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Original Research Article

BURDEN OF BIRTH DEFECTS IN INDIA: A HOSPITAL BASED COHORT STUDY

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Abstract

Background: With epidemiological transition and significant declines in infant mortality rates due to the reduction of infections and malnutrition, there is a relative increase in morbidity and mortality due to congenital malformations. With a birth cohort of almost 26 million per year, India would account for 6% of all births with congenital disabilities in the world. Our study aims to know the prevalence and clinical spectrum of congenital malformations in a tertiary care centre in India. **Materials and Methods:** This descriptive cohort study was conducted in the neonatal care unit of the Department of Paediatrics at Meenakshi Mission Hospital and Research Centre (MMHRC), Madurai, over 18 months from August 2013 to January 2015 after obtaining approval from the ethical and scientific committee of the institute. A thorough physical examination was done of all the babies by two examiners, and congenital malformations were identified. **Result:** One hundred and seven cases of congenital malformations are recorded with a prevalence of 7.7%. Cardiovascular anomalies 45.74%, predominate, of which multiple cardiac abnormalities (16.82%) are the highest, followed by atrial septal defects (13.08%). Second in order is the digestive system 23.32% followed by genitourinary 20.51% and the musculoskeletal system 11.21%, anomalies, respectively. **Conclusion:** Our study results complement the global trends. This may not be the actual epidemiological situation in India. So, it is imperative to know the burden of congenital anomalies, disability, and resource deficiency for equitable child health care through other multicentre or population-based studies.

INTRODUCTION

Contrary to the commonly held view that congenital disorders are not a public health issue in developing countries, in recent years, with epidemiological transition and significant declines in infant mortality rates due to the reduction of infections and malnutrition, there has been a relative increase in morbidity and mortality due to congenital malformations (CM).[1] Congenital anomalies (CA), or CM or congenital disabilities, may be recognized at birth or later in life. CA are a set of functional and morphological abnormalities occurring during embryonic development.[2-5] CA can occur in isolation (i.e., single defect) or as a group of defects (i.e., multiple defects)[6] and critical exposure (risk factor) can vary by organ system or type of anomaly. Approximately 65% of CA have no determined aetiology; among others, 25% have genetic causes, and 10% have environmental and maternal causes.[2,3] CA have two severity categories: major and minor. Anomalies affecting an individual's life and natural performance are significant anomalies. Minor anomalies are structural changes that do not require urgent treatment or can be corrected. CA are the leading cause of foetal loss and contributes significantly to preterm birth, childhood, and adult morbidity. Global estimates suggest that CA affect 2–3% of births.[7] Nine of ten children born with a severe congenital disorder are in low- and middle-income countries (LIC-MIC). With a large birth cohort of almost 26 million per year, India would account for the largest share of congenital disabilities in the world,[8] translating to an estimated 1.7 million babies (6% of all births) born with congenital disabilities annually. In the study conducted by National Neonatology Forum,[9] CM was the second commonest cause (9.9%) of mortality among stillbirths (SB) and the fourth commonest cause (9.6%) of neonatal mortality, accounting for 4 per cent of under-five mortality. With an annual birth cohort of 2.6 crores, every year, an estimated 15 lakh

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children -6 % of total births are born with a congenital disability in India.[10] According to 2015 World Health statistics, globally, about 303,000 new-borns die due to CA before they reach one month each year.[11] CA account for a staggering 25.3–38.8 million disability-adjusted life years worldwide.[12,13]

MATERIALS AND METHODS

Study Setting

This descriptive cohort study was conducted in the neonatal care unit of the Department of Paediatrics at Meenakshi Mission Hospital and Research Centre (MMHRC), Madurai, over 18 months from August 2013 to January 2015. After obtaining approval from the ethical and scientific committee of the institute, new-borns were included in this study, with informed consent obtained from the parents/guardians of the respective babies. Each participant's details were recorded on a performa. For each case, a detailed antenatal and maternal history, including the age of the mother and father, parity, and the history of consanguinity, was obtained by reviewing the maternal records and interviewing the parents. A thorough physical examination was done on all the babies by two examiners, and CM were identified. Necessary blood investigations, radiographs, Ultrasonography, Computed Tomography (CT) Scans, Magnetic Resonance Imaging (MRI) and Karyotyping were done whenever needed. The CM were classified according to the International Classification of Disease (ICD)-10 system.

