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Prevalence & spectrum of congenital anomalies at a tertiary care centre in north India over 20 years (1998-2017)

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***Background & objectives*: Congenital anomalies lead to significant morbidity and mortality. Systematically published data on the prevalence and spectrum of congenital anomalies from India are scarce. This study was aimed to ascertain the prevalence, spectrum, trend, and outcome of congenital anomalies at a tertiary care centre in north India over two decades.**

***Methods*: Electronic records of all live births from January 1998 to December 2017 were retrieved, and the neonates with congenital anomaly were included in this retrospective analysis. International Statistical Classification of Diseases and Related Health Problems, tenth revision (ICD-10) was used for uniformity and international comparison. The further sub-categorization was done as per the WHO birth defects surveillance manual. The prevalence of individual as well as overall congenital anomalies was calculated. Run charts were used to analyze the trends.**

***Results*: In the two decades studied (1998-2017), there were 86850 live births, of which 1578 [1.82%, 95% confidence interval (CI): 1.73-1.91%] neonates had a major congenital anomaly. The overall prevalence of anomalies was 182 (95% CI: 173-191) per 10,000 live births. Malformation of the circulatory system was the most common (28.0%) followed by musculoskeletal (18.6%) and urinary system (14.3%). Congenital anomaly-related death rate was 6.78 per 1000 live births. No significant trend was observed in the annual prevalence, individual malformations or contribution of congenital anomalies to overall mortality over the two decades.**

***Interpretation & conclusions*: Our results showed a high prevalence of congenital anomalies which could be responsible for significant mortality, warranting the need for a national surveillance programme and birth defect services. It is important to have a national database to know the overall burden and spectrum of congenital anomalies in the country.**

Key words Birth defects - congenital anomalies - malformation - mortality - neonate - stillbirth

Congenital anomalies are defined as structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth, or sometimes may only be detected later in the infancy[1]. Major congenital malformations occur in approximately two per cent of human births[2] and are an important cause

of neonatal mortality and morbidity. According to the Global Burden of Disease study, congenital anomalies were the fifth leading cause of under five mortality in 2015, and they were associated with 11 per cent of neonatal deaths[3-5]. These also contribute to long-term disability, which has significant impacts on individuals, families, healthcare systems, and societies. Therefore, the sixty-third World Health Assembly adopted a resolution on congenital anomalies[6], to encourage the member countries to develop national programmes for surveillance and prevention of congenital anomalies.

The frequency and type of congenital anomalies may vary in different populations due to variations in ethnicity, socio-economic status, nutrition, environmental factors, maternal age and lifestyle among different countries. In western countries, epidemiological surveillance networks and registries provide epidemiological data on birth defects and help in developing strategies for their prevention[4,7]. However, in India, the estimates of congenital anomalies come from small hospital-based studies, which are heterogeneous and provide little information on epidemiological data[8-14]. Now with the launch of *Rashtriya Bal Swasthya Karyakram (rbsk.gov.in)* in 2013, there is a felt need for systematic data on the magnitude, type, and healthcare impact of congenital anomalies. In response to World Health Assembly resolution, Southeast Asia Region (SEAR) countries developed a regional strategic framework for the prevention and control of birth defects[15]. A revised strategy was formulated to address the bottlenecks of individual countries and upgraded software on the neonatal-perinatal database and birth defect surveillance. 'Newborn and Birth Defects Database' was launched to ensure uniformity and completeness of the data[16].

We conducted this study to find the true prevalence and outcome of congenital anomalies in a large tertiary care centre in north India. This study was aimed to analyze data extracted from an electronic database to determine the prevalence, spectrum, trend over the past two decades (1998-2017), outcome (death/survival till discharge) and contribution of congenital anomalies to overall mortality among live births over two decades.

