Observational Study

Medicine

OPEN

Epidemiologic and clinical characteristics of selected congenital anomalies at the largest Bosnian pediatric surgery tertiary center

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Abstract

Congenital anomalies (CA) are any abnormality present at birth, either structural or functional, that may potentially affect an infant's health, development, and/or survival. There is a paucity of studies on clinical characteristics and outcomes of CA in Bosnia and Herzegovina, mainly due to the lack of a nationwide congenital malformations monitoring system. A 5-year hospital-based study was conducted to determine the prevalence at birth and clinical characteristics of selected major CA in Sarajevo Canton, Bosnia and Herzegovina. Ninety-one CA were observed from 2012 to 2016 (the overall prevalence was 39.6 cases/10,000 live births). The mean age of neonates at diagnosis was 3 days. The gastrointestinal tract was the most commonly affected system (76.9%), with esophageal atresia (EA) being the most frequent (17.6% of all CA). Major CA were more prevalent among preterm infants than term infants ($P = .001$), particularly in males (61.5% vs. 38.5%; $P = .028$; M:F ratio was 1.59). Multiple CA were seen in 37.4% of neonates. The overall mortality rate of neonates was 11%, and the median length of hospital stay was 19.8 days. Our study revealed the distribution and clinical patterns of common major CA in the largest tertiary care facility in Bosnia and Herzegovina. It also confirmed a relatively high mortality rate, which requires further efforts to improve the quality of neonatal care in the country.

Abbreviations: ARM = anorectal malformation, BE = bladder exstrophy, CA = congenital anomalies, CDH = congenital diaphragmatic hernia, DA = duodenal atresia, EA = esophageal atresia, ECMO = extracorporeal membrane oxygenation, GS = gastroschisis, HSCR = Hirschsprung disease, IA = intestinal atresia, IHPS = infantile hypertrophic pyloric stenosis, LOS = length of stay, OM = omphalocele, OMD = omphalomesenteric duct, OS = overall survival, PUV = posterior urethral valve.

Keywords: clinical characteristics, major congenital anomalies, outcome, prevalence, surgery

1. Introduction

Congenital anomalies (CA) refer to any morphological, functional, biochemical, or molecular defects that may develop in the embryo and fetus from conception until birth, whether detected at birth or later.[1] CA affect approximately 3% of all newborns,[2] contributing significantly to neonatal morbidity and mortality.[3] CA can be caused by single-gene defects, chromosomal aberrations, multifactorial disorders, and teratogenic factors.[4] However, despite rapid advances in understanding the causes of CA, the cause of 60% of birth defects remains unknown, making primary prevention impossible at present.[5,6] Correcting CA is challenging for pediatric surgeons, especially as repair quality requirements have changed from easy survival to improved quality of life.[7] However, evidence-based treatment recommendations above expert opinion do not exist.[8] In randomized studies, additional aggravating circumstances are related to statistical reasons due to the small number of analyzed cases.[9,10] Although reliable longitudinal studies also describe only small cohorts,[9,10] their importance is reflected in new insights into surgical corrections of major CAs, which is still the only way to ensure proper management and survival. The lack of local epidemiological data on CA significantly impacts interventions that impede policy and service development in many low-and middle-income countries. There have been substantial efforts to improve the observed shortcomings, using a systematic approach to the global and regional burden of CA and their risk factors.[11] Although several studies

The authors have no funding and conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

This study was performed per the ethical standards of the Declaration of Helsinki (1964). The local institutional review board approved the study (approval number: 0902-18910/17). All medical records were pseudo-anonymized for the current study. The requirement for informed consent was routinely waived due to its retrospective nature.

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How to cite this article: Zvizdic Z, Becirovic N, Milisic E, Jonuzi A, Terzic S, Vranic S. Epidemiologic and clinical characteristics of selected congenital anomalies at the largest Bosnian pediatric surgery tertiary center. Medicine 2022;101:48(e32148).

Received: 14 September 2022 / Received in final form: 10 November 2022 / Accepted: 11 November 2022

http://dx.doi.org/10.1097/MD.0000000000032148

worldwide have examined the characteristics of CA,[12,13] there is a paucity of studies on major CA in Bosnia and Herzegovina. Accordingly, the present study aimed to determine the prevalence at birth of selected major CA in Sarajevo Canton, Bosnia and Herzegovina, and to review the clinical patterns and outcomes of infants treated for selected surgically correctable major CA in our local setting in 5 consecutive years.

