TWO DIMENSIONAL ULTRASONOGRAPHY AT 14 - 16 WEEKS OF GESTATION FOR DETECTION OF FETAL STRUCTURAL ANOMALIES

By

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ABSTRACT

Background: Congenital anomalies occur in 2-3% of all births. This is an important cause of perinatal morbidity and mortality and account for 20-30% of perinatal death. The antenatal detection of fetal malformation by early ultrasound screening has been shown to reduce perinatal mortality by allowing elective termination of malformed fetuses.

Objective: To compare early targeted organ scanning at gestational ages ranging from 14-16 weeks versus 18-22 weeks.

Patients and methods: This prospective observational study was performed at Ultrasound special care unit for the fetus, Ain Shams Maternity Hospital, from January 2016 till December 2019, after obtaining approval from the local ethics committee. One hundred and fifty pregnant women were scanned twice for targeted detailed organ scanning once at 14-16 weeks, then rescanned again at 18-22 weeks.

Results: The early-second trimester detailed anatomy scan was significantly less accurate than that of the mid-trimester as regards the heart details. The four chamber view of the heart was well seen at 18-22 weeks in 144 pregnant women (96%) but was only seen at 14-16 weeks in 127 pregnant women (84.7%). The great vessels outflow tracts were better seen at 18-22 weeks in 141 pregnant women (94%), and only seen in 119 pregnant women (79.3%) at 14-16 weeks. Moreover, the kidneys were well visualized at 18-22 weeks in 144 pregnant women (96.0%), and only visualized in 127 pregnant women (84.7%) at 14-16 weeks. There was a significant difference between the two periods regarding all parameters in head, face, the umbilical cord and the external genitalia.

Conclusion: None of both gestational ages (14-16 weeks and 18-22 weeks) were clearly superior to the other.

Keywords: Fetal structural anomalies, Two-dimensional ultrasonography, Early second trimester screening, Obstetric ultrasound, Targeted organ scanning.

INTRODUCTION

In general, screening for fetal structural and chromosomal abnormalities is a crucial part of antenatal care. The main purpose of a fetal ultrasound scan is to provide a precise information that simplify the delivery of enhanced antenatal care with the best possible outcomes for both the mother and fetus *(Salomon et al., 2011)*.

Congenital anomalies occur in 2-3% of all births. They are an important cause of perinatal morbidity, and mortality and account for 20-30% of perinatal death. Survivors have mental and physical disability. The psychological trauma and

cost associated with fetal abnormalities have led to the use of ultrasound for the prenatal diagnosis as an essential part of antenatal care *(Mathews and Mac Dorman, 2012).*

Timor-Tritsch et al. (2010) cited that ultrasound examination, with state-of-the-art equipment and in expert hands, can visualize as many structures at 13-14 weeks as it could at 16 weeks 5-10 years previously and at 20-22 weeks 15-20 years previously. Towards the end of the first trimester, the scan additionally offers an opportunity to identify gross fetal irregularities and in health systems that offer first-trimester aneuploidy screening, the measuring of the nuchal translucency thickness (NT) is also available.

After about 18 weeks, fetal anatomy is evaluated thoroughly through ultrasound. It is essential to use methodical routine in the implementation and assessment of anatomic evaluation of high-risk pregnancies *(Hurt et al., 2016).*

The aim of this work was to evaluate the potentials of the scanning at 14-16 weeks, using two-dimensional trans-abdominal ultrasound, in high risk population group, concerning the precision in visualizing fetal organs at that age, and the accuracy in the diagnosis of fetal anomalies when compared with the mid-trimester ultrasound fetal anatomy scan.

PATIENTS AND METHODS

This prospective observational, study was performed at Ultrasound special care unit for the fetus, Ain Shams Maternity Hospital, from January 2016 till December 2019, after obtaining approval from the local ethics committee. One hundred and fifty pregnant women were scanned twice for targeted detailed organ scanning once at 14-16 weeks then rescanned again at 18-22 weeks.

Ethical Aspects: All participating women signed informed verbal consents before being recruited in the study after through explanation of the procedure and purpose of the study.

Inclusion criteria: Study was carried out on pregnant women of high-risk pregnancy as they visited the ultrasound unit for their antenatal care with the following criteria:

1. Gestational age (14 weeks to 16 weeks) for the early scan and (18 weeks to 22 weeks) for the late scan.

2. High risk pregnant women included one or more of the following criteria:

   • Positive family or personal history of congenital abnormalities.

