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RESEARCH ARTICLE

INCIDENCE AND PATTERNS OF MAJOR CONGENITAL ANOMALIES AT SAINT PAUL'S HOSPITAL MILLINIUM MEDICAL COLLEGE, ADDIS ABABA, ETHIOPIA

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ABSTRACT

Background: Early developmental stages are susceptible to disruption because it is the period for organogenesis which refers to the 4th to 8th weeks of development. Congenital malformation is defined as "a permanent change produced by an intrinsic abnormality of development in a body structure during prenatal life". Major congenital malformations in different population around the world has shown considerable variation and ranges from less than 1% up to 8%. For various reasons, there is scarce of data and research on birth defects in Ethiopia. **Objective**: - To assess the incidence of major congenital anomalies and their pattern of distribution at Saint Paul's Hospital Millennium Medical College**,** Addis Ababa, Ethiopia, 2023. **Methods**: A cross sectional study was conducted at SPHMMC for 4 months, from September 1, 2022 to December 31,2022.All Women admitted for elective termination of pregnancy for fetal congenital anomaly were involved in the study.Data were collected using interviewer-administered questionnaire. Data were cleaned and entered into Epi Info version 7 and then exported to SPSS version 20 for analysis. In the analysis process, the frequency distribution of variables was calculated. **Results:** Among a total of 4050 outcomes, there were 3675 deliveries and 375 cases of 2nd trimester abortion including elective termination of pregnancy for fetal anomalies (ETOPFA), safe and spontaneous abortions. Out of the total outcome, there were 115 major anomaly affected cases making an incidence of congenital anomaly of 312.93 per 10,000 births or overall proportion of birth defects 2.8%. The mean age of mothers was 28±5. Of all 115 major anomaly affected cases: nervous system accounted 33.3%, congenital heart disease 19.6%, digestive system 19%, genitourinary system 12.4%, musculoskeletal system 5.9%, genetic/chromosomal4.6%, respiratory system 3.9% and the rest 1.3% were unclassified. **Conclusions:** The overall magnitude of birth defect was 2.8%. Seven patterns of major congenital anomalies were identified; nervous system was the most frequent by accounting one third, followed by congenital heart disease and digestive system each accounting almost one fifth of major congenital anomalies. The medical workforce and managers should give emphasis to congenital anomalies.

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INTRODUCTION

Congenital anomaly, also known as birth defect, is any abnormal structural or medical condition that is present at birth. This can be recognized before birth (prenatal), at birth or even long after birth (postnatal). Congenital anomalies include minor physical defect such as birthmark, severe defects like congenital heart defect and combinations of other abnormalities affecting several parts of the body (1-3). Congenital anomalies may be inherited or sporadic, isolated or multiple, gross or microscopic. Birth defects (BDs) can be caused by genetic, chromosomal, environmental, and multifactor effects, as well as micronutrient deficiencies or unknown etiological agents (2, 4).

Congenital anomalies contribute a significant proportion of fetal and neonatal mortality as well as infant morbidity and mortality (1,3-5). The case fatality rate for most severe anomalies such as anencephaly, trisomy 13 and trisomy 18 and severe heart defects are virtually 100% by the child's first birthday (5).Literatures show that they account for 3.3% of all admissions into hospitals and up to 85% of all mortalities in a newborn in Tanzania (5). In India, it has been observed that they constitute 22% of all early neonatal deaths (5). Although it has been reported that out of the approximately 350,000 children born in Canada each year, most are born healthy and at term, about 2-3% of these babies present with serious congenital anomalies (5). Birth defect studies are important public health issues for planning and implementing prevention strategies and health services (3,8, 10).

Planning for the BD program activities with clear aims, objectives and intended short, medium and long term outcomes are essential to reduce the burden of BDs. In addition, establishing a surveillance system as well as obtaining political support, financial aid and identifying geographical regions and understanding the health care system capacity are also important components to reduce the occurrence of congenital anomalies. Implementing preventing strategies based on BD data, creating awareness about BDs and the uses of folic acid/multivitamins or nutritional status are necessary to reduce the events of BDs. The occurrence of most congenital anomalies are potentially preventable by creating awareness and providing health education on BDs and their etiologic factors to the community, particularly to women in the reproductive age groups, as well as by establishing well-organized registry and regular surveillance systems. For many reasons, research on the magnitude and burden of congenital anomalies are not conducted adequately in Ethiopia. There has been no active surveillance and monitoring system at national, regional, or local levels. As a result, data and research capable of providing information on congenital anomalies have been scarce in Ethiopia, making a thorough investigation of the situation essential.