2. Materials and Methods

A hospital-based retrospective study was conducted at the Clinic of Pediatric Surgery, Clinical Center University of Sarajevo (CCUS), over 5 years (January 2012–December 2016). Clinical Center University of Sarajevo (CCUS) is a tertiary care referral center in Sarajevo Canton, Bosnia and Herzegovina, and the largest tertiary health care facility in Bosnia and Herzegovina. Pediatric surgery unit provides comprehensive evaluation, pre-operative preparation, operative treatment, and postoperative care for the full spectrum of routine elective as well as urgent or emergent pediatric surgical conditions, including the treatment of CA of the gastrointestinal and male and female genitourinary tract, congenital abdominal wall defects, and some congenital thoracic anomalies (esophageal atresia [EA] cases and congenital diaphragmatic hernias [CDHs]). The Sarajevo Canton occupies the central part of Bosnia and Herzegovina, with 413,593 inhabitants (323 inhabitants/km^2). 15.3% of the population were youths <14 years of age, 70.7% were between 15 and 64 years of age, and 14% were over 65.

The inclusion criteria for the study were: All children aged 28 days or less with a diagnosis of selected major gastrointestinal, muscular, and genitourinary CA, who were born in medical facilities in the Sarajevo Canton and treated in our institution were included. The exclusion criteria were as follows: Children with major CA other than selected major gastrointestinal, muscular, and genitourinary CA, children with minor CA, children whose anomalies were detected over the age of 28 days, and children who were born outside the Sarajevo Canton and admitted for treatment in our institution.

According to the World Health Organization (WHO), CA includes any morphological, functional, biochemical, or molecular defects that may develop in the embryo and fetus from conception until birth that is present at birth, whether detected at that time or not.[14] Major CA were defined as severe structural malformations present at birth or later in life that affect an infant's life expectancy, health status, and physical or social functioning. CA were diagnosed based on anomalies detected on clinical examination. Suspected CA were subjected to further investigations for final diagnosis. Multiple CA are defined as 2 or more major anomalies that are unrelated. The infants with multiple CA were recorded only once, and the major anomaly interfering considerably with the function of all or part of the infant was considered. The total birth prevalence of CA was calculated by dividing the numerator (detected malformation cases) by the total live births delivered during the same period.

More detailed analysis was carried out for the following CA: CDH, EA, omphalocele (OM), gastroschisis (GS), omphalomesenteric duct (OMD), duodenal atresia (DA), intestinal atresia (IA) (jejunal/ileal/colonic), infantile hypertrophic pyloric stenosis (IHPS), Hirschsprung disease (HSCR), anorectal malformation (ARM), bladder exstrophy (BE), and posterior urethral valve (PUV). Although the recognition that IHPS is acquired and not a congenital disorder is increasing, the genetic background of isolated IHPS has been described in several studies,[15,16] contributing to the classification of IHPS as a congenital disorder in the present study. Clinical data were gathered from the medical records of patients undergoing surgical treatment for selected major gastrointestinal, muscular, orgenitourinary CA during the study period. The infants' variables included age, sex, birth weight, age of presentation, type of major CA, presenting clinical features and disease course, diagnostic procedures, and type of surgical procedures. We determined the total length of stay (LOS) for neonates with the 13 CA. Neonatal outcomes (death or discharge) were also recorded. Neonatal death was defined as an infant death before 28 days of age. We also analyzed maternal age (<20 years, 20–35 years, >35 years).

2.1. Statistical analysis

The data was collected and tabulated. Descriptive statistics were used to provide basic information about variables in a dataset and to highlight potential relationships between variables. The Chi-square test was used for testing continuous and categorical variables within contingency tables. All statistical assays were performed using the Statistical Package for the Social Sciences (SPSS) IBM Version 27 (SPSS) (UNICOM Systems, Inc., Chicago). Statistical significance was accepted at the $P < .05$ level.

3. Results

Table 1 summarizes our study's overall prevalence at birth of major CA, with the prevalence data for individual major CA.

