Original Article

Audit of level II scans in a tertiary center of a middle-income country (MIC)

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Abstract

Context: Significant anomalies are those that are lethal or those that require prolonged follow-up and unaffordable treatments. Detection of these anomalies allows early termination or the support systems necessary for pregnancies with these diagnoses. Anxiety associated with overdiagnosis makes the woman a victim of modern imaging technology. However, accurate detection of significant anomalies in a busy scan room of a developing country with the need to cater to large numbers is particularly challenging. **Aims:** The aim was to audit the diagnostic accuracy in a busy scan room. **Settings and Design:** Retrospective cohort in a tertiary center. **Methods and Materials:** Audit of significant anomalies identified at the 20-week scan was performed after the expected date of confinement. Anomalies that were missed or overdiagnosed were noted. **Statistical Analysis Used:** All the categorical variables in this research were summarized using counts and percentages. **Results:** Twenty-eight thousand women underwent morphology ultrasound during the study period. 963 (3.4%) women were detected to have anomalies at birth. Multiple anomalies were seen in 285 (30%) cases and isolated ones in 678 (70%) cases. Anomalies of the genitourinary system were the commonest followed by the anomalies of central nervous system. Only 53 (0.2%) anomalies were missed. They were mainly syndromes and anomalies of the cardiovascular system. The most significant anomalies that were identified could be diagnosed with a basic ultrasound machine. **Conclusions:** 910/963 (95%) of significant anomalies can be identified even in busy centers if a systematic assessment approach is ensured.

Keywords: Congenital anomalies, detection of anomalies, level-II ultrasound, missed diagnosis, morphology scan

Introduction

Primary health care facilities in middle-income countries (MIC) should be self-reliant and be able to cover all aspects of basic antenatal care. Correlation of obstetric morphology imaging with clinical outcomes, for facilities performing these scans, is recommended to ensure quality.[1-3] There is significant variation in efficacy depending on the quality of ultrasound machines, settings in which ultrasound is performed and the skill and experience of the examiner.[4,5] To our knowledge, significant data[6] from MIC are not available Therefore, the aim of our study was to audit the detection of congenital anomalies in this setting.

Subjects and Methods

An audit of detection of anomalies by ultrasound in a large tertiary center between April 2016 and March 2018 was conducted after an institutional review board (IRB Min No: 10495) clearance.

The primary objective was to ascertain the total number of significant anomalies detected in our hospital. The secondary objective was to classify the anomalies detected according to systems (such as genitourinary system, central nervous system (CNS), musculoskeletal system, gastrointestinal system/

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abdomen, cardiovascular system, thorax and facial anomalies) and to audit significant anomalies that were missed or overdiagnosed. All antenatal women who underwent a level-II ultrasound in our institution between April 2016 to March 2018 were included in the study. A routine morphology scan between 18 and 22 weeks of gestation by trained health providers with more than 5 years' experience. Recommended standard obstetrics ultrasound examination was performed and this included an examination of the head, face, neck, chest, abdomen, spine, and extremities.[7] The four-chamber view and left and right ventricular outflow tracts were used to identify cardiac anomalies. These ultrasounds were done using either Voluson GE S8 or Voluson GE E8 machines. Detected anomalies were counter checked by a multidisciplinary group comprising a neonatologist and a specialist when necessary. In the event of a controversy about the prognosis of a specific anomaly, the findings were counter-checked by the neonatologists or a specialist.

All anomalies were entered on a daily basis in a register that was maintained in the ultrasonography room. The outpatient records of women with detected anomalies were marked using a special sticker. A proforma was filled for each woman with a detected anomaly and data was entered into an Excel sheet for analysis. After the morphology scans were done the expected date of conception was documented. An audit of anomalies detected was conducted in the month following the expected date of conception.

This audit found anomalies that were not detected during the antenatal period but were diagnosed in the neonatal period. Anomalies that were diagnosed antenatally but not seen postnatally were also audited.

Statistical analysis

All the categorical variables in this research were summarized using counts and percentages. The data were analyzed using Microsoft Excel software.

Results

During the study period, 28,000 antenatal women underwent morphology ultrasounds of which 963 (3.4%) women were detected to have anomalies at birth. Anomalies were multiple in 285 (30%) cases and isolated involving only one system in 678 cases (70%) [Table 1].