Sample Size

N= 107, calculated with respect to the study population at MMHRC new-born unit with a precision value of 10%, confidence level of 95% and probability distribution of 24% (as per previous similar studies).

Study Group

All the new-borns 0 to 28 days of life getting birth in the institute or getting admitted to the neonatal intensive care unit (NICU) of the Department of Paediatrics were screened for CM, and those screened positive for any of the CA were included in the study. A neonate with multiple anomalies was counted once within each class of anomaly.

Statistical Methods

A descriptive analysis was done using Epidemiological Information Package (EPI 2008). The categorical data is represented as frequencies, percentages, means, and standard deviations. Chi-square and Fischer exact tests were used to assess the association between categorical variables, and a p-value less than 0.05 was considered significant.

RESULTS

During the study period, out of 1378 hospitalized neonates, 107(7.7%) had congenital malformations and were included in this study. Out of the 107 neonates, 64.48% were males, 33.64% were females, and 2 had ambiguous genitalia and were later confirmed to be females by karyotyping [Figure 1]. Most (82.24%) presented to us in the first week of life. Only 2.8% of them presented in the fourth week. Twenty neonates had multiple malformations.

In the study group, 58.87% of new-borns had birth weights in the 2.5 – 3.5 kg range, and 25.23% had low birth weights. The majority of babies (77.57%) were term born. There were no post-term babies in our study population. The presentation was cephalic in 97% of cases, with only ten babies having a breech presentation at birth. In 53.27%, vaginal birth was the standard mode of delivery, and 46.72% were caesarean section births. Our study population had one set of triplets and six sets of twins [Figure 1].

Cardiovascular anomalies (45.74%) were the highest documented, followed by digestive system 25(23.32%), genitourinary abnormalities 20(20.51%) and musculoskeletal system 12(11.21%), respectively. Five (4.66%) had nervous system (NS) malformations, and four had Down syndrome (DS) [Figure 2].

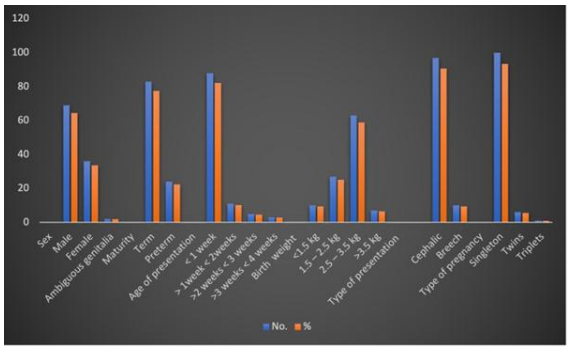

Figure 1: Distribution of neonatal characteristics

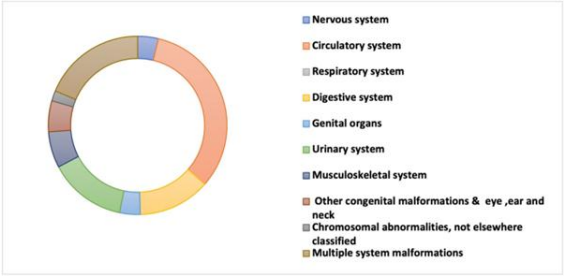

Figure 2: System wise distribution of congenital malformations

ASD was the most common anomaly in the cohort, with 14(13.08%) isolated cases, followed by cleft palate and cleft lip 8(7.47%). Otherwise, multiple cardiac anomalies seen in 18(16.82%) new-borns were the highest in incidence. 13.08% of the cardiovascular anomalies also have associated other system malformations. Hypospadiasis (4.67%) and congenital posterior valves (4.67%) were the most common genitourinary malformations, and congenital diaphragmatic hernia (5.6%) was the most common musculoskeletal malformation noted. Meningomyelocele is the most common malformation in NS [Table 1].