Ninety-one neonates had at least 1 selected major CA of the gastrointestinal, muscular, or genitourinary tracts, giving an overall prevalence rate of 3.96/1000 births (39.6 per 10,000 births or 1 out of 252 live births were affected by major CA). We found 3 pairs (3.3%) of twins, and 88 (96.7%) were from singleton pregnancies. At diagnosis, the mean age of neonates with CA was 3 days (interquartile range [IQR], 7 days). The mean birth weight of neonates was 2650 g. The vaginal mode of delivery was reported in 65 neonates with CA (71.4%), and 26 (28.5%) were delivered as preterm neonates. The mean (±SD) maternal age of infants with CA was 27.8 ± 4.2 years (range, 18–41 years).

Of all neonates with major CA, 57 (62.6%) had a single major CA, while the remaining 34 patients (37.4%) had multiple malformations. The gastrointestinal tract was the most affected according to the body system/site (70/91, 76.9%). The muscular system was second in frequency, involving 19 out of 91 patients (20.9%). The genitourinary tract involved 2 out of 91 patients (2.2%) (Table 1).

All patients were treated using a laparotomy approach. Among 13 types of surgically correctable major CA treated in our institution, EA was the most common, accounting for 17.6% of total CA identified, resulting in a prevalence rate of 6.97 per 10,000 births or 1 case per 1434 births. Major CA were more prevalent in males (61.5%) than in females (35 cases, 38.5%) ($P = .028$), with an M:F ratio of 1.59. We found that 7/13 (EA, IHPS, ARM, malrotation/volvulus, OM, OMD, and PUV) were more common in males, while 4/13 (CDH, BA, BE, and GS) had a higher prevalence in females. We also found that gender representation was equal in the 2 remaining CA (IA and HSCR). However, ARM and IHPS were more prevalent in males ($P = .001$ and $P = .008$, respectively).[17] At the same time, all 6 cases of GS were found in females.

Major CA were more prevalent among preterm neonates than in-term infants ($P = .001$). Similarly, we observed a higher prevalence of CA among neonates with a birth weight of ≤2.500 g than neonates with a birth weight of >2.500 g ($P = .007$). Individually, DA was significantly more present in neonates born with a birth weight of ≤2.500 g than in neonates born with a birth weight of >2.500 g ($P < .01$). In addition to birth weight, DA was significantly more diagnosed in preterm neonates than the term neonates ($P = .001$).

There was no significant association between maternal age and overall CA rate ($P = .211$). However, for maternal age <20 years, the association with GS was statistically significant

Table 1

Prevalence of selected major congenital anomalies identified and surgically treated at the Clinical Center University of Sarajevo between 2012 and 2016.

Congenital anomaly category	Type of anomalies	Frequency (n)	Percent (%)	*P*-value	Per 10,000 births	Confidence interval (prevalence per 10,000) (95%, z = 1.96)
Gastrointestinal system	Esophageal atresia	16	17.58	<.001	6.97	3.98–11.33
	Infantile hypertrophic pyloric stenosis	14	15.38	<.001	6.10	3.33–10.24
	Duodenal atresia	9	9.89	<.001	3.92	1.78–7.45
	Intestinal atresia	6	6.59	<.001	2.61	0.95–5.70
	Malrotation/volvulus	8	8.79	<.001	3.49	1.49–6.88
	Omphalomesenteric duct anomalies	1	1.10	<.001	0.44	0.0–2.47
	Hirschsprung disease	2	2.20	<.001	0.87	0.08–3.18
	Anorectal malformation	14	15.38	<.001	6.10	3.33–10.24
	Gastrointestinal system parameters	**70**	**76.92**	**.003**		
Muscular system	Diaphragmatic hernia	7	7.69	<.001	3.05	1.21–6.30
	Gastroschisis	6	6.59	<.001	2.61	0.95–5.70
	Omphalocele	6	6.59	<.001	2.61	0.95–5.70
	Musculoskeletal system parameters	**19**	**20.88**	<.001		
Genitourinary system	Bladder exstrophy	1	1.10	.00004	0.44	0.00–2.47
	Posterior urethral valve	1	1.10	.00004	0.44	0.00–2.47
	Urological system parameters	**2**	**2.20**	**<.001**		
	Overall prevalence				**39.65**	
	Total – Sample of newborns with malformations (Ns)	**91**	**100**			
	Total – Newborn population (Np)	**22.949**		**<.001**		

Table 2

Median total LOS for the 13 congenital anomalies diagnosed and treated between 2012 and 2016.