The aim of this study was to determine the incidence, pattern of distribution and health care burden of congenital anomalies presenting at SPHMMC. Congenital anomaly remains one of the leading perinatal mortality and morbidity at SPHMMC and the surrounding. Thus the place of this research in contributing to the programming of a better health care delivery cannot be overemphasized. This research will also provide a database for further studies on risk factors and causative agents of congenital anomalies at SPHMMC and the surrounding, and help in the suggestion of preventive measures in years to come. When compared with other geographical zones, the findings of this research will be used to compare and contrast findings in other parts of Ethiopia.

METHODS

Study design and setting: Institution-based cross-sectional study design was conducted. This study was undertaken in Saint Paul's Hospital Millennium Medical College in Addis Ababa, capital city of Ethiopia. St Paul's hospital millennium medical college was first called St. Paul General Specialized hospital and was referral hospital in Addis Ababa under the Ethiopia Federal Ministry of Health (FMOH). It was built in 1961 EC by the Emperor Hailesilassie with the help of the German Evangelical Church. The hospital was established mainly to serve the economically under privileged population, providing services free of charge to about 75% of its patients. Since 2007, it has become a medical college which is currently named St Paul Hospital Millennium Medical College. This college has started postgraduate training program in 2012 and its core services are medical care, teaching and research. Nowadays it is one of the tertiary referral hospitals directly under the federal ministry of health. The hospital gives service to about 200,000 people annually who are referred from all corners of the country. It has a total bed of 360 and on average 650 patients visit the hospital as outpatient and emergency daily. It gives service under different clinical disciplines which include obstetrics and gynecology.

The Obstetrics and Gynecology department has near to 80 residents of year I- IV supervised by 20 consultants of which 4 are perinatologists. Nearly 10,400 attended antenatal care and around 9850 deliveries were attended in 2009 Ethiopian fiscal year. Around 1,200 women receive abortion care including safe and elective termination of pregnancy for fetal anomalies (ETOPFA), in the hospital annually. Perinatal mortality in this hospital approaches 50 per 1000 deliveries, out of this congenital anomalies account approximately for 10-11 %. (Statistics office of the hospital)

Sample size determination and Sampling Procedure: From all pregnant women admitted for 2nd trimester abortion care services including safe, miscarriage and elective termination of pregnancy for fetal anomalies and all those giving birth at Saint Paul's Hospital Millennium Medical College;115 cases were obtained by enrolling all congenitally malformed births(including life birth and stillbirth) and abortuses during the study period. All eligible pregnant women who consented for involvement in the study to go through their chart were included in the study during the study period.

Data Collection: The data was collected by BSC midwifes, nurses and interns working at abortion care and service unit, NICU and labor and delivery ward after training was given for three days. One data collector was responsible at one of the three data collection sites all the time. Posters with images of common anomalies were put up in the aforementioned wards; Operational manual for the study was prepared to assure a uniform standard to carrying out the study with good quality control. To know the perinatal outcome of those live born neonates with BD we called the mother/father on the 7th postnatal day. All data were collected and stored anonymously. We believe this is the best way to ensure confidentiality of participants. We have not collected or stored any identifying information about participants. Each questionnaire was checked for completeness on twice weekly basis by the principal investigator.

Categorization of congenital anomalies: General physical examination of all newborns or stillborns were undertaken immediately after delivery to look for possible CM. Congenital anomalies were diagnosed through prenatal sonography, 2D echocardiography and visual examination of newborn or stillborn with BD or abortus of those admitted for abortion care and services. Anomaly data was abstracted from general physical examination, prenatal ultrasound reports, patient/mother and neonatal chart and other clinical records. Anomalies were assigned ICD-10 codes by the researchers in order to facilitate system-wise classification of anomalies.

Data Analysis: After data collection, each questionnaire was checked for completeness before entering to software. Data was entered in to SPSS version 20 statistical package. Coding of individual questionnaires was checked before data entry in to the software. Further, data cleaning was performed to check for outliers, missed values and any inconsistencies before the data analysis. Descriptive analysis was done to obtain the prevalence and pattern of CA. Analysis was also done on type of BD, gender of abortus, stillborn or newborn and perinatal outcome. The findings were compared to those of other similar prevalence studies on BDs in any region of the world.

