Original Article

DOI: 10.7860/IJNMR/2022/56379.2343

# Spectrum of Congenital Malformations and Associated Factors: A Cross-sectional Study from Eastern India

Paediatrics Section

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## ABSTRACT

**Introduction:** Congenital malformations are important contributors for neonatal and infant mortality after prematurity, intrapartum complications and infections.

**Aim:** To find out the prevalence and pattern of congenital malformations among the live born neonates in study area as well as to identify the associated risk factors.

**Materials and Methods:** This descriptive hospital based cross-sectional study was carried out in 305 cases at Midnapore Medical College, Medinipur, West Bengal, from July 2016 to June 2017. All live inborn neonates were assessed for the presence of any malformation(s). The still born or out born babies were excluded. Congenital malformations were diagnosed by clinical examination as well as imaging studies. Data regarding risk factors were collected from the history and the case records. Chi-square test was done to find out the significance of the risk factors.

**Results:** During the study period, there were 14240 live births, out of which 305 cases of congenital malformations were noted. Prevalence of congenital malformations was 214.1 per 10,000 live births or 2.14%. Out of 305 cases, 165 (54.10%) were males, 137 (44.92%) were females, and 3 (0.98%) had ambiguous genitalia. Prevalence of malformations was not significantly different between primi and multipara mothers, and for the different socio-economic backgrounds. A higher prevalence of congenital malformations in mothers above 30 years, consanguinity, low birth weight and prematurity were observed. History of abortion and still birth were associated with higher prevalence. Polyhydramnios, pregnancy induced hypertension and previous abortion and still birth were also associated with higher prevalence of malformations. Musculoskeletal system was majorly involved in 92 (30.16%) cases, followed by central nervous system 48 (15.74%).

**Conclusion:** Prevalence of congenital malformations was found to be 214.1 per 10,000 live births or 2.14%. Maternal age >30, consanguinity, prematurity and low birth weight were associated with increased prevalence of congenital malformations. Musculoskeletal system was the most commonly involved system.

**Keywords:** Birth defects, Congenital anomaly, Consanguinity, Prevalence, Risk factors

## INTRODUCTION

Congenital malformations are defined by World Health Organisation (WHO) as structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth, or sometimes later in infancy [1]. Though the WHO definition includes functional defects such as metabolic disorders as well, congenital malformations generally refer to birth defects or morphological defects of organs or body parts identifiable at birth [2]. Congenital malformations can be major or minor. Major malformations can lead to death or severe dysfunction if no remedial measures are provided, whereas minor malformations only produce cosmetic disfigurement. Congenital malformations particularly major, are more prevalent in still births. Thus nervous system and cardiac defects are more common in still births whereas skeletal system is more affected in live births [3].

Congenital malformations are important contributors for neonatal and infant mortality. These are the largest cause of neonatal mortality after prematurity, intrapartum complications and infections in India and other developing countries. These are likely to rise to more prominence as these countries progress to reduce the infectious diseases and improve institutional deliveries [3].

The prevalence of congenital malformations at birth is estimated to be around 2-3% [2]. Congenital anomalies are not considered important in countries like India. True prevalence of congenital malformations in India is not known currently noted because of lack of national birth defect surveillance. However, it is estimated that they constitute the fifth largest cause (around 9%) of neonatal mortality in India. Using systematic literature search and meta-analysis, a pooled prevalence of congenital malformations in India was found to be 184 per 10,000 live births or 1.84% [3]. Though this was slightly lower than global prevalence, absolute number of congenital anomalies in India would be quite high.

Implementation of Sustainable Development Goals (SDG) started from 2016. The SDG hopes to bring down under the age of five mortality and neonatal mortality to 25 and 12 respectively per 1000 live births by 2030 [4]. The three leading causes of mortality are preterm birth complications, pneumonia and intrapartum related problems. It is expected that as these above mortality would come down, proportion of global neonatal mortality due to congenital malformations would rise [5,6].