Congenital anomaly	n	Median total LOS in days (range)
Esophageal atresia	16	21.1 (10–68)
Infantile hypertrophic pyloric stenosis	14	7.1 (5–19)
Duodenal atresia	9	22.6 (6–94)
Intestinal atresia	6	23.7 (9–67)
Malrotation/volvulus	8	30.8 (8–158)
Omphalomesenteric duct anomalies	1	8
Hirschsprung disease	2	16.6 (15–18)
Anorectal malformation	14	16.7 (7–87)
Congenital diaphragmatic hernia	7	26.1 (9–61)
Gastroschisis	6	28.2 (8–56)
Omphalocele	6	20.3 (8–41)
Bladder exstrophy	1	14
Posterior urethral valve	1	12

LOS = length of stay.

(*P* = .001). Advanced maternal age (>35 years) was also associated with an increased risk of IA (*P* = .023).

The median total LOS of all studied CA was 19.8 days (5–158 days). The median total LOS for neonates with the individual CA is provided in Table 2.

Major CA were responsible for 10 (11%) neonatal deaths in the present study (AE 2/16 or 12.5%, DA 1/9 or 11.1%, malrotation/volvulus 2/8 or 25%, KDH 2/7 or 28.6%, OM 2/6 or 33.3%, and GS 1/6 or 16.7%). No mortality was recorded in the patients with IHPS, ARM, OMD, IA, HSCR, BE, and PUV. In non-surviving infants with EA, a chromosomal abnormality was seen in 1 patient (trisomy 18/Edwards syndrome) who died after gastrostomy on the twelfth day of life. Another patient was a premature neonate (34 weeks) who died from an anastomotic leak and postoperative sepsis on the nineteenth day of life. One neonate with OM also had a chromosomal abnormality (trisomy 13/Patau syndrome). One neonate died due to a lethal multiple CA syndrome (Pentalogy of Cantrell) on the twenty-seventh day of life.[18] A neonate who died from GS died from postoperative sepsis. 55.6% of neonates with DA had associated anomalies; 3 had trisomy 21 (Down syndrome), while 2 had congenital heart disease.

4. Discussion

The present study presents the first study exploring the clinical features and outcome of selected surgically correctable CA in the pediatric population of Bosnia and Herzegovina.

In line with previous data, our study confirmed the preponderance of the selected CA among male infants.[19,20] Several social and biological reasons have been linked to these findings.[20,21] Thus, Libinsky suggested that females are more vulnerable to anomalies during the blastogenesis with consequent greater pregnancy losses than males, who exhibit a greater vulnerability during organogenesis/morphogenesis with a higher incidence of survivable CA.[21] Orzack et al found that the total female mortality during pregnancy exceeds the total male mortality, indicating that a higher prevalence of malformed males among live births occurs due to the non-survival of malformed females during pregnancy.[22]

The prevalence of CA varies among countries/regions, reflecting their complex pathogenesis.[23] CA affect approximately 2 to 3% of all births in Europe, including the UK.[24] In the present study, the overall prevalence of selected major CA at birth was 39.6 per 10,000 births, which is in line with the study of Türkbay et al (40.3/10,000 live births).[25]

Similar to the previous studies,[26,27] the leading CA of the gastrointestinal system (GI) system in our study were EA, ARM, IHPS, DA, and IA. Similar findings were reported in the

Saudi pediatric population.[28] The higher prevalence of EA in our study compared with the prevalence of EA in the UK population[29] could be caused by a significant number of pregnant women with prenatally suspected CA who moved to Canton Sarajevo from other parts of the country and were referred to our institution. Type C EA was the most prevalent in the present study, which aligns with the published data.[30] We found an overall mortality rate associated with a diagnosis of EA of ~12%, which is in keeping with published studies.[31,32]

Data from 11 US birth defect surveillance programs for the 1999 to 2010 period revealed the prevalence of IHPS in the range of 5.52 to 33.28 per 10,000 live births.[33] A similar prevalence has been observed in Western Europe.[34] In this study, the overall prevalence estimates (per 10,000 live births) were 6.10 for IHPS.