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No significant association is seen in the chi-square test and Fisher's exact test for the association of independent variables (neonatal and maternal characteristics) in two groups having single vs multiple congenital malformations [Table 2].

In our study, only one baby was born to a father older than 45; the rest were between 20 and 45. 6.54% of anomalous babies had mothers below 20 years, and 1.86% were above 35 years. In more than half of the cases, 54.20% of mothers were primigravida. There were no babies born to grand multipara in our study population. Amongst 68 babies born out of consanguineous marriage, 26.16% had second-degree consanguinity, and 10.28% had third-degree consanguinity.

All mothers had three antenatal visits and were under obstetric care. However, many mothers (34 out of 107) had their first antenatal visit in the second trimester. Most pregnancies were spontaneous, except for a few treated conceptions (6.54%). Twelve mothers had a history of previous abortion, and two had a history of stillbirth. Six gave a positive family history of recurrent early pregnancy loss [Table 3].

Nine mothers had gestational diabetes and were on insulin. Gestational hypertension was present in sixteen mothers, and one had chronic hypertension. All sixteen were on methyldopa, and four had received nifedipine also. Eight mothers had oligohydramnios, and three had polyhydramnios. One of them was on indomethacin for polyhydramnios. Four had hypothyroidism and were on regular treatment with levothyroxine. One had bronchial asthma, another had fever without rash in the third trimester, and one had seizure disorder.

Table 1: Prevalence of different types of congenital malformations

S.no.	Malformations	No.	%
Nervous system			
1.	Meningomyelocele	3	2.80
2.	Congenital hydrocephalus	2	1.86
Cardiovascular system			
1.	Ventricular septal defect	4	3.73
2.	Atrial septal defect	14	13.08
3.	Patent ductus arteriosus	3	2.80
4.	Tetralogy of fallots variant	2	1.86
5.	Total anomalous pulmonary venous connection	2	1.86
6.	Tricuspid atresia	3	2.80
7.	Hypoplastic left heart syndrome	1	0.93
8.	Endocardial cushion defect	2	1.86
9.	Multiple cardiac anomalies	18	16.82
Digestive system			
1.	Cleft palate	3	2.80
2.	Cleft palate and cleft lip	8	7.47
3.	Tracheoesophageal fistula	3	2.80
4.	Intestinal atresia	4	3.73
5.	Anorectal anomalies	4	3.73
6.	Hirschsprung disease	2	1.86
7.	Multiple gastrointestinal anomalies	1	0.93
Genitourinary system			
1.	Hypospadiasis	5	4.67
2.	Renal dysplasia	2	1.86
3.	Ectopic kidney	2	1.86
4.	Obstructive defects of renal pelvis and ureter	3	2.80
5.	Duplication of ureter	1	0.93
6.	Exstrophy of urinary bladder +epispadias's	2	1.86
7.	Congenital posterior urethral valves	5	4.67
8.	Ambiguous genitalia	2	1.86
Musculoskeletal system			
1.	Congenital dislocation of hip	1	0.93
2.	Congenital talipes equinovarus	2	1.86
3.	Polydactyly	2	1.86
4.	Congenital diaphragmatic hernia	6	5.60
5.	Omphalocele	1	0.93
Miscellaneous			
1.	Aplasia cutis	1	0.93
2.	Epidermolysis bullosa simplex	1	0.93
3.	Colloidon baby	1	0.93
4.	Pierre robin syndrome	1	0.93
5.	Congenital adrenal hyperplasia	2	1.86
6.	Cystic hygroma	1	0.93
7.	Downs syndrome	4	3.73
Total		124	

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Table 2: Chi square test and Fisher's Exact Test of association between congenital malformations and independent variables (neonatal and maternal characteristics)