Material & Methods

This was a retrospective, cross-sectional, hospital record-based study conducted at the department of Paediatrics, Postgraduate Institute of Medical Education & Research, Chandigarh, India. Our centre acts as a referral centre for the neighbouring States (Punjab, Haryana, Himachal Pradesh, Jammu and Kashmir, north part of Rajasthan, Uttarakhand, and Uttar Pradesh). The annual delivery rate is 4500-5500, most of which are high-risk pregnancies. All the live births at our facility from January 1998 to December 2017 were enrolled in this study. The electronic records of these live births were retrieved from the computerized patient record database of the unit. The entries in the electronic database are directly made by the clinicians involved in the care of the neonate. All newborns with congenital anomalies admitted in the newborn unit during this period were included. The diagnosis of congenital anomalies was based on consolidated interpretation of antenatal investigations (ultrasound or magnetic resonance imaging), postnatal clinical examination and relevant investigations as per findings. Systematic clinical examinations were done at birth, postnatal day one and pre-discharge. The final diagnosis of anomaly was assigned at discharge/death. The stillbirth's anomalies (which were not a part of the electronic database) and preterm neonates with patent ductus arteriosus alone were excluded. The data retrieval was done from June to October 2018. The analysis was done from January to March 2019. The details were recorded in predesigned excel proforma. The demographic profile of the mother and neonate, obstetric details, gestational age, birth weight and sex of the baby, a detailed description of congenital anomaly, the relevant investigation (if any) and the final outcome at discharge, were retrieved, Ethical clearance was obtained from the institute research ethics committee in 2019. Waiver of consent was given by the ethics committee.

Congenital anomalies were classified into major or minor as per the WHO birth defeats surveillance manual. Major anomaly is defined as structural changes that have significant medical, social or cosmetic consequences for the affected individual and typically require medical intervention[16]. For efficiency and practicality, we used major structural anomalies only in the study as these account for most of the mortality, morbidity, and disability. Anomalies were assigned International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) codes to facilitate system-wide classification of anomalies[17]. The major anomalies were further classified based upon developmental mechanism (malformation, deformation, disruption, and dysplasia)

and clinical presentation in a child (isolated, sequence, association, and syndrome) as described in the WHO birth defects surveillance manual[16].

The data were analyzed using Microsoft Excel and SPSS v.20 (IBM SPSS Statistics for Windows, Armonk, NY, USA). Frequency analysis was used to describe the distribution of the congenital anomalies. The prevalence of congenital anomalies was calculated as per the WHO birth defects surveillance manual[16]. Live birth prevalence (per 10,000 live births) was calculated using the total number of live births with congenital anomalies as a numerator and total live births as a denominator. A neonate with multiple anomalies was counted once within each class of anomaly. The prevalence of individual as well as overall malformation per year was calculated as the percentage of live births, and the trend over the years was compared. Deaths related to anomalies were divided into two categories, namely congenital anomaly as a direct cause of death and congenital anomaly as a contributory cause of death. This assignment was made by the clinical team at the time of death of the neonate and was recorded in a similar form in the database. The overall proportion of congenital anomaly-related deaths was calculated using congenital anomaly-related deaths as a numerator and the total number of deaths as a denominator. Congenital anomaly-related mortality rate (per 1000 live births) was calculated as the total number of congenital anomaly-related deaths as a numerator and total live births as a denominator. The trend of prevalence of congenital anomalies, individual malformations, and congenital anomaly-related deaths in the past two decades was analyzed using run (time series) charts (QI Macros).

Results

In the two decades included in the study (1998-2017), there were 86850 live births, of which 1578 [1.82%, 95% confidence interval (CI): 1.73-1.91%] neonates had a major congenital anomaly. The baseline characteristics of these neonates with congenital anomalies are described in Table I. Mean gestation and birth weight were 36 ±3 weeks and 2168 ±731 grams, respectively. Almost half of the babies had intrauterine growth restriction. Most (61.8%) of them were born to multigravida mothers. The overall prevalence of congenital anomalies was 182 (95% CI: 173-191) per 10,000 live births. The annual prevalence ranged from 162 to 242 per 10,000 live births. No significant trend was observed in annual prevalence over two decades. The systematic classification of anomalies according to ICD-10 is shown in Table II. A total of 2215 anomalies were detected in 1578 neonates (1.4 per neonate), indicating that many had multiple anomalies. Congenital malformation of the circulatory system was the most common (28%) followed by musculoskeletal (18.60%) and urinary system (14.3%). On observing the trend of individual system anomalies (Fig. 1) over years, it was evident that the proportion of cardiovascular system anomalies had increased. For the rest of the anomalies (musculoskeletal and central nervous system), the number of anomalies increased but the overall proportion remained the same.

