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Experience of Congenital Diaphragmatic Hernia in Neonates in a Tertiary Care Teaching Hospital in North Karnataka, India- A Prospective Cohort Study

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ABSTRACT

Background: Survival rates for congenital diaphragmatic hernia (CDH) neonates have increased with early prenatal detection and improved postnatal management.

Objectives: To assess the clinical profile, risk factors for mortality and the predictors affecting the outcome at discharge in neonates with CDH.

Method: A prospective observational cohort study was carried from October 2019 to September 2020 in a tertiary care teaching hospital in North Karnataka, India. Clinical characteristics and risk factors of 15 neonates diagnosed with CDH were compared between survivors and non-survivors.

Results: A total of 15 neonates diagnosed with CDH were included. CDH neonates who survived (87%) were significantly different from those who died (13%) in terms of onset of respiratory distress, pre-operative ventilation, presence of severe persistent pulmonary hypertension in the newborn (PPHN), maximum oxygenation index (OI) on day 1, surfactant administration, large defect size, intrathoracic liver, sepsis and length of hospital ($p<0.05$). The maximum OI on first day <15 and absence of severe PPHN predicted the survival for CDH neonates. ($p<0.005$).

Conclusions: The overall survival rate among CDH neonates in our institutional experience was 87%. Maximum OI on first day <15 and absence of severe PPHN were good predictors for the survival of CDH neonates.

Keywords: congenital diaphragmatic hernia, pulmonary hypertension, neonatal survival, outcomes

INTRODUCTION

Vincent Bochdalek first described congenital diaphragmatic hernia (CDH) in 1848 and Gross in 1946 did the first successful CDH repair[1].Harrison *et al*. stated that neonates with CDH reaching a tertiary care centre represent only 40%–50% of cases, reflecting the unknown mortality of CDH[2].Over the last decade, survival rates haveincreased from 50% to around 85% for CDH neonates, but the situationvaries in developing countries[3-6].In 2010, CDH EURO consortium developed guidelines for

CDH management which wererecently updated[7,8].The high mortality and morbidity of CDH prompt researchers to study the predictors of outcome in CDH[9]. Antenatal predictors involve markers for severity of lung hypoplasia and pulmonary hypertension[10]. Postnatal predictors for CDH include score for neonatal acute physiology on first day, CDH composite score, and oxygenation index (OI)[11,12]. Simple predictor scores such as OI have easy bedside application, rather than complicated composite scores[13].

Objectives

To assess the clinical profile, risk factors for mortality and the predictors affecting the outcome at discharge in neonates with CDH.

Method

Aprospective observational cohort study was carried out from October 2019 to September 2020 in Level II B neonatal intensive care unit (NICU) of Shri B M Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka, India.

Inclusion criteria: Neonates from day 0 to day 30 referred with a clinical suspicion and antenatal diagnoses of CDH were included in this study. All neonates with suspected or antenatally diagnosed CDH were admitted in NICU and started on supportive care as per standard protocol. The diagnosis of CDH was made from chest roentgenography and ultrasonography. Contrast- enhanced computerized tomography (CECT) was done in doubtful cases.

Exclusion Criteria: Neonates with diaphragmatic eventration andneonates aged more than 30 days were excluded from this study.

Baseline investigations (complete blood count, arterial blood gas) and echocardiogram were done on day 1 of NICU admission. Assistedventilationwasprovidedforneonatesrequiring ventilation both preoperatively and postoperatively as per unit protocol. Surgery was performed when the neonate's general condition improved and blood gases were stabilized for at least 24 hours. Repair of CDH under general anaesthesia was adopted as the treatment modality after initial medical stabilization.

