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Original Research Article

A prospective study to evaluate the efficacy of 11-13^{+6} weeks anatomy scan in detecting fetal structural anomalies compared to traditional 18-22 weeks scan

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ABSTRACT

Background: Congenital anomalies are one of the leading causes of infant mortality. Traditional TIFFA scan done at 18-22 weeks leads to delay in diagnosis, referral and management. With high resolution ultrasound and TVS probe, normal and abnormal fetal anatomy could be visualized in early gestation with good accuracy. Objective of present study was to evaluate the efficacy of 11-13^{+6} weeks anatomy scan in detecting fetal structural anomalies compared to traditional 18 -22weeks scan and in visualizing the complete normal fetal anatomy

Methods: An Observational study of 300 antenatal patients at Jubilee Mission Medical College for 1 year (Jan-Dec2014) was done. The scan was performed at 11-13^{+6} weeks by TAS first, if a full fetal anatomy survey not achieved, TVS added. A mid-trimester fetal anatomy scan was then performed in patients who had not dropped out, miscarried or undergone pregnancy termination at 18-22weeks.

Results: The incidence of anomalies in our study was 3.67% -11 cases; 9 detected at 11-13^{+6} weeks, 2 were newly detected at 18-22 weeks. At 11-13^{+6} weeks anatomy scan, the detection rate of anomalies was 81.8% and complete fetal anatomy survey was achieved in 92%. Heart and kidneys were not properly visualized in 4% and 12.7%, at 11-13^{+6} weeks compared with 0.7% and 0% at 18-22 weeks.

Conclusions: The 11-13^{+6} weeks anatomy scan is an important diagnostic tool which is underutilized and should be offered to all women as a routine standard of antenatal care. However as fetal anomalies can present at varying gestational age, standard 18-22 weeks anatomy scan cannot be abandoned.

Keywords: Targeted imaging for fetal anomaly, Transabdominal scan, Transvaginal Scan, Ultrasonography

INTRODUCTION

Congenital anomalies are still one of the leading causes of still birth and neonatal mortality and can be defined as structural or functional anomalies, including metabolic disorders, which are present at the time of birth. Congenital anomalies affect an estimated 1 in 33 infants and result in approximately 3.2 million birth defect related disabilities every year.[1]

The prevalence of congenital anomalies is grossly under reported in India. According to recent survey, 63 / 1000 live births have serious birth defects in India. The most common severe congenital anomalies are heart defects, neural tube defects and down syndrome.[2]

The traditional Targeted Imaging For Fetal Anomaly (TIFFA) scan done at 18-22 weeks leads to delay in diagnosis, referral and management.[3,4]

Since most of the major fetal structures complete its development by 12 weeks, proper visualization of the anatomy is possible at the time of routine NT scan at 11-13^{+6} weeks.[5]

Visualizing the complete fetal anatomy during 11-13^{+6} weeks scan needs high resolution ultrasound machine, well trained and experienced Sonographer.

Early detection of anomalies helps to decide about the option of further management by Chorionic villous sampling and if abnormal, medical termination of pregnancy, or delivery in a setting with specialized surgical and medical care possible.[6]

METHODS

300 low-risk women with viable singleton pregnancies who attended Obstetrics and Gynaecology department of Jubilee Mission Medical College Thrissur from December 2013 to November 2014 were enrolled in the study, after getting informed consent and approval from Institutional Ethics Committee. Estimated gestational age was calculated based on last menstrual date or previous ultrasound report if periods were irregular or not sure of her last menstrual period. After getting basic information regarding history followed by clinical examination (including height and weight) were subjected to Trans abdominal ultrasound between11-13^{+6} weeks and if fetal anatomy survey was not possible to be completed by TAS alone, a TVS was performed after counseling and getting consent from the women. All women enrolled in the study were again subjected to traditional 18-22 weeks anatomy scan using the TAS probe only.[7] A single experienced certified radiologist did all the anatomy scans for the study using Voluson 730 pro ultrasound machine with 3.5-5 MHz Trans abdominal transducer and 5-9 MHz Trans vaginal transducer.

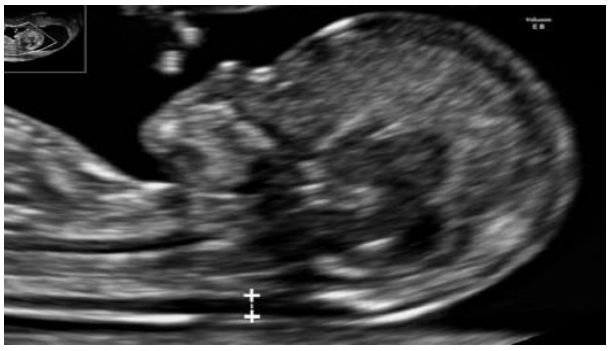

Figure 1: Fetus in neutral position in nuchal translucency measurement.