Significance level was considered when the P-value is <0.05. The results were presented in the form of texts and tables.

RESULTS

Socio-demographic characteristics of respondents: There were a total of 4050 pregnancy outcomes during the study 4 months study period. These include 375 cases of 2nd TM abortion and 3675 deliveries. Out of this a total of 115 women were approached for participation in the study and all accepted and enrolled in this study. The mean age of mothers was 28.97±5.96, with a range of 17- 41years.Of the affected mothers, 86.1% were married,12.2% divorced/widowed and 1.7% never married. About 7.8% of the mothers had no formal education, 32.2% had primary education, 39.1% had secondary school and 20.9% had college and above educational status. Almost 70.4% of respondents' age was in 20-34 years of age category. Near to half (52.2%) of the affected women are urban dwellers, and the remaining 47.8% are rural dwellers. By occupation, 56.5%, 27.8%, 10.4% and 5.2% of the mothers were house wives, employed, daily laborer, and jobless/un-employed, respectively. The socio-demographic characteristics of the study participants are presented in Table 1.

Table 1. Socio-demographic characteristics of mothers with pregnancy complicated by congenital anomalies at SPHMMC, Addis Ababa, Ethiopia, 2022

Variables		Frequency	Percent
Age(year)	<20	5	4.3
	20-34	81	70.4
	35-39	25	21.7
	>=40	4	3.5
Religion	Orthodox	41	35.7
	Protestant	37	32.2
	Muslim	37	32.2
Educational status	No formal education	9	7.8
	Primary school	37	32.2
	Secondary school	45	39.1
	College and above	24	20.9
Occupation	Daily laborer	12	10.4
	Student	4	3.5
	Employed	32	27.8
	House wife	65	56.5
	Other	2	1.7
Income category(ETB)	<3000	34	29.6
	3000-6000	58	50.4
	>6000	23	20.0
Marital status	Single	2	1.7
	Married	99	86.1
	Divorced	7	6.1
	Widowed	7	6.1
Place of residence	Urban	60	52.2
	Rural	55	47.8

Obstetric and reproductive characteristics of mothers with pregnancy complicated by congenital anomalies at SPHMMC: Regarding past obstetric characteristics or performance whose current pregnancy was complicated by CM, majority of mothers, 86(74.8%) were multigravid, while only 29(25.2%) were primigravida. Out of the 115 mothers whose current pregnancy is complicated by CM, 31(27.0%) had previous history of at least one abortion. Of these 31 mother with previous history of abortion, 3(9.7%) of them were electively terminated for major congenital anomaly; making 2.6% of mothers having repeat CM. About 13.9% had a history of at least 1 stillbirths or early neonatal death. Among the total of 115 cases with major malformation, there were 14 pairs (12.2%) of twins and the rest (87.8%) were from singleton pregnancy (See Table 2 below).

Table 2: Obstetric and reproductive characteristics of mothers with pregnancy complicated by congenitalanomalies at SPHMMC, Addis Ababa, Ethiopia, 2022

Gravidity	Primi	29	25.2
	2-5	77	67.0
	>5	9	7.8
Parity	1	36	31.3
	2-4	39	33.9
	>4	7	6.1
No of alive children	<3	71	61.7
	>=3	41	35.7
History of stillbirth	Yes	16	13.9
	No	99	86.1
History of ENND	Yes	15	13.0
	No	100	87.0
History of abortion	Yes	31	27.0
	No	84	73.0
Indication/Type of abortion(n=31)	safe/spont	28	90.3
	TOP for CA	3	9.7
Gestational Age	<28	42	36.5
	28-36	21	18.3
	>=37	52	45.2
Type of gestation	singleton	101	87.8
	Twin	14	12.2