The time of onset of respiratory distress after birth of the neonate was noted. Congenital cardiac malformations and persistent pulmonary hypertension of the newborn (PPHN) were diagnosed using two-dimensionalechocardiography (2D echo). The size of the diaphragmatic defect was determined by the operating surgeon. Stabilization of the neonate was defined by the following criteria (a) Normal haemodynamic parameters: Mean blood pressure >40 mmHg, heart rate 120-160beats/min, capillary filling time (CFT) <3 sec, oxygen saturation (Spo2) 87-95%(Pre-ductal) (b) improvement in signs of PPHN clinically and on 2D echo (c) Minimal pressure requirement (15–20 cmH_2O) while on ventilation[Conventional ventilation/ High frequency oscillatory ventilation (HFOV)]and adequate oxygenation achieved with minimal oxygen requirement (≤0.6). Oxygenation Index (OI) was calculated by the following formula: (MAP × FiO_2 × 100)/Pre ductal O_2, where MAP is mean airway pressure. FiO_2 is and P_aO_2 partial pressure of oxygen in arterial blood sample. Duration of mechanical ventilationwas the number of ventilation days prior to surgery.Approval for the study was obtained from the Institutional Ethics Committee.

Results

Fifteen neonates with CDH were enrolled in the study and underwent surgical procedures. Ten (67%) were males and 5 (33%) were females with a male to female ratio of 2:1. Of them 13 (86.7%) survived and 2 (13.3%) expired postoperatively.CDH was left sided in 13 (87%) and right sided in 2 (13%). None of the 15 neonates had any lethal or cyanotic congenital heart diseases. None of the 15 neonates had bilateral CDH, Baseline characteristics of survivors and non survivors among CDH neonates are shown in Table 1.

Mean onset of respiratory distress in hours was 6.07 ± 1.04 (median 6.0, range 2–10) in survivors and 4.03±1.51 in non survivors (P<0.005). Severe PPHN was observed in 02 (15%) of survivors and 02 (100%) of non survivors (P<0.005). Maximum OI on day 1(>15) was documented in 2(15%) of survivors and 2(100%) in non survivors (P<0.005). Need of surfactant administration was stated in 2(15%) of survivors and 2(100%) in non survivors (P<0.005). 03/13(23%) of survivors and 02(100%) of non survivors required preoperative ventilation among which 02 (67%) required HFOV in survivors and 02(100%) in non survivors. Above mentioned

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parameters were statistically significant. (P<0.005) Inotropic Requirement was observed in 09(69%) in survivors and 02(100%) in non survivors which was not statistically significant (P>0.005). (Table-2)

Ventilation parameters showed statistically significant observations in CDH neonates. Max OI on Day 1 was 08 ±5.3 among survivors and 17±4.4 among non survivors (P=0.041). Max Fio2 needed on Day 1 was 0.50±0.1 among survivors and 0.9±0.1among non survivors (P<0.001). Max MAP required on first day was 8.30±1.4 among survivors and 11.38±2.5 among non survivors (P=0.018). (Table-3)

There was a total of 2/15 (13.3%) deaths in our study. Whilst 01/13 (7.6%) neonates with left- sided CDH died 01/02 (50%) neonates with right- sided CDHalso died. Overall mortality was 13.3%.Univariate analysis comparing survivors and nonsurvivors with CDH revealed that mortality was not significantly associated with the following factors: gestational age (weeks), birth weight (g), gender, antenatal diagnosis, mode of delivery, Apgar score at 1 min and 5 min, age at admission, presence of cardiac malformation and laterality(p >0.05). However, mortality was associated with the following factors; onset of respiratory distress, preoperative ventilation, the presence of severe PPHN, maximum OI on day 1, surfactant administration, large defect size, intrathoracic liver, pneumothorax, sepsis and length of hospital stay (p<0.05).The survival at discharge for CDH was 86.7% (13/15 neonates). We analysed the absence of severe pulmonary hypertension, maximum OI on first day <15, and absence of pneumothorax for predictors of survival (Table 4).

