Original Article

DOI: 10.7860/JCDR/2023/63034.17970

Paediatrics Section

Gross Congenital Anomalies at Birth in Northeast India- A Retrospective Observational Study

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ABSTRACT

Introduction: Congenital Anomalies (CA) are a significant cause of neonatal mortality both in developed and developing nations. Congenital abnormalities can have different patterns, prevalence rates, and risk factors across time and across different geographic regions.

Aim: To find out the incidence of CA occurring among institutional live births and to study the associated maternal and perinatal risk factors in Northeast region of India.

Materials and Methods: This retrospective observational study was carried out in the Neonatal Intensive Care Unit (NICU) at a Tertiary Care Hospital, Guwahati, Assam, India. The duration of the study was from January 2019 to December 2019. All newborns with CA during this period were included. Maternal and labour ward records were obtained. Data of maternal and antenatal factors such as age, parity, history of consanguinity, family history of congenital abnormality and mode of delivery were collected. The data were analysed using Microsoft Excel and Statistical Package for Social Sciences (SPSS) version 26.0 (IBM SPSS Statistics for Windows, Armonk, NY, USA). Proportion was calculated and the association was tested with Chi-square test and Fisher's-exact test. $p<0.05$ was considered to be statistically significant. Multivariate regression analysis was done to find the independent factor(s) for congenital anomaly.

Results: During this study, there were 13530 deliveries, which include 13290 (98.2%) live births and 240 (1.8%) stillbirths. Out of 13290 newborns, 349 had one or more CA accounting for an incidence of 2.6%. The Gastrointestinal (GIT) System was the most commonly affected (33.8%), followed by the Central Nervous System (CNS) (20.9%) and craniofacial (11.7%) system. Cases of the congenital anomaly were found in 2.7% of multiparas, whereas in primiparas, the proportion was only 2.3%. In univariate analysis birth weight, gender, gestational age, maternal age, parity and mode of delivery showed significant association with incidence of congenital anomaly $p<0.05$*. Regression analysis showed three variables were significantly affecting the occurrence of CAs: gender Odd's Ratio (OR) (OR=0.341), gestational age (OR=32.7) and parity (OR=0.016).

Conclusion: This study highlights the prevalence of GIT, CNS and craniofacial anomalies in this region. The major determinants for CAs were gestational age, gender and parity.

Keywords: Malformations, Newborn, Prematurity, Risk factors

INTRODUCTION

Congenital anomaly represents defects in morphogenesis during early foetal life. Recent World Health Organisation (WHO) fact sheet of February 2022, defined CA as structural or functional anomalies, including metabolic disorders, which are present at the time of birth. Environmental factors like maternal infections (syphilis, rubella), radiation exposure, certain pollutants, maternal nutritional deficiencies (e.g., iodine, folate deficiency), illnesses (maternal diabetes), or certain drugs (alcohol, phenytoin) are all other factors that cause birth defects [1]. As neonatal and under-5 mortality rates decline owing to the improvement in perinatal and neonatal care, birth defects have become a larger proportion of the cause of neonatal and under-5 deaths. It accounts for 8%-15% of perinatal deaths and 13%-16% of neonatal deaths in India [2,3]. It is not only a leading cause of foetal loss but, also contributes significantly to preterm birth, childhood and adult morbidity along with a significant toll on individuals, families, healthcare systems, and societies [1]. There is scant data on the number of live born children with birth defects in North-eastern region of the country [4,5]. Previous literature has shown that, birth prevalence of CA is affected due to social, racial, economical, and ecological factors [6].

So, to reduce the incidence of various CA, it is important to identify prevalence of various anomalies in the society and the risk factors for them. Therefore, the aim of this study was to find the incidence of CA occurring among institutional live births and to study the associated maternal and perinatal risk factors.

MATERIALS AND METHODS

A retrospective observational study was carried out in the NICU at Gauhati Medical College and Hospital, Guwahati, Assam, India, for a period of one year from January 2019 to December 2019. Data were collected and analysed from August 2021 to February 2022 after obtaining approval from Institutional Ethics Committee (IEC) of Gauhati Medical College and Hospital, Guwahati (Reference No MC/190/2007/Pt-11/July 2021/44).