Assessment of risk factors for mothers with pregnancy complicated by congenital anomalies at SPHMMC: In this study, of the 115 cases of major congenital anomalies recorded, 27(23.5%) mothers have chronic illness; and these include DM 10(8.7%) taking insulin or Metformin; HIV positive 7(6.1%) taking HAART; chronic hypertension 3(2.6%), 2 of them using different antihypertensives; Epilepsy 2(1.7%) each taking phenytoin; both pregnancies were complicated by CHD. As presented in Table 2, 10(8.7%) had a history of exposure to chemicals including 5 herbicide,3 pesticide and 2 unknown chemical types in factory; and 5(4.3%) had a history of exposure to radiation during early pregnancy(3 chest x-ray, 1 plain abdominal x-ray unknowingly and 1 chest CT scan); 3.5% had a history of smoking of cigarettes; 7.8% had history of alcohol consumption during current pregnancy. Out of the total mothers only 35(30.4%) of them had taken folic acid, out of which 30(85.7%) took it during the 1st 3 months and the remaining 5(14.3%) took before and during early pregnancy. The majority of the mothers (69.6%) have not consumed folic acid during early pregnancy. In terms of vegetables/fruits use, almost 65.2% of the mothers consumed vegetables/fruits combined with other food items (staple food) during pregnancy. Out of the 115 mothers, 7(6.1%) had previous history of congenital anomaly affected pregnancy (Fig.1).

Outcome of all pregnancies of mothers with pregnancy complicated by congenital anomalies at SPHMMC: Over the four months study period there were a total of 4050 outcomes including 3675 deliveries and 375 cases of 2nd trimester abortion which includes ETOPFA of any gestational age; safe and spontaneous abortions at or beyond 20 weeks of gestation. Out of the total deliveries 3569 were live birth and 106 stillbirth. Out of the live birth there were 62 cases of early neonatal death, making the total perinatal loss of 168 out of which 50 were congenitally malformed.

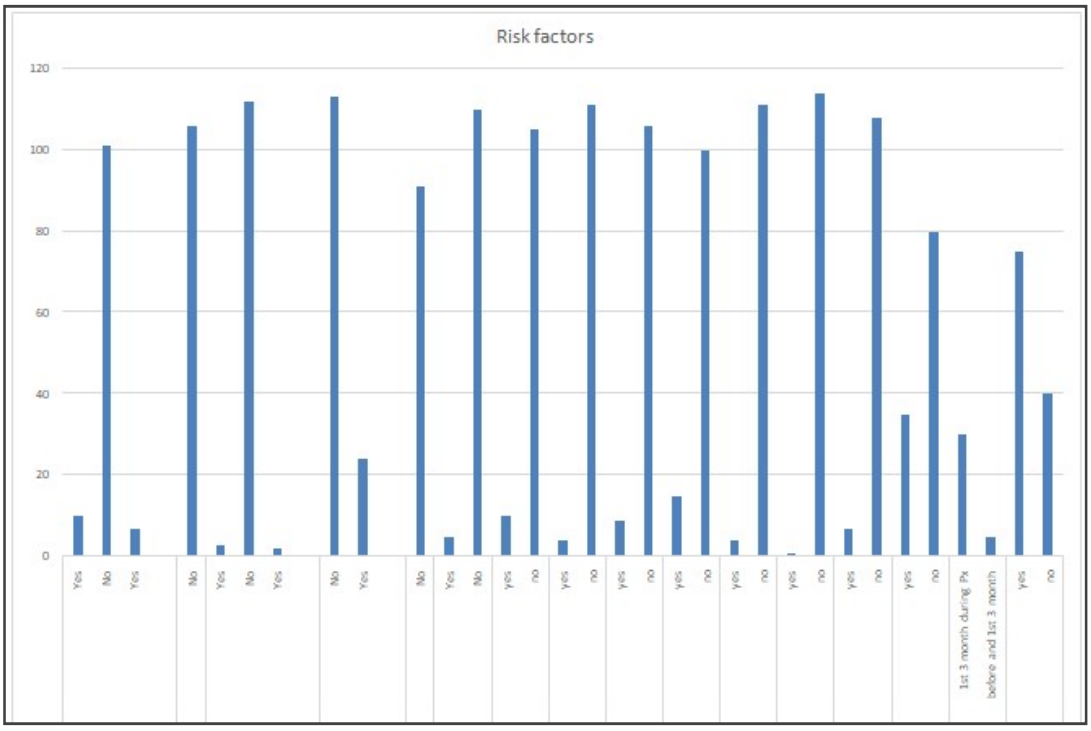

Figure1: Assessment of risk factors for mothers with pregnancy complicated by congenital anomalies at SPHMMC, Addis Ababa, Ethiopia, 2022

Table 3. Total Pregnancy Outcomes at SPHMMC, September 1 to December 31, 2022, Addis Ababa, Ethiopia