Maximum OI <15 on first day, absence of severe pulmonary hypertension and absence of pneumothorax were significantly associated with survival in CDH neonates (p<0.05). The sensitivity and specificity for maximum OI <15 on first day to predict survival was 0.85 (confidence interval 0.52-0.99) and 1.00 (90-0.99) respectivelySensitivity and specificity of risk factors for mortality were assessed in CDH neonates (Table 5). Onset of respiratory distress <6 hours of life had sensitivity and specificity of 100% and 69% respectively with negative predictive value of 100%.Requirement of pre-operative ventilation had sensitivity and specificity of 100% and 77% respectively with negative predictive value of 100. Maximum OI on first day >15 had sensitivity and specificity of 100% and 85% respectively with negative predictive value of 100%.

Discussion

Mean gestational age in the present study among survivors was 37.5 ± 01.20 weeks and among non survivors was 36.89±1.03 weeks which was not statistically significant. The median age on admission was 40±14.6 hours in survivors and 39±15.8 which was not statistically significant. In this study the non survivor group had lower Apgar scores compared to the survivor group at 1 and 5 minutes but this was not statistically significant. Low 1 and 5 minute Apgar scores have been found to be major independent predictors of mortality[14].Antenatal detection rate of CDH varies from 10% to 79%but is less in developing countries due to inadequate antenatal visits and lack of facilities[15]. In our cohort, 53% of the cases were diagnosed antenatally. Polyhydramnios is documented in around 80% of CDH cases[16]. 3D estimation of fetal lung volume, calculating right lung area to thoracic area ratio and calculating lung to thoracic circumference ratio are the most widely used antenatal prognosticindicators[17,18]. Postnatally, CDH presents with respiratory distress, scaphoid abdomen and bowel sounds in the chest[19]. Imaging modalities include chest and abdomen x-ray, ultrasonogram, contrast enhanced CT scan and barium meal follow through in doubtfulcases.

Respiratory distress in CDH is caused by pulmonary hypoplasia and pulmonary hypertension[17]. In this study, onset of respiratory distress and prevalence of PPHN with maximum OI >15 on the first day were risk factors associated with severity of clinical features in CDH neonates. In this study, survivors presented with respiratory distress at 6.07 ± 1.04 hours of life whereas non survivors presented with respiratory distress at 4.03±1.51 hours of life which was significant statistically (p=0.027). Degree of lung hypoplasia correlates with severity of PPHN[20]. In our study, 15% of survivor neonates had severe PPHN and among non survivors 100% had severe PPHN which was statistically highly significant (*p*< 0.001). In our study 15% of neonates with CDH in survivor group presented with maximum OI on first day >15 compared to 100% neonates with CDH in non

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survivor group which was statistically significant (p=0.001). In our study 15% neonates with CDH in survivor group required surfactant compared to 100% neonates with CDH in non survivor group which was statistically significant(p=0.001).

The novel concept of gentle ventilation strategies which includes preserving spontaneous ventilation, permitting levels of hypercapnia ($PaCO_2$ 60–65 mmHg) and avoiding high inspiratory airway pressures (>25 cm H_2O) is being followed in our centre[21,22].In our institute, most neonates were managed by conventional ventilation as per standard protocol. In this study, 23% of the survivors received pre-operative ventilation whereas100% of non survivors received pre-operative ventilation which was statistically significant(p=0.032).Surgical correction of CDH was generally performed through an upper transverse or subcostal abdominal incision. Minimally invasive approaches such as thoracoscopy and laparoscopy have been documented[17,23]. In our series, we operated on two right sided CDH cases through open surgical repair. Thirteen babies with left sided CDH underwent various surgical procedures including open surgical repair (10), thoracoscopic repair (2), in another one, laparoscopic procedure was attempted.