The prevalence of CDH in the present study was 3, which is in line with recent studies.[35,36] The most common type of CDH was the posterior lateral hernias (85%), with the majority occurring on the left side (85%), followed by anterior defects or Morgagni hernias (15%). Recent advances in the management of CDH have improved the overall survival (OS) to ~80% in non-extracorporeal membrane oxygenation (ECMO) infants and up to 50% in infants who need ECMO.[37] Similarly, the survival of patients with CDH in the study was 71%. However, 16% of infants with CDH did not undergo surgical repair and died due to the inability to achieve physiological stability and the lack of ECMO devices in our institution, indicating higher mortality associated with CDH.

The prevalence for OM and GS was 2.61, slightly lower than the US data.[38] The observed difference is likely related to the short observation period and the small sample size. We found that the ratio of OM to GS was 1:1, compared to the expected ratio of 3:2, probably due to the small sample size in each category. Overall survival (OS) for a neonate with GS is >95%.[39] Although the mortality from GS in our study was 16.7%, this observation was based on a small number of patients. In our study, the hospital discharge of infants with OM was 77%, aligning with published data.[40] The mortality rate of the patients with OM (33.3%) was more than twice that of GS (16.7%). Similar findings have been reported in the previous studies.[41]

We identified nine neonates with DA during the study period, with a prevalence of 3.92/10,000 live births, which is markedly higher than the estimated prevalence of DA in previous studies.[42,43] We also confirm the association between DA and other CA.[44]

The prevalence of malrotation was surprisingly high in our study. Such a high rate of detected malrotation was probably due to the institutional approach that any bilious emesis in the full-term neonate should be considered midgut volvulus until proven otherwise. However, in 2 of 8 cases, intestinal malrotation was detected in surgically treated preterm very-low birth weight infants with a clinical suspicion of necrotizing enterocolitis. Intestinal obstruction by bands was seen in 5/8 cases, and midgut volvulus in 3/8 infants operated on for intestinal malrotation. The viable intestine was found among infants with midgut volvulus, and volvulus reduction was performed in 2 patients. The entire non-viable intestine was found in 1 preterm infant in whom a non-viable bowel was excised and in whom it was planned to do a second look laparotomy after 24 hours. However, despite all efforts, the preterm infant died within a few hours after surgery. Another infant with midgut volvulus treated with volvulus reduction died due to overwhelming sepsis. The mortality of affected newborns with malrotation and midgut volvulus has markedly decreased from ~30% in the 1960s to 3 to 5% in the current era.[45] The higher mortality rate in our study was probably related to the small sample size and the short study period.

The neonatal mortality rate in our study was similar to that reported in the Saudi Arabian and Serbian populations.[46,47] However, the mortality rate was higher than in developed countries.[48–50] The higher mortality rate in our study could be due to the small number of the patients and rare pathologies such as trisomy 18 and the Pentalogy of Cantrell, both of which are associated with high mortality.

Comorbidity, the severity of the condition, birth weight, gestational age, social circumstances, and parental age impacted the LOS of neonates with major CA.[48] As in other studies,[48] our data showed a wide variation in the LOS of the neonates with CA. Midgut volvulus caused by malrotation, GS, and CDH had the longest LOS. Nevertheless, the median neonatal LOS in our survey was comparable with the published data.[48,51]

Our study has several limitations, including its retrospective nature, single-center experience, and small sample size. Individual CA were not divided by severity and analyzed (e.g., major/minor OM or long gap EA). Also, surgical procedures for individual anomalies were not analyzed by type (e.g., single-stage/staged correction of ARM). In addition, further efforts should be made to increase the use of minimally invasive surgical approaches. There may also be bias in the prevalence of selected CA in our sample because some pregnant women from other parts of Bosnia and Herzegovina are referred for childbirth in Sarajevo Canton due to prenatally diagnosed anomalies.

In conclusion, the present study is the first that provided insights into the prevalence, clinical characteristics, and outcome of selected surgically correctable major CA in Bosnia and Herzegovina. Most of the obtained results align with the published data, particularly from developing countries. The observed weaknesses and gaps will be used to improve the quality of local pediatric services.

Author contributions

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