7.9% for MIS with 8.8% for thoracoscopy compared to 2.6% for open operations. This higher recurrence rate may be anticipated for several reasons. First, technical limitations with thoracoscopy may not allow complete mobilization of the posterior muscular diaphragmatic rim, prohibiting a tension free primary repair or secure suturing of a patch to the posterior rim. Second, this study spans fifteen years of operative experience. However, with only the recent increase in MIS techniques, there may be a learning curve to neonatal MIS CDH repairs which require suturing in limited working spaces.

This study estimated an almost 4-fold increased odds of recurrence with MIS repairs (OR 3.59; 95% CI: 1.95–6.71). Despite the risk-adjusted estimation, the true impact of recurrence with MIS may be underestimated. First, CDHR data only exists for the initial hospitalization. Consequently, results from this study are limited to early recurrences during the initial hospitalization. Second, the CDHR does not account for MIS operations that result into conversions to open procedures. Consequently, thoracoscopic repairs that are attempted and eventually require thoracotomy may be coded as an open operation.

Limitations

A major limitation in evaluating operative techniques in regards to neonatal CDH repair resides in failure to precisely consider all factors that may influence recurrence such as defect size and disease severity. Within each institution, there is tremendous heterogeneity of disease severity, operative decision-making and management strategies, despite the general philosophy of preoperative stabilization and delayed repair. As a result, individual centers and surgeons may have a limited experience with various CDH infants and even less experience with specific operative approaches such as thoracoscopy. The CDHR has only recently adopted a standardized grading scale for defect size. As such, comparison of therapeutic modalities, like MIS, may be limited in their conclusions. Published studies often contain grouped data with heterogeneous patient populations and variable defect sizes. Subsequently, reported outcomes should be standardized and stratified for disease severity and patient characteristics. In this study, defect size and disease severity were crudely measured as need for patch repair and need for ECMO, respectively.

Conclusion

Despite its wide application, longitudinal outcomes regarding the durability and recurrence rates for MIS techniques for neonatal CDH remain limited. Prospective comparative studies between MIS and open approaches are lacking due to limited incidence of CDH and tremendous heterogeneity of disease severity. Multi-institutional registries for rare disease such as the CDHR offer some advantages by ameliorating the institutional biases in patient selection and treatment variances. Outcomes from the CDHR may be helpful to develop clinical guidelines but each institution and surgeon must still recognize their therapeutic limitations.

Although MIS approaches to CDH have gained in popularity, its true impact on the newborn remains undetermined. The registry data does not identify those patients that undergo conversion from MIS to open repairs. In addition, the consequences of an operation for recurrence cannot be determined. The current small series and case reports have demonstrated the technical feasibility and initial safety of MIS techniques. However, these reports are subject to the pitfalls of retrospective studies such as selection bias and inadequate follow-up. The current report provides a risk-adjusted estimation for recurrence of CDH with MIS. However, the impact of CDH recurrence or conversions to open surgery on morbidity and mortality are unknown. Although MIS approaches for repair of neonatal CDH are widely practiced and its incisional benefits are recognized, there appears to be a higher recurrence rate, especially for thoracoscopic cases.

In summary, minimally invasive approaches to the repair of CDH appear to have a significantly higher in-hospital recurrence rate. Despite this morbidity, MIS patients still had a higher survival rate. These discordant results suggest there may be underlying unmeasured confounders such as patient stability or surgical skill or experience that may have contributed to a selection bias favoring the MIS group. The true overall benefit of MIS repairs for newborns with CDH has yet to be demonstrated.

Appendix: Current CDHSG institutions

Arkansas Children's Hospital	Little Rock, AR
Astrid Lindgren Children's Hospital	Stockholm, Sweden
BC Children's & Women's Health Centre	Vancouver, BC, Canada
Cardinal Glennon Children's Hospital	St. Louis, MO
Carolinas Medical Center, Levine Children's Hospital	Charlotte, NC
Cedars Sinai Medical Center	Los Angeles, CA
Central Hospital Aichi Prefectural Colony	Kasugai, Aichi, Japan
Children's Hospital Boston	Boston, MA
Children's Hospital of Akron	Akron, OH
Children's Hospital of Austin	Austin, TX
Children's Hospital of Buffalo	Buffalo, NY
Children's Hospital of Illinois	Peoria, IL
Children's Hospital of Los Angeles	Los Angeles, CA
Children's Hospital of Michigan	Detroit, MI
Children's Hospital of Oakland	Oakland, CA
Children's Hospital of Oklahoma	Oklahoma City, OK
Children's Hospital of Philadelphia	Philadelphia, PA

