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Original Research Article

The role of foetal assessment by ultrasound at 11-13+6 weeks of gestation

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ABSTRACT

Background: The prevalence of congenital anomalies has been increasing over the years, and it is estimated that every year 1 in 33 infants are affected by some sort of congenital anomaly. At 12 weeks of intrauterine gestation, most of the major foetal structures complete their development and also proper delineation of the foetal anatomy is possible by the time of routine NT scan at 11-13+6 weeks.

Methods: This was a prospective study of 110 cases who underwent a first trimester 11-13+6 weeks scan for congenital foetal abnormalities. The eligibility criteria for selection of cases were first trimester pregnancy between the 11-13+6 weeks gestation and CRL between 45 mm and 84 mm.

Results: The study found that the detection rate of foetus abnormalities was 15.4% in mothers over 35 years old. Total 2.7% of the present study population were detected to be high risk for trisomy 21. All the 110 cases in present study were followed up till delivery/ termination. MTP was performed in 8.1% cases with lethal anomalies and in 1 cases of structural anomaly with missed abortion, D and E was done. 91% delivered live and healthy babies. There was no intrauterine foetal death or still born in present study.

Conclusions: Ultrasound at 11-13+6 weeks must be mandatory, not only for the detection of major foetal anomalies but also for diagnosis of multiple pregnancy and abnormal pregnancy like missed abortion, molar pregnancy and ectopic pregnancy.

Keywords: Congenital anomalies, Foetal assessment, Ultrasound foetal assessment, 11-13+6 weeks foetal assessment

INTRODUCTION

The prevalence of congenital anomalies has been increasing over the years, and it is estimated that every year 1 in 33 infants are affected by some sort of congenital anomaly.¹ Congenital anomalies are defined as structural or functional anomalies, including inborn errors of metabolism, which are present at birth and are still one of the leading causes of still birth and neonatal mortality.¹ In India, the prevalence of congenital anomalies is grossly underreported, and recent surveys have documented severe congenital anomalies in 63 out of 1000 live births. Most of the serious birth defects includes down syndrome, heart defects and neural tube defects.¹ During the first trimester scan, major foetal structural anomalies-

abdominal wall defects (omphalocele, gastroschisis), major central nervous system anomalies (anencephaly, spina bifida), congenital heart defects and skeletal anomalies (osteogenesis imperfecta) can be detected which may or may not be associated with increased nuchal translucency.² However, if these anomalies are not detected until the routine NT scan at 11-13+6 weeks, the baby may experience significant health complications, such as Down syndrome, heart defects, and neural tube defects. The traditional targeted imaging for foetal anomaly (TIFFA) scan which is performed at 18-22 weeks leads to delay in diagnosis, referral and management.^{3,4} At 12 weeks of intrauterine gestation, most of the major foetal structures complete their development and also proper

delineation of the foetal anatomy is possible by the time of routine NT scan at 11-13+6 weeks.⁵

Objective of our study was to date the pregnancy accurately, to diagnose multiple pregnancy and determine the chorionicity and amnionicity, to diagnose major congenital foetal abnormalities, to diagnose miscarriage early, to assess the risks of trisomy 21 and other chromosomal abnormalities.

METHODS

This was a prospective study of 110 cases who underwent a first trimester 11-13+6 weeks scan for congenital foetal

abnormalities at SVP Hospital, Ahmedabad during duration of May 2019 to Sept 2021. The eligibility criteria for selection of cases were first trimester pregnancy between the 11-1-3+6 weeks gestation and CRL between 45 mm and 84 mm.

After getting relevant obstetric history, they were subjected to an 11-13+6 weeks scan by TAS and if foetal anatomical survey was not possible to be completed by TAS alone, TVS was performed. Evaluation of foetal anatomy was performed according to the ISUOG Practice Guidelines for 11-13+6 weeks scan, which is based on the checklist depicted in Table 1.

Table 1: Checklist of ISUOG practice guidelines for 11-13+6 weeks scan.

Organ/ anatomical area	Present and/or normal	Organ/anatomical area	Present and/or normal
Head	Shape	Heart	Cardiac regular activity
	Cranial ossification		Size
	Midline falx		Cardiac axis
	Choroid-plexus-filled ventricles		Four symmetrical chambers
	Cerebellum		Major vessels
Neck	Normal appearance	Abdomen	Stomach present in left upper quadrant
	Nuchal translucency thickness		Intestines
Face	Eyes with lens	Bladder	
	Nasal bone	Kidneys*	
	Normal profile/mandible	Abdominal wall	Normal cord insertion
	Intact lips		No umbilical defects
Spine	Vertebrae (longitudinal and axial)	Extremities three segments	Four limbs each with
	Intact overlying skin		Hands and feet with normal orientation
Thorax	Symmetrical lung fields	Cord	Three-vessel cord
	No effusions or masses		
	Diaphragm		

*Visualization of kidneys and intestines are considered optional for completion of scan

At the 11th through 13th week of pregnancy, by the combination of the foetal NT thickness, the nasal bone, and the mother's age, the patient-specific estimated risk for trisomy 21 was calculated. High-risk women were then subjected to maternal serum screening by double marker test (serum β -hCG and PAPP-A). The reference standard, or best available method for establishing the presence of the target condition in high-risk women, was prenatal foetal karyotyping by chorionic villus sampling or amniocentesis.

RESULTS

Age distribution of patients and number of cases with anomalous scan detected is as shown in Table 2.

Detection rate of foetal anomalies when scan done at various gestational age is shown in Table 3.

Table 2: Age distribution of patients.