Among the 285 women who were diagnosed to have multiple anomalies, 90 neonates were alive and 195 neonates were dead

Table 1: Congenital anomalies involving systems detected by morphology ultrasound

System	Number (*n*) 963	Percentage (%)	Alive	Died or TOP	Lost to follow-up	Anomalies missed or not detected n=53
Multiple anomalies or syndromes	285	30%	90	195	-	16
Isolated anomalies	678	70%				
Genitourinary System (Total)	241/678	36%				
Renal pelvic dilatation >10mm	193		182	7	4	
Multicystic kidney	31		20	11	0	
Others	17		12	4	1	2
Central nervous system	176/678	26%				
Hydrocephalus spectrum	89		48	39	2	
Anencephaly	32		0	32	0	
Meningocele and others	55		21	32	2	3
Musculoskeletal System	87/678	13%				
*CTEV	52		45	3	4	7
Short limbs, skeletal dysplasia + others	35		27	7	1	2
Gastrointestinal system/abdomen	58/678	8%				
Omphalocele and gastroschisis	7		2	4	1	
Abdominal cyst	16		15	1	0	
Stomach bubbles absent/small	18		12	6	0	
Others	17		11	6	0	3
Cardiovascular system	56/678	8%				
†VSD with or without Tetralogy of Fallot spectrum	13		10	3	0	7
Hypoplastic left heart	11		0	11	0	2
‡TGA	7		3	4	0	0
Others	25		11	13	1	6
Thorax	31/678	5%				
§CDH	6		3	3	0	
ǁCCAM + Hyperechoic	25		23	1	1	
Facial Anomalies	29/678	4%				
Cleft lip + palate	16		15	1	0	5
Cystic hygroma	13		2	11	1	

*CTEV: congenital talipes equinovarus. † VSD: ventricular septal defect. ‡TGA: transposition of the great arteries. §CDH: congenital diaphragmatic hernia. ǁCCAM: congenital cystic adenomatoid malformation

or had a termination of pregnancy. Sixteen known syndromes were identified among the 90 neonates born alive. All the six syndromes that could have been detected antenatally were missed in our centre.

Among the 678 isolated anomalies, 241 were anomalies of the genitourinary system and of these 22 pregnancies were terminated and five were lost to follow-up. The majority of the cases were renal pelvic dilation (RPD). Two cases of bladder exstrophy were missed. CNS anomalies were seen in 176 pregnancies. Among these, 103 pregnancies were terminated and four women were lost to follow-up. Three cases of meningomyelocele were missed. Nine cases were overdiagnosed as mild hydrocephalus. Eighty-seven women had anomalies of the musculoskeletal system and only 10 pregnancies were terminated and five were lost to follow up. Seven cases of congenital talipes equinovarus (CTEV) and two cases of skeletal dysplasia were missed. Ten cases of CTEV were overdiagnosed. Fifty-eight women had anomalies of the gastrointestinal system or abdominal anomalies. Seventeen of these pregnancies were terminated and only one was lost to follow-up. There were no cases of the gastrointestinal system or abdomen that were missed or overdiagnosed. Anomalies of the cardiovascular system were seen in 56 women. 15 cases of cardiovascular anomalies were missed. Thirty-one women had a termination of pregnancy and one woman was lost to follow-up. Ten neonates were alive and referred for treatment.

Six women were diagnosed to have a congenital diaphragmatic hernia. Three of these pregnancies were terminated. Twenty-five with congenital cystic adenomatoid malformation (CCAM) spectrum were diagnosed and only one death was reported and one pregnancy was lost to follow-up.

Twenty-nine women had isolated facial or neck anomalies and twelve of these pregnancies were terminated. Five cases of cleft lips were missed and one case of cleft palate was overdiagnosed.

Discussion

The results of our study like other studies[6-9] have confirmed that significant anomalies are seen in 3.4% of births. Our study also found that RPD was the most common anomaly and was associated with the best prognosis.[10] Anomalies of the CNS were the second commonest as seen in other studies.[11] Both RPDs and CNS anomalies were easy to diagnose but unlike RPD, the prognosis was bad with CNS anomalies. The detection of anomalies of the heart was the most challenging. However, like other published studies,[12] only 0.2% of the women had cardiac anomalies and almost 30% of these anomalies could be identified using the easy four-chamber view which can be done using a basic ultrasound machine. Though we used high-end machines and our health providers had more than 5 years' experience, 27% of cardiac anomalies were missed in our study and this concurs with previous population-based studies.[12] Only 6 out of the 16 missed syndromes could have been identified antenatally. Thus, overall malformations in 0.2% of all women screened were missed in our study. CTEV and cleft lip are anomalies that could be missed with an elementary morphology scan. However, it is well known that both cleft lip and CTEV are easily treated and have a good long-term prognosis. Optimal use of resources while tackling the challenge of coverage with quality is paramount in an LMIC. Our audit has shown that the majority of anomalies detected could be identified easily even with a basic ultrasound machine with elementary training.

The drawback of the study was that it was a retrospective study. Therefore it could not study the negative impact of the overdiagnosis of anomalies or of diagnosing soft markers of unknown significance. Thus, from a family practice point of view, even a basic morphology scan can identify most anomalies of the fetus. Though we embarked on a study that audited the diagnostic performance of morphology scans, an observation which will improve the utility and accessibility of this test during the care of an antenatal patient in family practice has been made.

The study has reiterated, like other studies[13-15] that the majority of the significant anomalies complicating pregnancy are those that can be easily identified. Valuable information from this audit can be used to initiate more research that could contribute to rational guidelines for the diagnosis of congenital anomalies in low-risk antenatal mothers.

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Conflicts of interest

There are no conflicts of interest.

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