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Paediatrics Section

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

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## ABSTRACT

**Introduction:** Congenital Anomalies (CAs) are a significant cause of neonatal mortality in both developed and developing nations. CAs can have different patterns, prevalence rates, and risk factors across time and 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 conducted in the Neonatal Intensive Care Unit (NICU) at a Tertiary Care Hospital in Guwahati, Assam, India from January 2019 to December 2019. All newborns with CAs during this period were included. Maternal and labour ward records were obtained, including data on maternal and antenatal factors such as age, parity, history of consanguinity, family history of congenital abnormality, and mode of delivery. 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). Proportions were calculated, and associations were tested with the Chi-square test and Fisher's-exact test. A p-value of less than 0.05 was considered statistically significant. Multivariate regression analysis was performed to find the independent factor(s) for congenital anomaly.

**Results:** During the study period, there were 13,530 deliveries, which included 13,290 (98.2%) live births and 240 (1.8%) stillbirths. Out of 13,290 newborns, 349 had one or more CAs, 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 congenital anomalies 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 a significant association with the incidence of congenital anomaly ($p<0.05$*). Regression analysis showed that three variables significantly affected 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. The 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 due 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 the north-eastern region of the country [4,5]. Previous literature has shown that the birth prevalence of CA is affected due to social, racial, economical, and ecological factors [6].

To reduce the incidence of various CAs, it is important to identify the 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 the 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 using the formula $n=Z^2\times p\times q/e^2$, where '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 a statistical table, which contains the area under the normal curve. Here, Z=1.96 for 95% confidence. The margin of error was taken as 2%. Putting the values in the equation, the calculated sample size was 252, but a total of 349 samples were finally included in the study.

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

### 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

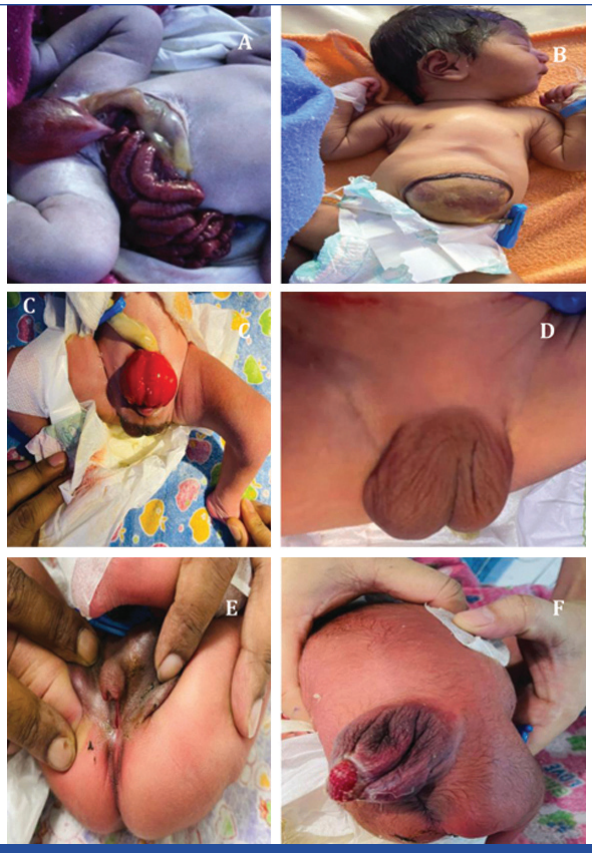
| Foetal factors | | | | |
|---|---|---|---|---|
| Variables | Total cases | Congenital anomalies (CA) | Percentage (%) | χ2 value, df, p-value |
| **Birth weight (grams)** | | | | |
| <1000 | 310 | 20 | 6.45 | 291.9, 4, <0.001** |
| 1000-1500 | 897 | 54 | 6.02 | |
| 1501-2000 | 1264 | 56 | 4.43 | |
| 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 (%) | χ2 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




**[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

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

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 pattern of congenital malformations in a Tertiary Care Hospital in Northeast India. CA was found to be more likely associated with gender, gestational age, and parity. This study provides a stimulus for further research on the subject and the development of healthcare plans for prevention strategies. Regular antenatal visits and prenatal diagnosis are recommended for prevention, early intervention, and even planned termination when necessary. Screening high-risk cases, routine prenatal folic acid supplementation, regular antenatal visits, early prenatal diagnosis, and termination of foetuses with lethal anomaies before attaining viability can reduce perinatal morbidity and mortality. Additionally, establishing a registration system for congenital abnormalities is necessary. More research is needed to determine the factors underlying the various types of congenital malformations encountered in the Northeast region.

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