Children's Hospital of Wisconsin	Milwaukee, WI
Children's Hospital Omaha	Omaha, NE
Children's Hospitals and Clinics (Minneapolis)	Minneapolis, MN
Children's Memorial Hermann Hospital	Houston, TX
Children's Mercy Hospitals & Clinics	Overland Park, KS
Children's National Medical Center	Washington, DC
Cincinnati Children's Hospital Medical Center	Cleveland, OH
Cook Children's Medical Center	Ft. Worth, TX
Duke University Medical Center	Durham, NC
Emory University	Atlanta, GA
Freie Universitat Berlin	Berlin, Germany
Golisano Children’s Hospital at Strong	Rochester, NY
Hasbro Children's Hospital, Brown Medical School	Providence, RI
Helen DeVos Children's Hospital	Grand Rapids, MI
Hershey Medical Center	Hershey, PA
James Whitcomb Riley Children's Hospital	Indianapolis, IN
Kosair Children's Hospital	Louisville, KY
Le Bonheur Children’s Medical Center	Memphis, TN
Legacy Emanuel Children's Hospital	Portland, OR
Loma Linda University Children's Hospital	Palo Alto, CA
Lutheran General Hospital	Park Ridge, IL
Massachusetts General Hospital	Boston, MA
Mattel Children's Hospital at UCLA	Los Angeles, CA
Mayo Clinic	Rochester, MN
Medical College of Georgia	Richmond, VA
Medical University of South Carolina	Charleston, SC
Miami Valley Hospital	Dayton, OH
National Center for Child Health and Development	Setagaya-ku, Tokyo, Japan
North Carolina Baptist Hospital	Winston-Salem, NC
Oespedale Pediatrico Bambino Gesu	Rome, Italy
Oespedale Riuniti Bergamo	Bergamo, Italy
Osaka Medical Center for Maternal and Child Health	Izumi, Osaka, Japan
Osaka University Graduate School of Medicine	Suita, Osaka, Japan
Phoenix Children's Hospital	Phoenix, AZ
Primary Children's Hospital	Salt Lake City, UT
Radboud University Nijmegen Medical Centre	Nijmegen, The Netherlands
Rainbow Babies and Children Hospital	Cleveland, OH
Rockford Memorial Children's Hospital	Rockford, IL
Royal Alexandra Hospital	Edmonton, Alberta, Canada
Royal Children's Hospital	Parkville, Victoria, Australia
Royal Hospital for Sick Children	Glasgow, Yorkhill, Scotland
Salesi Children's Hospital	Ancona, Italy
San Diego Children's Hospital	San Diego, CA

Santa Rosa Children's Hospital	San Antonio, TX
Shands Children's Hospital/University of Florida	Gainesville, FL
Sophia Children's Hospital	Rotterdam, The Netherlands
St. Christopher's Children's Hospital	Philadelphia, PA
St. Francis Children's Hospital	Tulsa, OK
St. Joseph's Hospital and Medical Center	Phoenix, AZ
St. Louis Children's Hospital	St. Louis, MO
St. Paul Campus Children's Minneapolis	Edmonton, Alberta, Canada
Sydney Children's Hospital	Randwick, NSW, Australia
T.C. Thompson Hospital	Chattanooga, TN
Texas Children's Hospital	Houston, TX
The Children's Hospital of Alabama	Birmingham, AL
The Hospital for Sick Children	Toronto, Ontario, Canada
The Research Institute at Nationwide Children's Hospital	Columbus, OH
Tulane University Hospital	New Orleans, LA
Universitatsklinikum Mannheim	Mannheim, Germany
University Hospital Gasthuisberg	Leuven, Belgium
University of California, San Diego	San Diego, CA
University of Chicago	Chicago, IL
University of Kentucky Medical Center	Lexington, KY
University of Michigan, C.S. Mott Children's Hospital	Ann Arbor, MI
University of Mississippi Medical Center	Jackson, MS
University of Nebraska Medical Center	Omaha, NE
University of New Mexico Children's Hospital	Albuquerque, NM
University of North Carolina	Chapel Hill, NC
University of Padua	Padua, Italy
University of Puerto Rico Medical Center	San Juan, Puerto Rico
University of Texas Medical Branch at Galveston	Galveston, TX
University of Virginia Medical School	Charlottesville, VA
Vanderbilt Children's Hospital	Nashville, TN
Wilford Hall USAF Medical Center	Lackland AFB, TX
Winnie Palmer Hospital for Women & Babies	Orlando, FL
Yale New Haven Children's Hospital	New Haven, CT

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Table 1

Patient characteristics for operative cohort

n = 4390 total		Open (n=4239)	MIS (n=151)	p value
Mean EGA (weeks)		37.9 ± 2.2	38.4 ± 1.7	0.01
Birth weight (kg)		3.03 ± 0.60	3.18 ± 0.50	0.00
Major cardiac anomaly		220 (5.2%)	4 (2.6%)	0.16
Chromosomal anomaly		115 (2.7%)	2 (1.3%)	0.30
Side	Left	3475 (82.0%)	128 (84.8%)	
	Right	723 (17.1%)	22 (14.6%)	
	Bilateral	31 (0.1%)	1 (0.1%)	
	Central	8 (0.1%)	0 (0%)	
ECMO		1419 (33.5%)	8 (5.3%)	0.00
Days to repair		6.9 ± 13.0	5.4 ± 4.2	0.15
Patch repair		2188 (51.9%)	49 (32.5%)	0.00
Survival		3509 (82.9%)	148 (98.7%)	0.00

Table 2

Recurrence of CDH by operative approach

		Total	Recurrence (%)[a]	Days to recurrence
Open		4239	114 (2.6%)[b]	105.2 ± 85.4
	Abdominal	4012	106 (2.6%)	106.5 ± 85.1
	Thoracic	167	7 (4.2%)	73.5 ± 110.5
	Both	60	1 (1.7%)	111
MIS		151	12 (7.9%)[b]	68.4 ± 85.4
	Laparoscopic	26	1 (3.8%)	14
	Thoracoscopic	125	11 (8.8%)	73.4 ± 84.1

[a] % per operative approach

[b] overall open versus MIS, $p < 0.05$

Table 3

Recurrence of CDH by primary or patch repair

	Open	MIS
Primary repair	80/2118 (3.8%)	3/49 (6.1%)
Patch repair	34/2,099 (1.6%)	9/102 (8.8%)*

* $p < 0.05$