In this study, large diaphragmatic defect size was observed in 23% of survivors and 100% of non survivors which was statistically significant (*p*= 0.032). Touloukian RJ,*et al* stated that defect size does not independently predictor mortality[24].A hernial sac of parietal peritoneum and lung pleura, found in around 20% cases,significantly improves the prognosis in CDH neonates[6]. In our study, we found a sac intraoperatively in 13%neonates andallofthemsurvived.Presence of intrathoracic liver in the chest cavityis a poor prognostic indicator[25].Albanese CT,*et al*has reported higher mortality among neonates with right sided CDH with intrathoracic liver[26]. In our study, we found intrathoracic liver in 100% cases of non survivors and 7.7% cases of survivors which was statistically significant.(p=0.002).Usui*et al*[27]found a 14% incidence of pneumothoraxin 510 CDH neonates. In our study 15% neonates among survivors and 100% neonates among non survivors had pre-operative pneumothorax which was statistically significant (p=0.011). In this study, survivors (20.84±4.4 days) among CDH neonates had a longer NICU hospital stay compared to non survivors (13.42±3.1 days) which was statistically significant (p=0.042).Similarly a study by Schaible T,*et al*[28]found an increased duration of NICU stay in neonates with CDH who survived, compared to non survivors.Among other associated conditions were infection, acidosis, and neonatal jaundice which adds to the morbidity[28]. In ourstudy, 23% neonates among survivors and 100% neonates among non survivors had sepsis which was statistically significant (p=0.032).

Right sided CDH is associated with a higher mortality[29].In our study, 01/13 (7.6%) neonates with left- sided CDH and 01/02 (50%) neonates with right- sided CDH died.This was not statistically significant (p=0.101).In recent studies overall survival rate of CDH neonates in NICU ranges from 21% to 83%[30,31]. In ourstudy, conducted over a period of 3 years, the survival rate among CDH neonates was 87%. Chandrasekaran*et al*[32], have reported a survival rate of 78% in their 12 year experience.Panda SS, *et al*[6]had a survival rate of 61% in postoperative CDH neonates. Jain A,*etal*[33] had a survival rate of 87.5% for CDH.Recent studies have shown survival for isolated CDH from 85%–90%, with improved standard protocols involving pulmonary hypertension management and availability ofECMO[33].

OI is widely used to assess the need for inhaled nitric oxide in cases of severe PPHN and need for ECMO[34].In our study maximumOIonday one oflifewasagoodpredictor of survival in CDH neonates with 100%sensitivity and 69%specificity at a cut-off of 15.Basiewicz-Slaczka E, *et al*[35] reported a 94%sensitivityand88%specificityata cut-offof12for OI on day one.Ali K, *et al*[36] found that the lowest OI on day 1 predicted survivalin neonates with CDH.Tan YW, *etal*[37] in their study suggested that serialOI measurementsis the best predictor of survival rather than single best OI. In our study, absence of severe pulmonary hypertension and absence of pre-operative pneumothorax were significant predictors for survival (p= 0.001). Lusk LA, *et al*[38] stated that the presence of severepulmonary hypertension and PPHNalso predict the short-term mortality and morbidity.In this study, we assessed the risk factors for mortality such as onset of respiratory distress within 6 hours, need of pre-operative ventilation and

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maximum OI on first day >15 which were found to be significant with negative predictive value of 100%. Similarly, Aihole JS, *et al*[39] stated that the onset of respiratory distress and pre-operative ventilation were significant risk factors for mortality in neonates with CDH.

Conclusions

In this study there was a survival rate of 87% in CDH neonates using the standard protocol in management. Risk factors for mortality included onset of respiratory distress and need for preoperative ventilation. Maximum Oxygenation Index on first day less than 15 and absence of severe pulmonary hypertension were good predictors for survival.

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Table 1: ***Baseline characteristics of survivors and non survivors among CDH neonates***

Parameters	**Survivors (*n*=13)**	**Non survivors (*n*=2)**	***p*-value**
*Gestational age (weeks)*Mean ± SD	37.5 ± 01.20	36.89±1.03	0.518
*Birth weight (g)*Mean ± SD	2810 ± 450	2570±340	0.487
*Age on admission (hours)*Mean ± SD	40±14.6	39±15.8	0.926
Sex Male n (%) Female n (%)	 09 (69) 04 (31)	 01 (50) 01 (50)	0.591
Antenatal diagnosis No n (%) Yes n (%)	 05 (32) 08 (68)	 02 (100) 00(00)	0.104
Mode of delivery Normal vaginal delivery n (%) Caesarean section n (%)	 03 (23) 10 (77)	 01(50) 01 (50)	0.423
Apgar score 1 minute Apgar score Mean ± SD 5 minute Apgar score Mean ±	 6.4 ± 0.80 8.5 ± 0.40	 6.1 ± 1.10 7.9 ± 0.90	 0.641 0.108