   • Maternal age above 35 years.

   • Positive consanguinity.

   • Bad obstetric history as previous IUFD, recurrent pregnancy loss.

   • Maternal disease, history of drug intake or radiation exposure.

Intervention:

The recruited patients were subjected to the following:

1. **Detailed history:**

A. **Personal history:** Name, age, occupation, residence, consanguinity and special habits of medical importance.

B. **Obstetric history:** First day of last menstrual period for accurate estimation of gestational age.

C. Past history: History of any medical disorder, bad obstetric history as previous IUFD, recurrent pregnancy loss.

D. History of the present pregnancy:

- Medical condition to define high risk pregnancy.

- History of drug intake or radiation exposure in the first trimester.

2. Transabdominal Ultrasound scans to determine fetal gestational age and any existing fetal anomaly through measuring the biparietal diameter, abdominal circumference, femur length and detailed cardiac scan.

Follow up:

Each pregnant woman was scheduled for two ultrasound examinations:

1. First ultrasound was done at the time of booking (14-16 weeks).

2. A second examination was scheduled at mid trimester between 18-22 weeks.

3. All ultrasonographic examinations were performed using the same ultrasound device, which will be Voluson E6 BT 12 (GE) with a convex abdominal probe RAB 6D-4D curved array at The Special Care Center for Fetus Unit at Ain Shams University Maternity Hospital.

Sample size calculation: Based on the results published by Ebrashy et al. (2010), Alpha error = 5% (two-sided), power of the study = 80%, ability of 2D ultrasonography to visualize cranium abnormality = 85%, ability of 2D ultrasonography to visualize complete fetal abnormality = 63%, and estimated required sample sizes: N =150 pregnant women.

Statistical methods:

All statistical calculations were done using computer program SPSS (Statistical Package for the Social Sciences; SPSS Inc., Chicago, IL, USA) release 15 for Microsoft Windows. Continuous data were presented as range, mean and standard deviation categorical data were presented as number and percentage and were comqunce by chi-square test. Significance level was set at 0.05.

RESULTS

Maternal demographic data showed that the mean (+SD) of age was 31.5 ± 6.344288 years, Percentage of consanguinity was 14.0%, percentage of PG is 12.0%, P1 was 20.0%, P2 was 32.0%, and P3 or more was 36.0%, percentage of pregnant women with positive past history was 34.0%, percentage of those with positive family history was 9.0%, and percentage of those with positive present history was 32.0% **(Table 1)**.

Table (1): Maternal background parameters (maternal demographic data)

Parameters		N = 150
Age	Mean ± SD	31.5 ± 6.344288
	Range	21 – 42
	Negative (21-35)	105 (70%)
	Positive (> 35)	45 (30%)
Consanguinity	Negative	129 (86.0%)
	Positive	21 (14.0%)
Parity	PG	18 (12.0%)
	One	30 (20.0%)
	Two	48 (32.0%)
	Three or more	54 (36.0%)
Past history of medical disorder	Negative	99 (66.0%)
	Positive	51 (34.0%)
Family history of congenital anomalies	Negative	138 (92.0%)
	Positive	12 (8.0%)
History of drug intake, smoking or radiation exposure	Negative	135 (90.0%)
	Positive	15 (10.0%)
Bad obstetric history (previous congenital anomalies, previous IUFD, recurrent miscarriage)	Negative	129 (86.0%)
	Positive	21 (14.0%)
History of present illness (maternal disease)	Negative	102 (68.0%)
	Positive	48 (32.0%)

The current study showed that there was a statistically significant difference between the two periods regarding all parameters in head. The intact cranium, midline falx and thalami were detected at 14 -16 weeks more than 18 – 22 weeks while cavum septi pellucidi, cerebral ventricles, cerebellum and cisterna magna were detected at 18 – 22 weeks more than 14 – 16 weeks. There was a statistically significant difference between the two periods regarding all parameters in face. There was no statistically significant difference found between patients at 14 - 16 weeks and at 18 – 22 weeks regarding stomach in normal position and bowel not dilated, while the presence of both kidneys was seen in 78 patients (52.0%) at the period of 14 - 16 weeks and seen in 144 patients (96.0%) at the period of 18-22 weeks which was highly statistically significant difference between the two periods with p-value < 0.001.