Though there are several studies on congenital malformations from different centres in India, but there is no national surveillance for congenital malformation at present. Indian studies have reported local incidence rates from 0.3% to 3.6% [7]. Recently Bhide P et al., (2016), from a population based study with a robust study design, reports prevalence of 230.51 per 10,000 live births [8]. Recently Government of India has initiated Rastriya Bal Swasthya Karyakarm (RBSK) which focuses on management of birth defects [9]. The significance of congenital malformations lies not only in their contribution to neonatal mortality but also in causing morbidly, physical and mental handicap in later life. Moreover, the effect is not limited to the affected individuals only but extends to their families adding a social and economic burden to

the society at large. Mortality and morbidity due to these conditions can be reduced to certain extent by early detection and accurate diagnosis. Though it will be impossible to prevent all congenital malformations, knowledge regarding the associated or causative factors can be used to our advantage to reduce the future prevalence. For example, consanguinity is a well-known preventable factor [7,10]. Also, the knowledge of magnitude and pattern of congenital malformations would be a great help in the plan of better management of the same.

The present study was undertaken to find out the local prevalence and pattern of congenital malformations among the live born neonates as well as to identify the associated risk factors.

## MATERIALS AND METHODS

This descriptive, cross-sectional hospital based study was carried out at Midnapore Medical College, Medinipur, West Bengal, in Eastern India, from July 2016 to June 2017. Ethical clearance was obtained from the Institutional Ethics Review Committee of the study institute (ERC No. IEC/ MMC/72) on 15/01/2016. All live inborn neonates were carefully assessed as a part of routine examination for the presence of any malformation(s), major or minor.

**Inclusion criteria:** The neonates born with congenital malformations during the study period were included in the study, after obtaining consent from the parents.

**Exclusion criteria:** All still birth or out born babies were excluded from the study.

### Study Procedure

Congenital malformations were diagnosed by clinical examination and imaging studies such as radiography, ultrasonography, echocardiography, if needed. System wise distribution of detected congenital malformations was done according to organ involvement. Detailed antenatal, perinatal history and social history particularly history of consanguinity was obtained. The demographic and socio-economic data was also collected from the hospital records. BG Prasad's scale was used to determine the socio-economic status of the mother [11].

## STATISTICAL ANALYSIS

Data was entered into Microsoft Excel spreadsheet. Chi-square test for was done to find out the significance of maternal and foetal variables associated with congenital malformations. A cut-off p-value of <0.05 was taken for statistical significance. Online software Medcalc comparison of proportion calculator was used for statistical analysis [12].

## RESULTS

During the study period, out of 14240 live births in the institute, 305 cases of congenital malformation were noted. Thus, the prevalence of congenital malformations was 214.1 per 10,000 live births or 2.14%. Out of 305 cases, 165 (54.10%) were males, 137 (44.92%) were females, and 3 (0.98%) had ambiguous genitalia. The parity of mothers was not significantly associated with congenital malformations in the baby. However, >30 years age in mothers was significantly associated with congenital malformations (p=0.0002). Consanguinity was highly significant (p<0.0001). Maternal diseases such as polyhyrdamnios, pregnancy induced hypertension and foetal factors (prematurity and low birth weight) were also significantly associated (p<0.0001). Socio-economic status of the family was not significantly associated association. Various factors associated with congenital malformation are summarised in [Table/Fig-1].