Table I. Baseline characteristics of the neonates with congenital anomalies

Characteristics	Value
Gestation (wk), mean±SD	36±3
Birth weight (g), mean±SD	2168±731
Sex, (n%)	n=1578
Male	900 (57)
Female	634 (40)
Ambiguous	44 (3)
Appropriateness for gestational age, n(%)	n=1508
Appropriate for gestational age	719 (48)
Small for gestational age	688 (46)
Large for gestational age	101 (6)
Mode of delivery, n(%)	n=1261
Vaginal	861 (68)
LSCS	400 (32)
Gravida, n(%)	n=1462
1	573 (39)
2	195 (13)
≥3	694 (48)

LSCS, lower segment caesarean section

The individual organ-system wise distribution (ICD-10 sub-classification) of clinically important major anomalies is shown in Table III. Congenital malformations of cardiac septa (ventricular septal defect, atrial septal defect, atrioventricular septal defect, tetralogy of Fallot) were the most common anomalies followed by congenital malformations of great arteries (patent ductus arteriosus, coarctation of the aorta, aortic stenosis) and congenital malformation of lung, respectively. One hundred and ten (1.27 per 1000 live births) neonates had neural tube defects (NTDs). The classification of congenital

Table II. Systematic classification of congenital anomalies (ICD-10)[16]

System (ICD-10 code)	n (%)*	Prevalence per 10,000 live births (95% CI)
Nervous system (Q00-Q07)	189 (8.5)	21.8 (19-25)
Eye, ear, face and neck (Q10-Q18)	83 (3.7)	9.6 (8-12)
Circulatory system (Q20-Q28)	621 (28.0)	71.5 (65-77)
Respiratory system (Q30-Q34)	200 (9.0)	23.0 (20-26)
Cleft lip and palate (Q35-Q37)	37 (1.7)	4.3 (3-6)
Digestive system (Q38-Q45)	144 (6.5)	16.6 (14-19)
Genital organs (Q50-Q56)	80 (3.6)	9.2 (7-11)
Urinary system (Q60-Q64)	316 (14.3)	36.9 (33-41)
Musculoskeletal system (Q65-Q79)	412 (18.6)	47.4 (43-52)
Others (Q80-Q89)	24 (1.1)	2.8 (2-4)
Not elsewhere classifies (Q90-Q99)	109 (4.9)	12.6 (10-15)

*Denominator is total number of congenital anomalies, *i.e.*, 2215. ICD-10, International Classification of Diseases, tenth revision; CI, Confidence interval