Outcomes	N	Rates	Outcomes with major anomalies	Congenital anomaly affected rates
Total Outcomes	4050		115	312.93per 10 000 births
Live births	3569		63	179.52per 10 000 live births
Early neonatal deaths	62	17.37 1000 live births	33(53.23%)	9.25 1000 live births
Stillbirths	106	28.83 per 1000 births	17(16.04%)	4.63per 1000 births
Perinatal deaths	168	45.71per 1000 births	50(29.76%)	13.61per 1000 births
Terminations of pregnancy	375		35(9.33%)	9.52per 1000 births

Table 4. System-wise description of all congenital anomalies of mothers with pregnancy complicated by congenital anomalies at SPHMMC, Addis Ababa, Ethiopia, 2022

Variables		Frequency	Percent
Nervous system anomalies(n=51)	Isolated anencephaly	24	47.1
	Chiary II malformation	10	19.6
	Isolated ventriculome	6	11.8
	Isolated s/bifida	4	7.8
	Others	7	13.7
Digestive system anomalies (n=29)	gastrochisis	9	31.0
	omphalocele	8	27.6
	tracheoesophageal fistula	4	13.8
	cleft palate/lip	4	13.8
	Other	4	13.8
Congenital heart diseases (n=30)	ASD	6	20.0
	VSD	11	36.7
	Multiple CHD	10	33.3
	Others	3	10.0
Urinary system anomalies (n=16)	Congenital hydronephros	5	31.3
	polycystic KD	4	25.0
	Bladder exstrophy	3	18.8
	Others	4	25.0
MS system anomalies (n=9)	skeletal dysplasia	8	88.9
	clubfoot	1	11.1
Respiratory system anomalies (n=6)	Cong diaph hernia	2	33.3
	Pulmonary hypoplasia	2	33.3
	Others	2	33.3
Genital anomalies (n=3)	Indeterminate sex	1	33.3
	hypospadiasis	1	33.3
	Cong hydrocele	1	33.3
Genetic/chromosomal dis (n=7)	Down syndrome	6	85.7
	Others	1	14.3
Unclassified(n=2)			