| Variables | Total live births (n=14240) | Congenital malforma-tions (n=305) | p-value |
|---|---|---|---|
| **Parity** | | | |
| Primi | 7346 (51.6%) | 172 (56.4%) | 0.097 |
| Multi | 6894 (48.4%) | 133 (43.6%) | 0.097 |
| **Age of mother (in years)** | | | |
| <20 | 3415 (24%) | 81 (26.6%) | 0.2932 |
| 20- 30 | 10438 (73.3%) | 205 (67.2%) | 0.0174 |
| >30 | 387 (2.7%) | 19 (6.2%) | 0.0002 |
| **Consanguinity** | | | |
| Consanguinity | 147 (1.03%) | 59 (19.34%) | <0.0001 |
| Non consanguineous parents | 14093 (98.96%) | 246 (80.66%) | <0.0001 |
| **Socio-economic status** | | | |
| Lower class | 3110 (21.9%) | 75 (24.6%) | 0.2597 |
| Lower middle class | 8677 (60.9%) | 192 (62.9%) | 0.4787 |
| Upper middle class | 2453 (17.2%) | 38 (12.5%) | 0.31 |
| **Maternal diseases** | | | |
| Polyhydramnios | 104 (0.7%) | 19 (6.2%) | <0.0001 |
| Pregnancy induced hypertension | 239 (1.7%) | 25 (8.2%) | <0.0001 |
| Previous abortion and still birth | 101 (0.7%) | 32 (10.5%) | 0.0001 |
| Gestational diabetes | 345 (2.4%) | 12 (3.9%) | 0.0914 |
| No obvious disease | 13451 (94.5%) | 217(71.2%) | 0.0001 |
| **Gestational age** | | | |
| Prematurity (<37 weeks) | 2036 (14.3%) | 96 (31.4%) | <0.0001 |
| Term pregnancy (37-40 weeks) | 12110 (85%) | 207 (67.9%) | <0.0001 |
| Postmaturity (>40 weeks) | 94 (0.7%) | 2 (0.7%) | 0.8356 |
| **Birth weight** | | | |
| Low birth weight (<2.5 kg) | 4384 (30.9%) | 201 (65.9%) | <0.0001 |
| Normal birth weight (2.5-3.5 kg) | 9839 (69%) | 103 (33.8%) | <0.0001 |
| Large ( >3.5 kg) | 17 (0.1%) | 1 (0.3%) | 0.2481 |

**[Table/Fig-1]:** Factors associated with congenital malformation.
p-value<0.05 was considered significant

Musculoskeletal system 92 (30.16%) was found to be most commonly involved system. Congenital Talipes Equinovarus (CTEV) 38 (12.5%) was found to be the most common malformation among cases having musculoskeletal system involvement, whereas among cases having Central Nervous System (CNS) involvement meningocele 14 (4.59%) was most common [Table/Fig-2].

| Type of congenital malformation | Number (%) |
|---|---|
| **Musculoskeletal system** | |
| CTEV* | 38 (12.5%) |
| Syndactyly | 15 (4.9%) |
| Polydactyly | 5 (1.6%) |
| Calcaneovarus | 5 (1.6%) |
| Absent Pectoralis major | 4 (1.3%) |
| Rhizomelic limb defect | 3 (0.9%) |
| Arthrogyroposis | 3 (0.9%) |
| Genu recurvatum | 3 (0.9%) |
| Congemital tortecolles | 1 (0.3%) |
| Total | 77 (25.2%) |