Sample size calculation: Sample size was calculated by the formula, $n=Z^2\times p\times q/e^2$ ('p' is the prevalence and q is 1-p.) The prevalence of congenital anomaly was taken as 2.7% [6]. The value for 'Z' was found in statistical table, which contains area under the normal curve. Here, Z=1.96 for 95% confidence. The margin of error here was taken as 2%. Putting the values in the equation, calculated sample size was 252 but a total of 349 samples were finally included in the study.

All the babies born with CA during this period were included. A paediatrician in the delivery room examined both the mother and her baby.

Study Procedure

System-wise distribution of the CA was performed. CA was classified according to the system involved into musculoskeletal, CNS, gastrointestinal, genitourinary, craniofacial, cardiovascular, cutaneous and miscellaneous groups. A detailed antenatal and maternal history, including the mothers' ages, parity, and history of

consanguinity, was obtained for each case by reviewing maternal and labour ward records and interviewing the parents. Diagnosis of CA was based on the clinical evaluation of newborn babies by the paediatrician and other appropriate investigations such as radiography, Ultrasonography (USG), 2D echocardiography, chromosomal analysis, etc. Computed Tomography (CT) scans and Magnetic Resonance Imaging (MRI) were advised only for certain special cases.

Marriage was considered consanguineous, when it was found to have occurred between a male and a female who were blood-related, e.g., between brother and sister, between first cousins, etc., [7]. Birth weights >2.5 kg were considered to be normal; whereas, birth weights <2.5 kg and <1.5 kg were termed as Low Birth Weight (LBW) and Very Low Birth Weight (VLBW) respectively. Babies born at <37 completed weeks (i.e., <259 days), calculated from the first day of the last menstrual period, were considered premature [8]. International Classification of Diseases, Tenth Revision (ICD-10) system was used to classify the major CAs and multiple major CAs were counted only once by the system for the most serious anomaly [9]. Malformations were divided into the CNS, musculoskeletal, gastrointestinal, genitourinary, Cardiovascular System (CVS), syndromes, and others. Maternal factors like maternal age, parity, consanguinity, history of congenital anomaly in the family and mode of delivery were collected. Foetal factors like gestational age, birth weight and gender were collected.

STATISTICAL ANALYSIS

The data were analysed using Microsoft Excel and SPSS v.26.0 (IBM SPSS Statistics for Windows, Armonk, NY, USA). Proportion was calculated and the association was tested with Chi-square test and Fisher's-exact test. The p-value of <0.05 was considered to be statistically significant. Multivariate logistic regression was used considering the dependent variable as CA and other parameters were considered as independent variable.

RESULTS

During this one year study, there were 13530 deliveries, which included 13290 (98.2%) live births and 240 (1.8%) stillbirths. Among stillbirths, CA was found in 11 (4.6%) babies. Out of 13290 newborns, 349 had one or more CA accounting for an incidence of 2.6%. Out of these, 289 (82.8%) had a single congenital anomaly and the other 60 (17.2%) had multiple malformations. Three of the 28 pairs of twins and one of one set of triplets had birth defects. The predominant system involved was GIT (33.8%), followed by the CNS (20.9%) and craniofacial (11.7%) system. Anorectal malformation (22.1%) was the most common anomaly seen in the gastrointestinal group and likewise meningomyelocele (13.8%) in CNS and cleft lip and cleft palate (5.2%) in craniofacial system. Systemic distribution and the incidence of individual congenital malformations are described in [Table/Fig-1]. CNS defects were most commonly seen in stillborns.

Regarding the parity of the mothers, 3160 were primiparas, and the rest 10130 were multiparas. Cases of the congenital anomaly were found in 2.7% of multiparas, whereas in primiparas, the proportion was only 2.3%. Women less than 20 years had 0.6% babies with CA, and the mothers of babies with CA were between 21 to 25 years, i.e. 2.7%, and 3.6% of the mothers were above 30 years of age. In the present study, 324 mothers had a history of consanguinity and six of them showed some congenital anomaly (1.8%) in their babies, whereas in non consanguineous couples, the prevalence was 2.6%. There was a significant difference in the frequency of CAs in male, female and ambigious babies (p-value <0.001**). Prematurity and LBW was found to have a higher association with CA. The occurrence was about 1.8 times more in case of preterm delivery as compared with the term ones, making it statistically significant. Mode of delivery was also significantly associated with congenital anomaly and it was more in case of assisted vaginal delivery [Table/Fig-2].