Age distribution (years)	Number of cases N (%)	Number of cases with anomalous scan N (%)
≤ 20	2 (1.8)	1 (0.9)
21-30	70 (63.7)	11 (10)
31-40	38 (34.5)	3 (2.7)
Total	110	15 (13.6)

Table 3: Detection rate of foetal anomalies at various gestational age.

Foetal scan at gestational age	No. of cases with foetal anomalies detected (%)
11-13 (+6) weeks	13 (11.8)
18-22 weeks	2 (1.8)
Total	15 (13.6)

NT thickness frequency distribution among patients in study population were as shown in Table 4.

Table 4: NT thickness frequency distribution.

NT Thickness percentile	No. of cases (%)
<95	98 (89.1)
95-99	7 (6.4)
>99	5 (4.5)
Total (sample size)	110

Table 5: Effect of maternal age on foetal anomalies.

Maternal age (years)	Total scan (N)	Cases with anomalous foetal scan N (%)
<35	97	13 (13.4)
≥35	13	2 (15.4)

This study has found that the incidence of foetal anomalies is increased in older mothers as seen in Table 5. This is likely due to factors such as age-related decreases in egg

quality and increases in health conditions such as hypertension and gestational diabetes.

Table 6: Risk for trisomy 21.

Risk calculation based on	Number of cases n (%)		
	Low risk (<1/1000)	Intermediate risk (1/51 to 1/1000)	High risk (≥1/50)
Maternal age	39 (35.4)	71 (64.6)	00
Maternal age + NT thickness	96 (87.3)	11 (10)	3 (2.7)
Maternal age + NT thickness + nasal bone	101 (91.9)	6 (5.4)	3 (2.7)

The risk for trisomy 21 was calculated based on the maternal age and ultrasound soft markers (NT thickness and nasal bone) by foetal medicine foundation software and the results are as shown in Table 6.

Table 7: Pregnancy outcome.

Pregnancy Outcome	Number of patients N (%)	
Live birth	Normal delivery	95 (86.3)
	Cesarean section	55 (57.8)
Singleton	40 (42.2)	
Twins	DCDA	87 (79.1)
	MCDA	7 (6.3)
Cases yet to be delivered	6 (5.4)	
Medical termination of pregnancy	1 (0.9)	
Intra-uterine foetal death	5 (4.5)	
Normal phenotype at birth	10 (9)	
Absent nasal bone at birth	Unilateral	0
	Bilateral	99/100
	1/100	
	0	

All the 110 cases in present study were followed up till delivery/termination and their outcome are shown in Table 7.

DISCUSSION

Among 110 cases, 1.8% were ≤20 years age, 63.7% were between the age group 21-30 years (commonest age group) and 34.5% were between the age group 31-40 years. The study by Nazer et al has showed similar age distribution with commonest (49.9%) between 21-30 years and 41.5% of cases between 31-40 years age.⁶ All the cases were primarily subjected to TAS. Additional TVS was required for completion of scan when foetal position was not favourable for TAS in 10% at 11-13+6 weeks scan. In 18-22 weeks scan, additional TVS was performed in all the cases for measurement of cervical length. Study by Elamaram et al have showed that 25% cases required additional TVS for completion of scans.⁷ During the study period, 13 foetuses (11.8%) were detected with anomalies

at 11-13+6 weeks scan and 2 foetuses (1.8%) were detected with anomalies at 18-22 weeks scan; which shows the detection rate of 13.6% on ultrasonography. In the study by Hollander et al, 11% of foetal anomalies were diagnosed on ultrasonography, of which 9% were detected in 11-13+6 weeks scan and 2% were detected in 18-22 weeks scan.⁸ The nuchal translucency was <95th centile in majority of cases (89.1%) and NT was between 95th-99th centile in 6.4% cases which is comparable to study by Dinç et al in which there were 6.7% cases with NT between 95th-99th centile.⁹ Present study showed normal foetal anatomy in 88.2% cases at 11-13+6 scan which is comparable with 91% in study by Hollander et al.⁸ Present study reported the detection rate of foetal anomalies was 15.4% in cases of maternal age >35 years while it was 30% in study by Elamaram et al. Present study as well as Elamaram et al have observed increased incidence of foetal anomalies in advanced maternal age.⁷ Of the 110 cases which were subjected to screening, 2.7% of present study population were detected to be high risk for trisomy 21. The study by

Luo et al has reported that 1.70% cases were screened to be high risk for trisomy 21.¹⁰ Non-invasive prenatal test (NIPT) was carried out in 3 cases and out of them, 2 were screened low risk for trisomy 21; 3 were screened low risk for trisomy 18 and trisomy 13. A study by Zhang et al has reported that 4.26% cases were screened high risk for trisomy 21 and 5.42% were screened low risk.¹¹ Invasive testing and karyotyping were done in 10.9%, Chitty et al has reported abnormal karyotype in 9.6% of cases which had undergone invasive prenatal diagnostic testing.¹²

The limitation of present study is inapplicability of first trimester sonography protocol in peripheral area due to scarcity in availability of qualified medical personnel who can detect congenital anomalies as well as ultrasonography machine.

CONCLUSION

The detection of the major anomalies at this early gestation (11 to 13+6 weeks) offers to the parents the option of an earlier, safer and psychologically less traumatic termination of pregnancy. The ultrasound examination at 11 to 13+6 weeks to screen for foetal abnormalities is effective and can be an adjunct to the routine 18-20 weeks anomaly scan. Hence the ultrasound at 11-13+6 weeks must be mandatory, not only for the detection of major foetal anomalies but also for diagnosis of multiple pregnancy and abnormal pregnancy like missed abortion, molar pregnancy and ectopic pregnancy.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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