| Central nervous system | |
|---|---|
| Meningocele | 14 (4.6%) |
| Meningomyelocele | 10 (3.3%) |
| Spina bifida oculta | 4 (1.3%) |
| Encephalocele | 3 (0.9%) |
| Anencephaly | 3 (0.9%) |
| Microcephaly | 3 (0.9%) |
| Arnold Chiari malformation | 3 (0.9%) |
| Dandy Walker malformation | 3 (0.9%) |
| Congenital hydrocephalous | 2 (0.6%) |
| Holoprosencephaly | 2 (0.6%) |
| Cerebellar hypoplasia | 1 (0.3%) |
| Total | 48 (15.7%) |
| **Gastrointestinal system** | |
| Cleft lip | 9 (2.9%) |
| Cleft lip and cleft palate | 7 (2.3%) |
| Gastroschisis | 5 (1.6%) |
| Imperforate anus | 4 (1.3%) |
| Tracheosophageal fistula | 3 (0.9%) |
| Omphalocele | 3 (0.9%) |
| Ranula | 1 (0.3%) |
| Tounge tie | 1 (0.3%) |
| Malrotation of gut | 1 (0.3%) |
| Total | 34 (11.1%) |
| **Cardiovascular system** | |
| Acyanotic heart disease | 18 (5.9%) |
| Cyanotic heart disease | 12 (3.9%) |
| Single umbilical artery | 3 (0.9%) |
| Total | 33 (10.8%) |
| **Genitourinary system** | |
| Hypospadiasis | 7 (2.3%) |
| Epispadiasis | 4 (1.3%) |
| Post urethral valve | 4 (1.3%) |
| Ambigious genitalia | 3 (0.9%) |
| Undescended testes | 3 (0.9%) |
| Extrophy of bladder | 2 (0.6%) |
| Congenital hydronephrosis | 1 (0.3%) |
| Polycystic kidney | 1 (0.3%) |
| Pelvic uereteric junction obstruction | 1 (0.3%) |
| Congenital hydrocele | 1 (0.3%) |
| Total | 27 (8.8%) |
| **Dermatological** | |
| Haemangioma | 7 (2.3%) |
| Preauricular tag | 4 (1.3%) |
| Aplasia cutis congenital | 2 (0.6%) |
| Congenital melanocytic nevus | 1 (0.3%) |
| Congenital icthyosis | 2 (0.6%) |
| Cystic hygroma | 1 (0.3%) |
| Total | 17 (5.6%) |
| **Respiratory system** | |
| Diaphragmtic hernia | 5 (1.6%) |
| Eventeration of diaphragm | 1 (0.3%) |
| Choanal atresia | 1 (0.3%) |
| Total | 7 (2.3%) |
| **Others** | |
| Down's syndrome | 9 (2.9%) |
| Pierre-Robin syndrome | 2 (0.6%) |
| Congenital hearing abnormality | 21 (6.9%) |
| Congenital cataract | 7 (2.3%) |
| Hydrops fetalis | 2 (0.6%) |
| Total | 41 (13.4%) |

**[Table/Fig-2]:** Details of congenital malformations detected (n=305).
*-Congenital talipes equinovarus

## DISCUSSION

The prevalence of congenital malformations varied widely in various studies from different places of India done during last decade [Table/Fig-3]. Bhide P et al., did a meta-analysis of 878 studies on congenital malformations done in India to find out a pooled prevalence of 184.48 per 10,000 live births [3]. The prevalence of 214.1 in the present study is close to the above study and also to the global prevalence of 2-3% or 200-300 per 10,000 live births [2].

The present study reported CTEV as the most common congenital malformation and musculoskeletal system as the most common affected system. Similar findings were reported in many other studies. Some studies reported circulatory system and central nervous system to be more common [8,13-26] [Table/Fig-3]. The present study found the following factors consanguinity, polyhydramnios, previous abortion and still birth, pregnancy-induced hypertension, low birth weight and prematurity was found to be significantly associated with congenital malformations ($p<0.0001$). Similar associations had been reported in other studies [Table/Fig-3].

Congenital malformations thus constitute 2.14% of live births, which is similar to the prevalence in other parts of the country. Their burden may be prevented by addressing the associated factors such as maternal age >30 years, consanguinity, prematurity and low birth weight. This will help in reducing the neonatal mortality rate and achieving the SDG goals by 2030. As progress will be done in the maternal and child health in the country, focus has to shifted to prevent these congenital malformations. Universal screening for congenial malformation may be another approach.

### Limitation(s)

The place of the study being a tertiary hospital, the study population might not represent the general population, as severe cases were usually referred from peripheral hospitals. Hence, the above fact must be kept in mind while interpreting the results. Many congenital problems for example, ventricular septal defect and metabolic disorders manifest at a later month, hence might be missed at birth. Results for investigations for intrauterine infections take time in the study setup, for which reason the specific diagnosis could not be in these cases.