Family history of congenital anomaly was present in 3.34% cases whereas in 2.61% babies, did not have any family history of congenital anomaly. Congenital malformations were seen more in stillbirths as compared to live births, the frequency being 4.6% and 2.6%, respectively, however it was not statistically significant (p<0.06). Maternal and foetal factors associated with CAs at birth were described in [Table/Fig-2].

System type	Malformations	N (%)
Gastrointestinal	Duodenal atresia	4 (1.12)
	Gastrochisis	13 (3.7)
	Pyloric stenosis	2 (0.6)
	Anorectal malformation	77 (22.1)
	Hirschsprung's disease	3 (0.9)
	Jejunal atresia	1 (0.3)
	Tracheoesophageal fistula	8 (2.3)
	Omphalocele	10 (2.9)
Central nervous system	Hydrocephalus	19 (5.4)
	Microcephaly	3 (0.9)
	Meningomyelocele	48 (13.8)
	Neural tube defect with hydrocephalus	1 (0.3)
	Anencephaly	2 (0.6)
Craniofacial	Anophthalmia	1 (0.3)
	Microphthalmia	3 (0.9)
	Aniridia	1 (0.3)
	Cleft lip	9 (2.6)
	Cleft Palate	7 (2)
	Cleft lip cleft palate	18 (5.2)
	Absence of depressor anguli oris	2 (0.6)
Genitourinary	Amibigious genitalia	9 (2.6)
	Bladder extrophy	6 (1.7)
	Ambigious genitalis with bladder extrophy	1 (0.3)
	Hypospadias	2 (0.6)
	Hydronephrosis	4 (1.12)
	Absent penis	1 (0.3)
	Posterior urethral valve	3 (0.9)
	Chordee	2 (0.6)
Cardiovascular	Dextrocardia	1 (0.3)
	Acyanotic	18 (5.2)
	Cyanotic	6 (1.7)
Musculoskeletal	CTEV	4 (1.12)
	CTEV with hydrocephalus	1 (0.3)
	Congenital dysplasia of hip	1 (0.3)
	Polydactyly	4 (1.12)
	Syndactyly	3 (0.9)
	Clinodactyly	2 (0.6)
Cutaneous	Preauricular tag	2 (0.6)
	Haemangioma	5 (1.4)
	Giant hairy naevus	3 (0.9)
Miscellaneous/ syndromes	Syndromic	21 (6)
	Others	18 (5.2)

[Table/Fig-1]: Type of congenital malformations observed in patients (n=349).
CTEV: Congenital talipes equinovarus

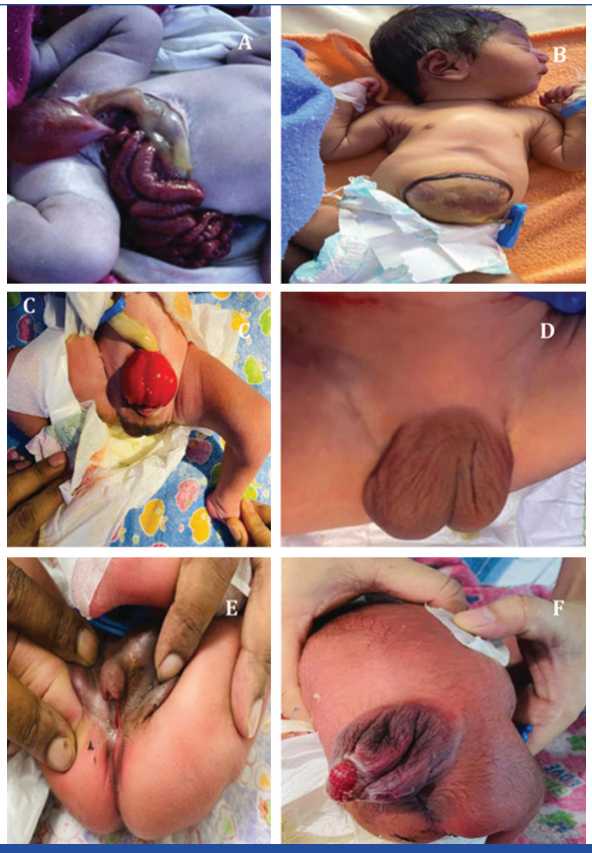
Foetal factors				
Variables	Total cases	Congenital anomalies (CA)	Percentage (%)	$\chi 2$ value, df, p-value
Birth weight (grams)				
<1000	310	20	6.45	291.9, 4, <0.001**
1000-1500	897	54	6.02	
1501-2000	1264	56	4.43	
2001-2500	1567	115	7.33	
>2501	9252	104	1.12	
Gender				
Male	198		56.7	28.8, 2
Female	141		40.4	<0.001**
Ambigious	10		2.9	
Gestation				
Preterm	930	42	4.52	15.8, 2
Term	11602	294	2.53	<0.001**
Post-term	758	13	1.71	
Pregnancy outcome				
Live birth	13290	349	2.6	3.487, 1
Still birth	240	11	4.6	0.061
Maternal factor				
Variables	Total cases	Congenital anomalies (CA)	Percentage (%)	$\chi 2$ value, df, p-value
Maternal age (years)				
<20	640	4	0.6	45,3
21-25	5832	160	2.7	<0.001**
26-30	2890	40	1.38	
>30	3928	145	3.69	
Parity				
Primi	3160	74	2.3	53.8,2
Para 1-3	9152	214	2.3	<0.001**
Para 4 and more	978	61	6.2	
Parental consanguinity				
Consanguineous marriage	324	6	1.85	0.778,1
Non consanguineous marriage	12966	343	2.64	0.378
History of an anomaly				
Family	209	7	3.34	0.434, 1
Positive	13081	342	2.61	0.510
Negative				
Mode of delivery				
Normal vaginal delivery	9303	238	2.5	18.7,2
Assisted vaginal delivery	7	2	28.5	<0.001**
LSCS	3980	109	2.7	