Scanning procedure

11-13^{+6} weeks scan

- Fetal viability was examined and CRL, BPD, FL were measured.
- Nuchal translucency measurement was done as per fetal medicine foundation guidelines.

18-22 weeks follow-up scan

- This was performed by the same examiner and using the same equipment as for the first-trimester scan, following the protocols proposed by the Clinical Standards Committee of the ISUOG.

Table 1: Evaluation of fetal anatomy according to the checklist based on ISUOG Practice Guidelines: performance of first-trimester fetal ultrasound

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

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

Statistical analysis

Continuous measurements presented in Mean±SD and categorical measurements presented in number (%). Analysis of variance (ANOVA) has been used to find the

significance of study parameters between three or more groups of patients. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.[8,9]

P value ≤0.05 has been considered as statistically significant. The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and microsoft word and excel have been used to generate graphs, tables etc.

RESULTS

In the 300 pregnant women studied, most of them belonged to 20-30 years and 13 women 4.3% belonged to advanced maternal age (35 and above), 4 women, 1.3% were obese.

171 women were primi gravida and 129 were multi gravida and all had singleton pregnancies. The mean gestational age for 11-13+6 weeks' scan was 12 weeks 5days and for 18-22 weeks scant is 20 weeks 1 day.

Table 2: All variables.

Variables	Minimum	Maximum	Mean±SD
Age	17	43	25.57±4.35
BMI	16.24	35.12	21.94±2.92
GA	11w0d	13w6d	12.70±0.71
CRL	45	81	63.84±9.34
NT	1	10.9	1.49±0.82

Table 3: NT findings of patients studied.

NT(mm)	No. of patients	%
<1.5	217	72.3
1.5-2.5	70	23.3
2.5-3.5	9	3.0
>3.5	4	1.3
Total	300	100.0

Table 4: Mode of scan used in the study.

Mode of scan	11-14 weeks		18-22weeks	
	No. of patients	%	No. of patients	%
TAS	300	100	292	100
Addl TVS	75	25	0	0

In 25% cases, additional TVS was required in early scan. All the cases in followup scan were done only by TAS.

So, among 11 anomalies detected in our study, early scan detected 9 and follow up scan detected 2 anomalies, which was missed by the early scan. Thus, the detection rate of anomalies by early scan in our study was 81.8%.

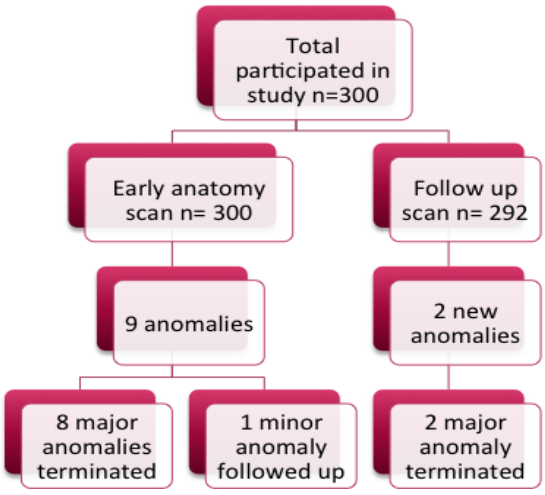

Figure 2: Anomalies in present study.

High incidence of anomaly was found in advanced age group women.

Table 5: Early scan-outcome.

Early scan	No. of patients	Outcome
Acrania	1	0.3
Anencephaly	1	0.3
Diffuse skin edema	2	0.7
Omphalocele	1	0.3
Single outlet	1	0.3
Thanatophoric dwarfism	1	0.3
Abn NT, absent nasal bone, single ventricle in heart, absent radius	1	0.3
Renal pelviectasis	1	0.3
Normal scan	291	97.0
Total	300	100.0

Table 6: Follow up scan-outcome.

Follow scan	No. of patients (n=292)	%
Renal anomaly	1	0.3
Arnold chiari	1	0.3
Renal pelviectasis	1	0.3
Normalscan	289	96.3
Total	292	97.3

Table 7: Advanced age and anomaly.

Age in years	Anomalous scan	Total scan	%
<35 years	7	287	2.4
>35yrs	4	13	13.3

P<0.001**, Significant, Chi-Square test

Additional TVS was significantly better in visualizing all structures with strong significance for visualizing head, spine, heart, abdomen, kidney, urinary bladder and limbs.

Table 8: Individual structures visualization in 11-13^{+6} weeks scan.