## CONCLUSION(S)

Prevalence of congenital malformations was found to be 214.1 per 10,000 live births or 2.14%. Maternal age >30, consanguinity, prematurity and low birth weight were associated with increased prevalence of congenital malformations. Muskuloskeletal system was the most common type of birth defect.

### Acknowledgement

Authors are thankful to Prof MD Alauddin, HOD Gynaecology and Obstetrics Department, Midnapore Medical College, Medinipur; Prof Arun Kumar De HOD Paediatrics Department, Midnapore Medical

| Study/place of study/year | Prevalence per 10,000 live births | Most common congenital anomaly | Most common system involved | Associated risk factors |
|---|---|---|---|---|
| Present study | 214.1 | Congenital talipes equinovarus | Musculoskeletal system | Consanguinity, polyhydramnios, hypertension, low birth weight, prematurity |
| Kumar J et al., Chandigarh 2021 [13] | 182 | Congenital malformations of cardiac septa | Circulatory system | NA |
| Bhide P et al., Pune 2016 [8] | 230.51 | Atrial septal defect | Circulatory system | NA |
| Cherian AG et al., Vellore 2013 [14] | 125.3 | Congenital talipes equinovarus | Musculoskeletal system | Maternal age >30, low birth weight |
| Sankar VH et al., Kerala 2017 [15] | 190 | NA | Musculoskeletal system | Maternal diabetes, amniotic fluid abnormality, consanguinity |
| Ara A et al., Jammu 2018 [16] | 337 | Umbilical hernia | Digestive system | Extremes of maternal age and parity, muslims |
| Basavanthappa SP et al., Karnataka 2014 [17] | 308 | NA | Musculoskeletal system | NA |
| Marwah A et al., Haryana 2016 [18] | 170 | Meningomyelocele | Central nervous system | Prematurity |
| Kokate P and Bang R, Mumbai 2017 [19] | 90 | Meningomyelocele | Central nervous system | Consanguinity, prematurity, polyhydramnios |
| Bhalerao A and Garg R, Nagpur 2016 [20] | 138 | Congenital talipes equinovarus | Musculoskeletal system | Maternal age >30, Multiparity, consanguinity, male sex, low birth weight |
| Pandala P et al., Hyderabad 2019 [21] | 215 | Meningo myelocele | Central nervous system | Low birth weight, consanguinity |
| Thaddanee R et al., Gujarat 2016 [22] | 123 | NA | NA | Maternal age, consanguinity |
| Pattnaik T et al., Odisha 2016 [23] | 1250 | Hydrocephalous | Central nervous system | Amniotic fluid abnormality, consanguinity |
| Sarkar S et al., Kolkata (West Bengal) 2013 [24] | 222 | Congenital talipes equinovarus | Musculoskeletal system | Consanguinity, low birth weight, prematurity, multiparity |
| Pal AC et al., Bankuda (West Bengal) 2015 [25] | 230 | Congenital acyanotic heart disease | Circulatory system | Consanguinity, amniotic fluid abnormality, diabetes |
| Baruah J et al., Assam 2015 [26] | 120 | NA | Musculoskeletal system | Maternal age >30, Low birth weight |

**[Table/Fig-3]:** Comparison with other similar recent Indian studies on congenital malformation [8,13-26].

College, Medinipur and Prof Gadadhar Sarangi, HOD Paediatric Department, Hitech Medical College, Bhubaneswar for their help and guidance.

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**PLAGIARISM CHECKING METHODS:** [Jain H et al.]
- Plagiarism X-checker: Mar 25, 2022
- Manual Googling: Apr 09, 2022
- iThenticate Software: May 23, 2022 (4%)

**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. NA

Date of Submission: **Mar 15, 2022**
Date of Peer Review: **Mar 31, 2022**
Date of Acceptance: **Apr 11, 2022**
Date of Publishing: **Jun 30, 2022**