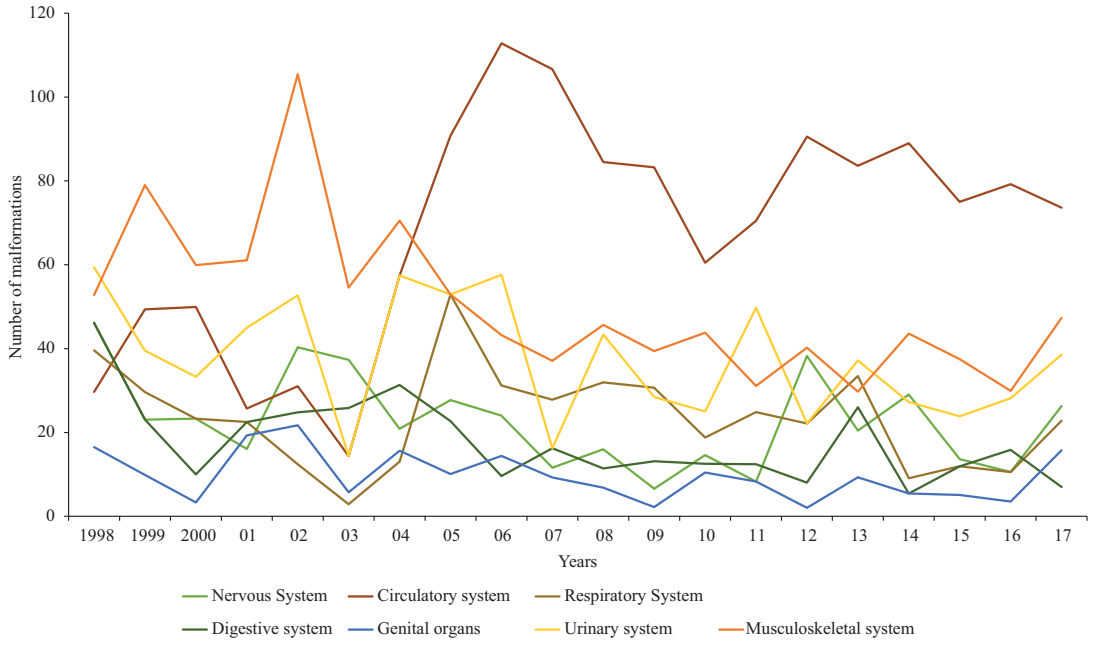

Fig. 1. Trend of system-wise malformations over 20 years (per 1000 live births).

malformations according to the developmental mechanism and clinical presentation in the neonate is shown in Table IV. By the developmental mechanism, most of the neonates had malformation followed by deformation. Clinically most had isolated anomalies followed by association.

The final outcome (death/discharge/left against medical advice) was available for 1500 neonates. Of these, 649 (43.3%) died and 197 (13.1%) left against medical advice. The contribution of congenital anomalies in the death of these neonates was also analyzed. Three-fourth (84.6%) of all deaths were directly caused due to malformation itself, and in the rest (15.4 %), it was a contributory cause. In the past 20 yr, there were 86850 live births and 589 CMF (congenital anomaly) related deaths. Hence, cumulatively deaths due to CMF were 0.678 per cent, with a death rate of 6.78 per 1000. Overall, complete

Table III. System-wise major anomalies as per International Classification of Diseases, tenth revision classification (ICD-10)[16]

System	n (% of individual system)
Nervous system (Q00-Q07) (n=189)	
Anencephaly	16 (8.5)
Encephalocele	14 (7.4)
Microcephaly	10 (5.3)
Congenital hydrocephalus	63 (33.3)
Spina bifida	80 (42.3)
Arnold-Chiari malformation	3 (1.6)
Circulatory system (Q20-Q28) (n=621)	
Congenital malformations of cardiac chambers and connections	56 (9.0)
Congenital malformations of cardiac septa	225 (36.2)
Congenital malformations of pulmonary and tricuspid valves	54 (8.7)
Congenital malformations of aortic and mitral valves	39 (6.3)
Congenital malformation of great arteries	189 (30.4)
Respiratory system (Q30-Q34) (n=200)	
Congenital malformations of nose	6 (3.0)
Congenital malformations of larynx	7 (3.5)
Congenital malformations of trachea and bronchus	15 (7.5)
Congenital malformations of lung	164 (82.0)
Cleft lip and cleft palate (Q35-Q37) (n=37)	
Cleft palate	5 (13.5)
Cleft lip	3 (8.1)
Cleft palate with cleft lip	29 (78.4)
Digestive system (Q38-Q45) (n=144)	
Congenital malformations of oesophagus	41 (28.5)
Congenital absence, atresia and stenosis of small intestine	37 (25.7)
Congenital absence, atresia and stenosis of large intestine	39 (27.1)
Genital organs (Q50-Q56) (n=80)	
Ambiguous genitalia	44 (55.0)
Hypospadias	22 (27.5)
Urinary system (Q60-Q64) (n=316)	
Renal agenesis and other reduction defects of kidney	66 (20.9)
Cystic kidney disease	107 (33.5)
Congenital obstructive defects of renal pelvis and ureter	145 (45.9)
Musculoskeletal system (Q65-Q79) (n=412)	
Congenital deformities of hip	3 (0.7)
Congenital deformities of feet	60 (14.5)
Congenital diaphragmatic hernia	110 (26.7)