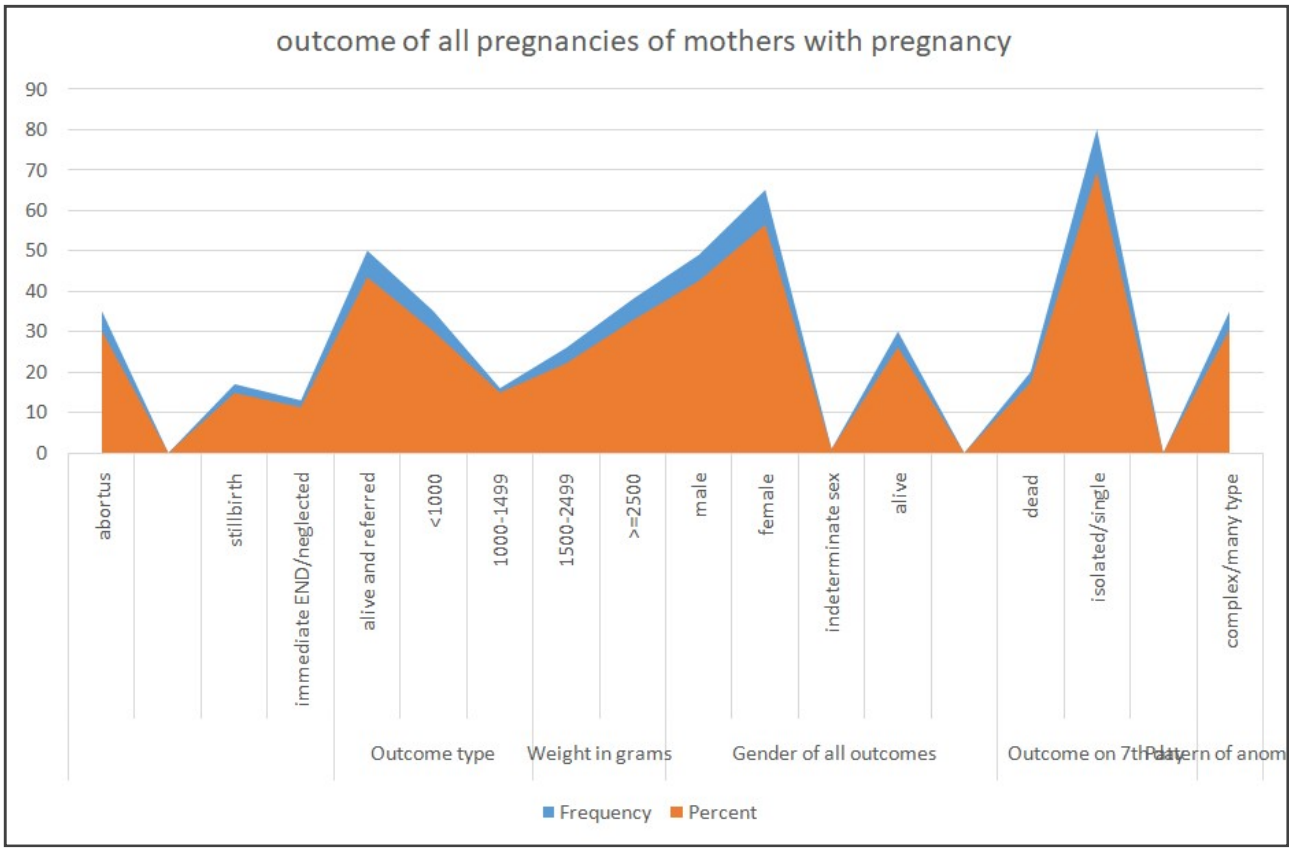

Figure 2. Outcome of all pregnancies of mothers with pregnancy complicated by congenital anomalies at SPHMMC, Addis Ababa, Ethiopia, 2022

Out of the total outcome there were 115 major anomaly affected cases; of which 63 (54.8%) were live born of which 13(11.3%) died immediately or neglected,17(14.8%) were stillbirths and 35(30.1%) were abortuses. Of the total 115 major congenital anomaly affected outcomes, 65(56.5%) were female, 49(42.6%) male and there was one case of indeterminate sex. The gross perinatal mortality rate over the study period was 45.71 per 1000 birth, of which 29.8% was contributed by major/lethal CM; making congenital anomaly PMR of 13.61 per 1000 birth. Total prevalence of congenital anomalies was 312.93 per 10,000 births or 2.8% overall proportion of birth defects in this study. Overall, 35 (30.4%) of cases had multiple major congenital malformations involving two or more systems (see Table 3 and Fig. 2).

System-wise description of all congenital anomalies of mothers with pregnancy complicated by congenital anomalies at SPHMMC: The pattern of congenital malformation categorized according to the system involvement using the ICD-10 classification is shown in Table 6. A fetus/baby with multiple anomalies was counted once within each class of anomaly. Out of a total of 115 major congenital malformations recorded, that of the nervous system was the highest, 51 cases out of the total and accounting for 33.3% of all the major malformations. Anencephaly emerges as the highest occurring congenital anomaly of the nervous system with 47.1% occurrence; followed by Chiari II malformation which accounts for 19.6% of all nervous system anomalies. Isolated ventriculomegaly and spina bifida each accounted for 11.8% and 5.9% respectively. Other nervous system anomalies included 3 cases of encephaloceles (2 occiputal and 1 frontal); and 1 case each of hydrancephally, sacrococcygeal teratoma, Dandy-walker anomaly and huge intracranial mass. The data showed that congenital heart defects (CHDs) were the second most prevalent anomalies, 30 cases out of the total and accounting for 19.6% of all the major malformations, with ventricular septal defects (36.7%) and multiple congenital defects (33.3%) being the most commonly presenting heart defects. The other CHDs include 3 cases of tetralogy of fallot, 2 cases of PDA, 2 cases of left ventricular hypoplasia, one case each of double outlet right ventricle and Atrioventricular septal defect or AV canal defect .

Other common systemic categories of malformations in order of frequency were those of the Digestive system-29 cases (19.0%), Genitor-urinary system-19 cases (12.4%), Musculoskeletal system-9 cases (5.9%), Genetic/Chromosomal-7 cases (4.6%) ,Respiratory system-6 cases (3.9%) and 2 cases (1.3%) were unclassified. Malformations of the digestive system were primarily contributed by gastrochisis (31.0%), followed by omphalocele(27.6%).Other digestive system malformations include 4 cases each of tracheoesophageal fistula and cleft palate/lip, two duodnal atresias; one case of imperforate anus and one case of multiple malformations (GUS and digestive system involvement) (Table 4).

DISCUSSION

Prevalence studies of congenital anomalies are useful to establish baseline rates, to document changes over time, and to identify clues to etiology.