[Table/Fig-2]: Frequency of Congenital Malformations in relation to various foetal and maternal factors.
**Statistically significant; LSCS: Lower segment caesarian section

A few examples of the discovered CA are shown in [Table/Fig-3]. Parents gave their approval for the publication of photographic material. A stepwise logistic regression was done for the determinants of CAs. Six independent variables were used to build the stepwise logistic regression model, namely birth weight, gender, gestational age, maternal age, parity and mode of delivery. Three variables were significantly affecting the occurrence of CAs: gender (OR=0.341), gestational age (OR=32.7) and parity (OR=0.016) (p<0.05*) [Table/Fig-4].

DISCUSSION

With a decline in death from infectious diseases and malnutrition, child mortality rates worldwide are trending downward [10]. The causes of child mortality in developing countries are anticipated to change along with this decrease, leading to a corresponding rise in noncommunicable diseases including congenital abnormalities. Another reason to study CA in developing countries is that, all CA are not lethal but the disastrous expenditures, need for life long care and survival with disability affects the families with non fatal CA [11-13]. There is scant data on the number of live born children with



[Table/Fig-3]: a) Gastroschisis; b) Omphalocele; c) Bladder exostrophy; d) Absent penis; e) Imperforate anus with cordee; f) Meningomyelocele.

Independent variables	Coefficient B	Standard error	df	p-value	Odds ratio
Birth weight (gm)					
<1000	103.649	5139.518	1	0.966	1.846
1000-1500	81.641	1469.291	1	0.956	2.859
1501-2000	61.272	1257.308	1	0.961	4.072
2001-2500	36.204	681.665	1	0.958	5.285
Gender					
Male	-1.838	1433.874	1	0.999	0.159
Female	-1.075	0.347	1	0.002*	0.341
Gestation					
Preterm	3.490	0.433	1	0.001	32.777
Term	0.533	0.363	1	0.143	1.704
Maternal age (year)					
Less than 20	-59.800	3493.361	1	0.986	0.001
21-25	-39.574	2735.298	1	0.988	0.001
26-30	-16.299	2680.862	1	0.995	0.001
Parity					
Primi	-41.933	1301.595	1	0.974	0.001
Para 1-3	-4.131	0.304	1	0.001	0.016
Mode of delivery					
NVD	0.983	3040.175	1	1.000	2.672
Assisted delivery	-2.069	31761.482	1	1.000	0.126

[Table/Fig-4]: Stepwise logistic regression analysis results for the determinants affecting the presence of CAs among neonates.
df: Degrees of freedom; NVD: Normal vaginal delivery

birth defects in this region of the country [4,5]. In the present study, the overall incidence of CAs was 2.6% (349 of 13290) of live born neonates. The prevalence in the current study was similar to other studies from Europe, Nepal and Pakistan [14-16]. However, a few studies from Kuwait, UAE, Egypt and India have showed lower prevalence than the current study [17-20]. These differences may be due to regional and referral differences. These percentages also reflect prevalence at tertiary centres rather than the general population because of the greater referral rates at these facilities. A recent systematic prospective analysis of 1781 live births conducted by the Pune Urban Birth Outcome Study group (PUBOS) revealed a prevalence rate of 168.44 per 10,000 live births [21]. The PUBOS is the only prospective study carried out in India, making it the study that is most likely to represent the prevalence rate across the country.