mortality data were available for 15 years (2003-2017). In these 15 years, there were 3599 deaths, and CMF was related (direct or contributory) to 525 deaths (14.6% of total deaths). The trends for the proportion of CMF-related mortality over these 15 years are shown in Figure 2. No significant trend was observed in the contribution of congenital malformation to overall mortality.

Discussion

In this study, the prevalence of congenital anomalies was 0.018 per cent (95% CI: 0.017-0.019), *i.e.,* 182 cases per 10000 live births, and the congenital malformation of the circulatory system was the most common anomaly. In these 20 years, the CMF-related death rate was 6.78 per 1000 live births. The surveillance networks, as well as individual studies, have shown a varying prevalence of congenital defects with inter-centre and international variation. These variations may be explained by the variation of risk factors, racial, social, ecological, and economic differences among populations, and variation in the methodology[18-20]. The prevalence in the current study was similar to other studies from India[12,19,20] and West Africa[21]; however, a few showed lower prevalence than ours[11]. These differences may be due to regional and referral differences. National Neonatal Perinatal Database 2002-03 of India reported 2385 birth defects in 145623 births (prevalence rate 164 per 10000)[22]. Moreover, these rates are reflective of prevalence at tertiary centres rather than the community population, which may differ due to increased referral rates at these centres. A recent, well-planned, systematic prospective study by Pune birth defect research group in 1781 live births reported the prevalence rate of 168.44 per 10,000 live births[19], which was similar our study. Since the Pune study[19] is the only prospective study from India, therefore, it is likely to better reflect the overall prevalence rate of the country.

Table IV. Classification of congenital anomalies based upon developmental mechanism and clinical presentation (n=1578)

Developmental mechanism, n (%)	
Malformation	1432 (90.7)
Deformation	63 (4.0)
Disruption	37 (2.3)
Dysplasia	46 (2.9)
Clinical presentation, n (%)	
Isolated	1099 (69.6)
Sequence	98 (6.2)
Association	220 (13.9)
Syndrome	161 (10.2)

In our study, the most common malformation was structural cardiac defects cardiovascular malformation (71.50; 95% CI: 65-77 per 10,000 live births) followed by musculoskeletal defects (47.44; 95% CI: 43-52 per 10,000) and urinary system (36.96; 95% CI: 33-41 per 10,000). These findings were like other large studies and database[19,20,23]. Studies from southern and eastern India reported musculoskeletal anomalies as the most common[11,18], which was the second-largest group of ours and other large studies[19,22]. Sachdeva *et al*[20] reported central nervous system followed by musculoskeletal anomalies as the most common malformations. On