Variables	Single Congenital Malformation (N=87)	Multiple Congenital Malformation (N=20)	Chi square/Fisher's Exact (p value)
Sex of baby			
Male	54(62.1%)	15(75%)	0.628*
Female	31(35.6%)	5(25.0%)	
Ambiguous genitalia	2(2.3%)	0	
Birth Weight			
<1.5 kg	8(9.2%)	2(10.0%)	0.701*
1.5 – 2.5 kg	20(23.0%)	7(35.0%)	
2.5 – 3.5 kg	53(60.9%)	10(50.0%)	
>3.5 kg	6(6.9%)	1(5.0%)	
Age of Mother			
< 20 years	6(6.9%)	1(5.0%)	1.00*
20-35 years	79(90.8%)	19(95.0%)	
>35 years	2(2.3%)	0	
Parity			
Primi	49(56.3%)	9(45.0%)	
Multi	38(43.7%)	11(55.0%)	0.457
Type of Delivery			
Vaginal delivery	47(54.0%)	10(50.0%)	0.807
Caesarean section	40(46.0%)	10(50.0%)	
Consanguinity			
Second degree	20(23.0%)	8(40.0%)	0.291*
Third degree	9(10.3%)	2(10.0%	
Non consanguineous marriage	58(66.7%)	10(50.0%)	
Maturity			
Preterm	19(21.8%)	5(25.0%)	0.770
Term	68(78.2%)	15(75.0%)	
Drug Intake			
Yes	8(9.2%)	1(5.0%)	0.100*
No	79(90.8%)	19(95.0%)	

*Fisher's Exact t

Table 3: Distribution of reproductive and obstetric characteristics

S.no.	Characteristics	No.	%
1.	Paternal age		
	< 20 years	0	0
	20-45 years	106	99.06
	>45 years	1	0.93
2.	Maternal age		
	< 20 years	7	6.54
	20-35 years	98	91.58
	>35 years	2	1.86
3.	Consanguinity		
	Non consanguineous marriage	68	63.55
	First degree	0	0
	Second degree	28	26.16
	Third degree	11	10.28
4.	Type of conception		
	Spontaneous	100	93.45
	Treated conception	7	6.54
5.	Type of delivery		
	Vaginal delivery	57	53.27
	Caesarean section	50	46.72
6.	No. Of antenatal visits		
	< 3 visits	0	0
	> 3 visits	107	100
7.	Drug intake /irradiation		
	Iron & folic acid	98	91.58
	Methyl dopa	16	14.97
	Nifedipine	4	3.73
	Insulin	4	3.73
	Aspirin	3	2.80
	Indomethacin	1	0.93
	Levothyroxine	4	3.73
8.	Maternal history of		
	Abortion	12	11.21
	Stillbirth	2	1.86
	Gestational diabetes mellitus	9	8.41
	Pregnancy induced hypertension	16	14.97

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	Oligohydramnios	8	7.47
	Polyhydramnios	3	2.80
	Hypothyroidism	4	3.73
	Bronchial asthma	1	0.93
	Fever	1	0.93
	Seizure disorder	1	0.93
9.	Family history	6	5.60
10.	Parity		
	Primigravida	58	54.20
	Multigravida	49	45.79

DISCUSSION

The term congenital disability is a diversity of conditions, including physical malformations such as cleft lip or palate, chromosomal abnormalities (ChA) such as DS, functional defects such as congenital deafness and congenital cataract, metabolic defects including inborn error of metabolism or haemoglobinopathies, neurodevelopmental disorders, and complications related to prematurity. Cutting across countries and their economic status, 64.3 infants per thousand live births are born annually with congenital disabilities. Of these, 7.9 have cardiovascular defects, 4.7 have neural tube defects, 1.2 have some form of hemoglobinopathy, 1.6 have DS, and 2.4 have G6PD deficiency (All figures are in per thousand).[8]

The prevalence rate of congenital abnormalities in our study is 7.7% which is similar to the findings of Hussain S et al,[14] and Thapar et al,[15] which showed a prevalence of 7% & 6.8%, respectively. All these are hospital-based studies. However, the prevalence differs from two prospective hospital-based studies by Ara A et al,[16] and Bhide P et al,[17] from India, which have a 3.3% & 2.3% prevalence, respectively. There are variations in the frequency of CMs reported from other parts of the world.[18,19] Tertiary care hospitals have an ill-defined catchment area and primarily receive patients of a particular type according to the expertise available, resulting in a misleading distribution of cases. The second reason could be the non-uniformity in the methodology applied while collecting data; focusing on the early neonatal period can miss a few anomalies. Community-based studies should be ideal for accurate estimation of the incidence of CA in a population.