In the present study, common system involved was the gastrointestinal system (33.8%), followed by the CNS (20.9%) and craniofacial (11.7%). Gastrointestinal anomalies were the most common malformations that required surgical intervention, as per the study from tertiary paediatric surgery centre from Rohtak, India [22]. The findings were similar to a study done by Dutta HK et al., in Assam that showed malformations involving the gastrointestinal tract (26%) and genitourinary tract (25.8%) were the most common anomalies [5]. However, higher incidence of CNS and CVS malformations followed by GIT and musculoskeletal system were found in a few studies [23,24]. Different rates might be attributed to the fact that the present study was a hospital based case series while the other study was conducted using a population based surveillance program. The current study found that CAs prevailed in babies of consanguineous marriages. The role of parental consanguinity in the development of CAs has been addressed by other studies [2,17]. Homozygous expression of recessive genes inherited from their common ancestors is the most likely cause of increased incidence of congenital malformation in the babies of consanguineous couple [25]. In the present study, incidence of congenital malformations was higher among LBW babies in comparison to normal weight babies and the association was statistically significant with a p-value <0.001**. This association of LBW and malformations has been well documented in other studies [16,26]. Several studies have documented a male preponderance among congenital malformed babies [16,27,28]. The present study also witnessed the male preponderance of congenital malformation in the present series with a p-value of <0.001**. It may be because of the fact that, the females were afflicted with more lethal congenital malformations and could not survive to be born with signs of life [29].

The association between LBW and increased risk of CAs are well-recognised [30]. According to a previous study from India, the incidence of congenital abnormalities was substantially higher in preterm babies than in term babies [31]. Although, the incidence of CAs in the current study differed significantly among mothers of various age groups, many authors have shown a higher incidence of malformations in babies born to mothers aged less than 20 years or in babies born to mothers aged over 35 years [22]. The present study, revealed that, a majority of malformed babies were born to mothers aged >30 years; it was statistically significant (p-value=0.0014*). Previously, a significantly higher incidence of malformations among the multiparas has been reported, which is concordant with the result of the current study [31]. Thus, CA is emerging as significant perinatal complication contributing considerably to the perinatal mortality and morbidity with substantial consequences on the affected families.

Limitation(s)

The present study was based on retrospective data from a hospital delivery unit in a tertiary care hospital and referral centre and, as such, is not the true representative of the situation in the community at large. In the absence of postmortem examination of stillborn infants, and those delivered at home who died in the neonatal period, an incomplete follow-up to age one year, and a lack of genetic evaluation; all of these may have resulted in an underestimation of the overall prevalence of CA. Hence, prevalence calculated in this study cannot be projected to the total population. A community based prospective study should preferably be carried out for true assessment of incidence of CA in a population.

CONCLUSION(S)

This study has highlighted the prevalence and analysis of pattern of congenital malformation in a Tertiary Care Hospital in Northeast India. CA was more likely to be associated with gender, gestational age and parity. This would give a stimulus for further studies on the subject and a healthcare plan for prevention strategies. Regular antenatal visits and prenatal diagnosis are recommended for prevention, early intervention, and even planned termination when needed. Screening of high risk cases, routine prenatal folic acid supplementation, regular antenatal visits, early prenatal diagnosis and termination of foetus with lethal anomaly before attaining viability will reduce perinatal morbidity and mortality. In addition, congenital abnormalities also require a registration system to be established. More research is needed to determine the factors underlying the various types of congenital malformation encountered in Northeast region.

Acknowledgement

To all the parents of the babies included in the present study and the paediatric residents of Gauhati Medical College and Hospital for their co-operation and helped in data collection.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jan 27, 2023
- Manual Googling: Feb 16, 2023
- iThenticate Software: Mar 02, 2023 (20%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Jan 21, 2023**
Date of Peer Review: **Feb 07, 2023**
Date of Acceptance: **Mar 06, 2023**
Date of Publishing: **May 01, 2023**