Structure	Visualized	% visualized (n=300)
Head		
Visualized	298	99.3
Not Visualized	2	0.7
Face		
Visualized	299	99.7
Not Visualized	1	0.3
Neck		
Visualized	300	100.0
Not Visualized	0	0.0
Spine		
Visualized	290	96.7
Not Visualized	10	3.3
Heart		
Visualized	288	96.0
Not Visualized	12	4.0
Abdomen		
Visualized	300	100.0
Not Visualized	0	0.0
Kidneys		
Visualized	262	87.3
Not Visualized	38	12.7
UB		
Visualized	288	96.0
Not Visualized	12	4.0
Abdominal wall		
Visualized	300	100.0
Not Visualized	0	0.0
Cord vessel		
Visualized	300	100.0
Not Visualized	0	0.0
Limbs		
Visualized	300	100.0
Not Visualized	0	0.0

There is a moderately strong correlation suggesting follow up scan was better in achieving complete scan compared to early scan.

Spine, heart, kidneys and urinary bladder were difficult to visualize by early scan and were better visualized with follow up scan

DISCUSSION

In our study, here on, 11-13^{+6} weeks scan will be referred as early scan and 18-22 weeks as followup scan. The mean gestational age for early scan was 12 weeks 5 days and for late scan it is 20 weeks 1 day.[10,11]

In this study, we chose the time period of 111-13^{+6} weeks because it is the optimum gestational age to examine fetal anatomy and measure nuchal translucency in the first trimester and also because visualization of fetal anatomy was found to improve with increasing gestational age; from 6% at the 10th gestational week to 75% at the 11th week, 96% at the 12th week, and 98% at the 13th and 14th weeks.[12,13]

We decided, not to exclude chromosomally abnormal cases. Our study was aimed to assess in a single scanning session, the structural anomalies suitable for evaluation at this gestational age, following the checklist mentioned.[14]

A total of 300 pregnant women completed the study, 292 had both early and follow up anatomy scans while 8 cases with confirmed lethal anomalies by early scan chose to terminate their pregnancies and the anomalies were confirmed after termination.[15]

The incidence of anomaly in our study was 3.67%. We found anomalies were more in advanced age group women in our study (p<0.001).

Table 9: Difference in ability to visualize individual structures in 11-13^{+6} weeks scan by mode of scan and significance.

Structures visualized	TAS alone		TAS+TVS		P value
	No. of patients	%	No. of patients	%	
Head	248	82.7	298	99.3	<0.001**
Face	271	90.3	299	99.7	<0.001**
Neck	288	96	300	100	<0.001**
Spine	233	77.7	290	96.7	<0.001**
Thorax	292	97.3	300	100	0.004**
Heart	217	72.3	288	96	<0.001**
Abdomen	278	92.7	300	100	<0.001**
Kidneys	188	62.7	262	87.3	<0.001**
Urinary bladder	228	76	288	96	<0.001**
Abdominal wall	281	93.7	300	100	<0.001**
Cord vessels	288	96	300	100	<0.001**
Limbs	229	76.3	300	100	<0.001**

Table 10: Mode of scan and ability to achieve complete scan and its significance.

Mode of scan	Complete scan	Incomplete scan	% complete
TAS	225	75	75.0
Addl TVS	276	24	92.0

P<0.001**, Significant Chi-Square test

Table 11: GA and ability to achieve complete scan and its significance.

GA	Complete scan	Incomplete scan	Total scan	% complete
11-11^{+6}	26	19	45	57.8
12- 12^{+6}	122	2	124	98.4
13-13^{+6}	128	3	131	97.7

P<0.001**, Significant, Chi-Square test

Table 12: Comparing early and follow up scan in achieving complete scan.

USG	Ability to achieve complete scan	%	Significance
Early scan	276/300	92.0	0.013*
Follow up scan	290/292	99.32	

In present study, the early scan detected 9 anomalies out of 300 cases (3%).

The detected anomalies were 1 case of acrania, 1 case of anencephaly, 2 cases of diffuse skin edema, 1case of omphalocele, 1 case of single cardiac outlet, 1 case of than atophoric dwarfism, 1 case of multiple anomalies with single cardiac ventricle, absent radius and non immunehydrops.

Of the 5 cases who underwent karyotyping, 4 fetuses were found to have abnormal karyotype. Eight patients had termination, upon their request, after the early scan due to the presence of lethal fetal anomalies.[16]

The detected anomalies in the follow up scan were 3 cases (1%) out of 292 cases.

The 3 cases included the 1 remaining case from the early scan and 2 new cases detected only by the follow up scan (one was a case of Arnold chiari malformation with cranial defect and meningomyelocele and a case of renal anomaly with anhydramnios.[17,18]

So, among 11 anomalies detected in our study early scan detected 9 and follow up scan detected 2 anomalies, which was missed by early scan. Thus, the detection rate of anomalies by early scan in our study was 81.8%.[19,20]

Table 13: Failure to properly visualize different fetal organs by the 11-14 weeks scan compared to the 18-22 weeks scan.