Out of the 107 neonates, 64.48% were males, 33.64 % were females, and two had ambiguous genitalia and were later confirmed to be females by karyotyping. This pattern of male preponderance is similar to the studies done by Mashuda F et al,[20] and Naoom M B et al.[21]

In this study, cardiovascular anomalies (30.5%) are the most common malformations, followed by the musculoskeletal system at 21.1%, similar to the study by Kumar J et al,[22] and other extensive studies and databases.[17,23,24] This increase in our study may be due to pulse oximetry screening leading to an early diagnosis of critical congenital heart diseases and increased availability of postnatal echocardiography. Moreover, in other studies, it may be because of increased awareness and the availability of foetal echocardiography facilities leading to an increased antenatal diagnosis of structural heart disease and hence increased referral to tertiary care centers.[25]

Third, in order are the gastrointestinal system anomalies (9.4%). The digestive system was the most commonly involved (35%), followed by the central nervous system (CNS) (26.6%) in the study by Ara A et al.[16] One tertiary paediatric surgery centre from north India reported gastrointestinal anomalies as the most common malformation requiring surgical intervention.[26]

Studies from southern and eastern India reported musculoskeletal anomalies as the most common,[27,28] the second-largest group of ours and other extensive studies.[9,17]

Sachdeva S et al,[23] reported the CNS, followed by musculoskeletal anomalies as the most common malformations. Contrarily, CNS malformations are the least reported in our study. Studies done by Hussain S et al,[14] Mashuda F et al,[20] and Singh A et al,[29] showed CNS as the most commonly affected system.

According to the European Registration of Congenital Anomalies and Twins (EUROCAT), the low prevalence of congenital heart defects compared to available registry data could be ascribed to only physical examination at birth.[30] Mashuda F et al,[20] did face-to-face interviews with parents/caretakers of young infants to collect socio-demographic and clinical information and performed physical examinations on all young infants and echocardiography, X-rays, cranial imaging, as well as abdominal ultrasonography, were performed when indicated.

Consanguinity is a common occurrence (36.44 %) in our study population. It is also a significant finding (73.3%) in a study by Naoom M B et al.[21] 6.54 % of new-borns with malformations in this study are born out of treated conception.

All the mothers had supervised pregnancies with more than three antenatal visits and adequate obstetric care. However, most mothers enrolled in ante-natal clinics during the second trimester, possibly because of local practices. Most anomalous conceptions are lost during the first trimester with SA or missed abortions. For others, there is antenatal screening, for which the crucial period is the first trimester.

In our study, 46.72% were born through vaginal delivery while 53.27% were through caesarean section, similar to Naoom M B et al,[21] who also had

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more surgical deliveries. More caesarean section in the present study was due to high-risk pregnancy referrals to this tertiary-level hospital from the catchment area requiring surgical deliveries. There was a history of early gestational and perinatal losses in the mothers of twenty new-borns in our study. A study done by Mashuda F et al,[20] showed similar results. Early spontaneous abortion (SA) can occur due to ChA in the conceptus. ChA is the cause of more than half of known SA. SA is a natural screening of embryos to reduce the incidence of CA, and SB can also be due to threatening CA.

The limitation of our study is that it does not consider the data on the termination of pregnancies due to foetal anomaly, SB, and their autopsies. Another limitation is the role of referral bias which cannot be ruled out.

CONCLUSION

The present study demonstrated a similar magnitude of CAs complementing the global trends prevalent in India, which may not be the actual epidemiological situation of India. At the same time, the evidence available to suggest the actual weight of the congenital anomalies concerning the disease's early recognition, morbidity, mortality, and economic load in low to middle-income countries like ours is scanty. So, it is imperative to know the burden of congenital disabilities and disability resource deficiency to provide equitable child health care through multicentre or population-based studies and thus have a registry. All this is important in these children with various congenital disabilities to help reach a potential by which they can exhibit a healthy state and be helpful to society and the nation.

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