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SD			
Cardiac malformation No n (%) Yes n (%)	 05 (38) 08 (62)	 01 (50) 01 (50)	 0.756
Side of diaphragmatic hernia Left Right	 05 (38) 01 (08)	 01 (50) 01 (50)	 0.756

Significant level p<0.05; CDH: congenital diaphragmatic hernia; SD: standard deviation

Table 2: ***Comparison of parameters in survivors and non survivors among CDH neonates***

Parameters	**Survivors (*n*=13)**	**Non survivors (*n*=2)**	***p*-value**
*Onset of respiratory distress (hours)*Mean ± SD	6.07 ± 1.04	4.03±1.51	0.027
Maximum oxygenation index on day 1(>15) n (%)	02 (15)	02 (100)	0.001
Surfactant Non *(%)* Yes*n (%)*	 11 (85) 02 (15)	 00 (00) 02 (100)	 0.001
Inotropic requirement n (%)	09 (69)	02(100)	0.359
Severe persistent pulmonary hypertension of newborn Non *(%)* Yes*n (%)*	 11 (85) 02 (15)	 00 (00) 02 (100)	 0.001
Pre-operative ventilation Non *(%)* Yes*n (%)*	 10 (77) 03 (23)	 00 (00) 02 (100)	 0.032
High frequency oscillatory ventilation Non *(%)* Yes*n (%)*	 01 (33) 02/03 (67)	 00 (00) 02 (100)	 0.36
*Operation (24-72hours)*Mean ± SD	60±6.4	68±5.1	0.059
Large defect size n (%)	03 (23)	02 (100)	0.032
Intrathoracic liver n (%)	01 (7.7)	02(100)	0.002
Pneumothorax n (%)	02 (15)	02 (100)	0.011
Sepsis n (%)	03 (23)	02 (100)	0.032
*Length of Hospital stay (days)*Mean ± SD	20.84±4.4	13.42±3.1	0.042

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Significant level p<0.05;SD: standard deviation;CDH: congenital diaphragmatic hernia;

Table 3: ***Ventilation details of survivors and non survivors among CDH neonates***

Parameters	Survivors (*n*=13) Mean ± SD	Non survivors (*n*=2) Mean ± SD	*p*
Maximum oxygenation index on Day 1	08 ±5.3	17±4.4	0.041
Maximum fractional inspired oxygen needed on Day 1	0.50±0.1	0.9±0.1	<0.001
Maximum mean airway pressure required on Day 1	8.30±1.4	11.38±2.5	0.018

Significant level p<0.05;SD: standard deviation; CDH: congenital diaphragmatic hernia

Table 4: ***Predictors of survival in CDH neonates***

Parameters	Survivors (*n*=13)	Non survivors (*n*=2)	*p*-value
Maximum OI on first day <15 n (%)	11(85%)	00(100%)	0.001
Absence of severe pulmonary hypertension	11(85%)	00(00%)	0.001
Absence of Pneumothorax	11(85%)	00(00%)	0.001

Significant level p<0.05; CDH: congenital diaphragmatic hernia

Table 5: ***Risk factors for mortality in neonates with congenital diaphragmatic hernia***

	Onset of respiratory distress (<6hours)	Preoperative ventilation	Maximum OI on first day >15
Sensitivity	100.00%	100.00%	100.00%
Specificity	69.23%	76.92%	84.62%
Positive predictive value	33.33%	40.00%	50.00%
Negative predictive value	100.00%	100.00%	100.00%
Accuracy	73.33%	80.00%	86.67%

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