Structures not visualized	11-14 weeks scan (n=300)		18-22 weeks scan (n=292)		P value
	No. of patients	%	No. of patients	%	
Head	2	0.7	0	0.0	0.162
Face	1	0.3	0	0.0	0.323
Neck	0	0.0	0	0.0	1.000
Spine	10	3.3	0	0.0	0.002**
Thorax	0	0.0	0	0.0	1.000
Heart	12	4.0	2	0.7	0.008**
Abdomen	0	0.0	0	0.0	1.000
Kidneys	38	12.7	0	0.0	<0.001**
Urinary bladder	12	4.0	0	0.0	0.001**
Abdominal wall	0	0.0	0	0.0	1.000
Cord vessels	0	0.0	0	0.0	1.000
Limbs	0	0.0	0	0.0	1.000

In present study, early scan was not superior to follow up scan but early anomaly scan helped in detection of many major anomalies when fetuses was less than 50 grams enabling earlier termination. Results of present study are in concurrence with earlier reports which have shown a detection rate of anomalies from 68 to 86.54 % with reference to follow up scan.[20]

In our study, 81.8% of the anomalies could be identified at the early scan. Yet, there are some structural anomalies that develop at later stages of pregnancy or that result from an evolving pathophysiological process which may not be detectable by first trimester ultrasound as hydrocephaly, spina bifida and others; that is why the role of the mid-trimester fetal anatomy scan is undisputed.

Almost, all the previous reported studies available had the same conclusion.[22,23]

Out of total 300 patients who underwent early anatomy scan, NT was normal (NT <2.28-95 percentile) in 285 patients and raised in 15 patients (NT more than 2.28). The mean NT of fetuses studied was 1.49±0.82. We found abnormal NT in 8 out of 9 cases with anomalies (sensitivity of 88.9).

When we compare early and follow up scan regarding complete visualization of structures, we found follow up scan was better in achieving the complete visualization (p=0.013). Follow up scan was better, especially in visualizing spine, heart, kidney and urinary bladder compared to early can (p <0.05). The heart and kidneys were not properly visualized in 4% and 12.7% of cases, respectively, at the 11-13^{+6}weeks scan compared with 0.7% and 0% at the 18-22 weeks scan.[24] In early scan, complete fetal anatomic survey was achieved in 76% of women who had TAS alone and in 92% of women who had additional TVS (p <0.001) and the need for additional TVS was 25% in present study.

We found our ability to achieve complete fetal anatomic survey was improved, when TAS was complemented with TVS, in particular, head, spine, heart, kidney, bladder and limbs were better visualized with TVS (p<0.001). The ability to achieve complete scan increases, as GA age increases, from 58% at 11-11^{+6} weeks to 98% at 12-14 weeks (p <0.001). Also, we found the need for additional TVS for completion of scan, decreases with increasing GA from 46.2% at 11-11^{+6} weeks to 18.8% at 12 to 12^{+6} weeks to 12.5% at 13-13^{+6} weeks (p<0.001).

However, the study can demonstrate only the added benefit of a TVS assessment in these cases rather than examine the relative sensitivities and specificities of TAS and TVS.[25] Various authors have reported, complete fetal anatomy survey was achieved between 82%-98% depending on the protocol and gestational age at the time of scan.[26]

The strength of the study includes the completeness of data, usage of good ultrasound machine for better visualization, the checklist for visualization of structures was based on ISUOG protocol for uniformity and standardization, and all the scans for the study were done by a single experienced radiologist with the same machine.[27] The limitation of our study was the small sample size.

CONCLUSION

The benefits of the 11-14 weeks early anatomy scan are unquestionable. It is an important tool in early diagnosis of certain major anomalies, there by suggesting the prognosis of such pregnancies at an early stage. It also helps in early reassurance of normalcy in high risk pregnancy. It also helps by detecting cases with increased NT to pick cases at risk for genetic syndromes.

When TVS is used along with TAS, it greatly enhances the ability to achieve complete fetal anatomic survey. Complete visualization of structures increases and need for additional TVS decreases when scan was done between 12-14 weeks compared to 11-12 weeks.

By establishing early anatomy scan as a part of routine antenatal care, helps in detecting major anomalies earlier and offers early counseling, karyotyping and termination of pregnancy if needed. Nevertheless, this early scan cannot rule out certain significant structural anomalies that appear later in pregnancy. Thus, the place of mid trimester fetal anatomy scan in practice remains crucial to complement the late first trimester scan.

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