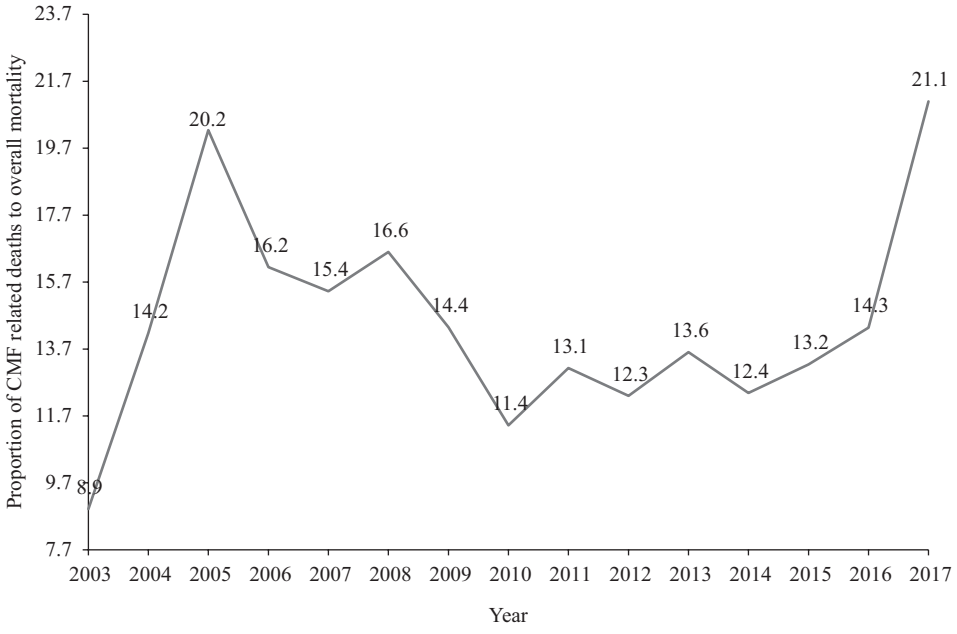

Fig. 2. Trend of contribution of congenital anomalies-related deaths to overall mortality.

the other hand, one tertiary paediatric surgery centre from north India reported gastrointestinal anomalies as the most common malformation requiring surgical intervention[10]. These differences in the spectrum of congenital anomalies are likely to be due to the difference in the spectrum of referral, centre experience and methodology used for classifying the anomalies. Moreover, most of the centre-based studies did not use any standard protocol for classification of the anomalies which might influence the reporting of system-wise anomalies. Bhide *et al*[19] from Pune using the ICD-10 classification system found results similar to our study.

Similar to other studies from India, we also did not observe any major trend or shift (except cardiovascular system) in the rate as well as proportion of congenital anomaly-related deaths[10,18]. At our centre, congenital anomaly was the third or fourth most common cause of death similar to the global pattern for developing countries[4,5]. There is a non-significant increase in cardiac malformations in recent years. This increase may be due to increased awareness as well as the availability of foetal echocardiography facility leading to an increased antenatal diagnosis of structural heart disease and hence increased referral to tertiary care centre[24]. Furthermore, there is increased use of pulse oximetry screening before discharge leading to an early diagnosis of critical congenital heart diseases and increased availability of postnatal echocardiography adds to the magnitude[25].

It is important to have a national database to know the overall burden, contribution to mortality and morbidity and the spectrum of congenital anomalies. By knowing the burden and spectrum, appropriate strategies for the antenatal diagnosis as well as prevention can be implemented strategically through an existing/new national health programme. For example, most of the lethal malformations (anencephaly, large encephalocele, tracheal agenesis) are amenable to diagnosis in early pregnancy and hence amenable to medical termination of pregnancy. Similarly, NTDs are well-known preventable defects and account for one-third of the neonatal deaths and significant morbidity[26].

This study highlights the need for a birth defects surveillance system which has several important implications on the national health system. There is a need of integral package involving diagnosis, surgical/medical intervention, financial support, counselling and psychosocial support along with follow up services, including rehabilitation.

The strength of this study was a large sample size, robust database, sufficient long duration to observe trends and use of the standard methodology for classification and reporting to make it comparable to other national and international databases. Limitations were inherent to retrospective study, *i.e*. lack of recording of risk factors (including socio-economic and demographic details), missing data for some births and non-uniformity of assessments. Our data are representative of a tertiary care referral centre only and do not include stillbirths. With limited availability of echocardiography and pulse oximetry screening in the previous decade, cardiac malformations may be underdiagnosed.

In conclusion, the prevalence of congenital anomalies was high and could be responsible for significant mortality and morbidity warranting the need for the national surveillance programme and birth defect services. A significant proportion of birth defects is preventable or correctable warranting the need for sensitization regarding taking antenatal measures as well as postnatal corrective surgeries for healthy disability-adjusted life years.

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