They are also important for planning and evaluating antenatal screening for congenital anomalies, particularly in high risk populations. The prevalence rates of major congenital malformations reported from around the world have shown large variations ranging from less than 100 to over 450 per 10,000 births (1-4). Much of the differences in the reported prevalence have probably resulted from the differences in the study design especially the data source, the length of observation, and the methods used for definition and categorization of the malformations.

A total of 115 congenital anomalies were recorded in this study. The overall prevalence of major congenital malformation at SPHMMC during the study period was 312.93 per 10,000 births or rate of 2.8% which is near to the **3.03** EUROCAT report (8). Our prevalence rate is higher than many of those reported in many other population based studies in published literature which varies between 100 and 450 per 10,000 births (1-3). However, this difference is most likely due to the fact that most of the complicated pregnancies, including those of CM, at catchment health centers and some rural ones are referred to SPHMMC. The other reason for higher prevalence rate in this study is the inclusion of those electively terminated for congenital anomaly, which is not a case for most of other reports, especially those from Ethiopia. The European Surveillance of Congenital Anomalies recommends inclusion of those electively terminated for congenital anomaly; safely terminated and spontaneously aborted fetuses with BD.

Majority of standard text books and most congenital anomaly studies show that the most prevalent congenital anomaly is congenital heart defects. A recent study in India and Barbados showed that congenital heart defects (CHDs) were the most prevalent anomalies (1,3). Another study from Nigeria and Ethiopia showed that gastrointestinal system anomalies had the highest occurrence, followed by that of the central nervous system (2,3).On the other hand, studies from Tanzania, Palestine, and China reported that central nervous system anomalies (NTDs) were the most frequently observed anomalies (2,5,7). Such differences in patterns of congenital anomalies may be due to genetic factors in studied population, the methodologies employed or the existence of multifactorial factors in the countries the studies were carried out. In this study data shows that congenital anomaly of the nervous system has the highest occurrence (33.3%). This high frequency rate, especially that of NTDs could be due to no or low use of folate during peri-conception and early pregnancy. The next most common CM identified in this study is that of congenital heart disease-19.6%. This was followed by malformations of the digestive system -19.0%, genitor-urinary system-12.4%, musculoskeletal system-5.9%,genetic/chromosomal-4.6%,respiratory system-3.9% and 1.3% was unclassified. During the study period there were a total of 3675 deliveries including 3569 live birth and 106 stillbirth. Out of the live birth there were 62 cases of early neonatal death, making the total perinatal loss of 168 out of which 50 were congenitally malformed. The gross perinatal mortality rate over the study period was 45.71 per 1000 birth, of which 29.8% was contributed by major/lethal CM; making congenital anomaly PMR of 13.61 per 1000 birth. Prenatal diagnosis and subsequent termination of affected pregnancies is one of secondary preventive strategies to reduce PNMR.

Limitation of the study

Being a single hospital based and relatively short period of study; we believe that this study suffers from the possibility of selection bias as the profile of those patients may be different from patients in other hospitals. Although WHO recommends early ultrasonography scan for all pregnant women, some of women enrolled in this study have no prenatal ultrasound examination, especially screening for congenital anomaly. So there is a chance of missing cases which can't be detected by physical examination after delivery. Furthermore, autopsies were not performed to confirm the diagnosis, and karyotypes were not performed where multiple malformations were detected to determine whether a chromosomal anomaly is present.

CONCLUSION

The findings of this study indicate that congenital anomalies are not insignificant conditions, as their birth prevalence rate is near to equivalent to global rates.Neural tube defects, congenital heart disease and malformations of the digestive system contributed more three-fourth of the birth defects/congenital anomalies.Major congenital malformation is becoming an increasing burden on the health care resources, including a significant contribution to admissions to the neonatal unit.

Recommendation

Based on the present study findings, the following recommendations are suggested to different levels of health professions and hospital managers:

- Screen all fetuses for birth defects, thoroughly examine every stillbirth, miscarriage, elective termination, and newborn baby for birth defects, record routinely all birth defects cases.
- Supply the recommended doses of folic acid/multivitamins containing folic acid to all women during their conception time and the first three months of pregnancy.
- Provide health education for women in the reproductive age group to create awareness about birth defects and their causes
- Screen and treat chronic diseases, such as diabetes, epilepsy, and anemia before conception and during early pregnancy period
- Establish reporting system with responsible bodies.

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