The study showed that no statistically significant difference between the two periods regarding all skeletal parameters and all placental parameters. Regarding the umbilical cord and the external genitalia, there was a statistically significant difference between the two periods.

There was a statistically significant difference between the two periods regarding the umbilical cord, but no statistically significant difference between the two periods regarding the external genitalia (**Table 2**).

Table (2): Comparison between patients at 14 – 16 weeks and at 18 – 22 weeks regarding head details, face, abdominal details, skeletal details, placenta, umbilical cord and genitalia

Parameters		Time	14 – 16 weeks		18 – 22 weeks		P-value
			No.	%	No.	%	
Head	Intact cranium	Negative	3	2.0%	8	5.33%	0.125
		Positive	147	98.0%	142	94.67%	
	Cavum septi pellucidi	Negative	17	11.3%	7	4.7%	0.033
		Positive	133	88.7%	143	95.3%	
	Midline falx	Negative	6	4.0%	9	6.0%	0.427
		Positive	144	96.0%	141	94.0%	
	Thalami	Negative	6	4.0%	9	6.0%	0.427
		Positive	144	96.0%	141	94.0%	
	Cerebral ventricles	Negative	21	14.0%	7	4.7%	0.005
		Positive	129	136.0%	143	95.3%	
	Cerebellum	Negative	23	15.3%	9	6.0%	0.009
		Positive	127	84.7%	141	94.0%	
	Cisterna magna	Negative	25	16.7%	7	4.7%	0.001
		Positive	125	83.3%	143	95.3%	
Face	Both orbits present	Negative	22	14.7%	9	6.0%	0.014
		Positive	128	85.3%	141	94.0%	
	Mouth present	Negative	26	17.3%	9	6.0%	0.002
		Positive	124	82.7%	141	94.0%	
	Upper lip intact	Negative	26	17.3%	9	6.0%	0.002
		Positive	124	82.7%	141	94.0%	
Abdominal	Stomach in normal position	Negative	6	4.0%	9	6 %	0.427
		Positive	144	96.0%	141	94 %	
	Bowel not dilated	Negative	6	4.0%	7	4.7%	0.777
		Positive	144	96.0%	143	95.3%	
	Both kidneys present	Negative	23	15.3%	6	4.0%	0.001
		Positive	127	84.7%	144	96.0%	
Skeletal	No spinal defects or masses (transverse and sagittal views)	Negative	6	4.0%	7	4.7%	0.777
		Positive	144	96.0%	143	95.3%	
	Upper & lower limbs	Negative	3	2.0%	6	4.0%	0.310
		Positive	147	98.0%	144	96.0%	
	Hands & Feet	Negative	3	2.0%	6	4.0%	0.310
		Positive	147	98.0%	144	96.0%	
Placenta	**Position**	Negative	6	4.0%	9	6.0%	0.427
		Positive	144	96.0%	141	94.0%	
	No masses present	Negative	6	4.0%	9	6.0%	0.427
		Positive	144	96.0%	141	94.0%	
Umbilical cord and genitalia	Umbilical cord (3 cord vessels)	Negative	22	14.7%	9	6.0%	0.014
		Positive	128	85.3%	141	94.0%	
	Genitalia	Female	84	57.1%	73	50.7%	0.270
		Male	63	42.9%	71	49.3%	

DISCUSSION

This study showed that the mean (+SD) of age was 31.5 ± 6.344288 years. As regards consanguinity 14.0% have positive consanguinity and 86% have negative consanguinity and as regards parity 12.0% were PG, 20.0% were P1, 32.0% were P2 and 36.0% were P3 or more.

In the current study, the early-second trimester detailed anatomy scan was significantly less accurate than that of the mid-trimester. As regards the heart details, the four chamber view of the heart were well seen at 18-22 weeks in 144 pregnant women (96%), but was only seen at 14-16 weeks in 127 pregnant women (84.7%). The great vessels outflow tracts were better seen at 18-22 weeks in 141 pregnant women (94%), and was only seen in 119 pregnant women (79.3%) at 14-16 weeks. Moreover, the kidneys were well visualized at 18-22 weeks in 144 pregnant women (96.0%) and only visualized in 127 pregnant women (84.7%) at 14-16 weeks.

This was supported by *Yagel et al. (2015)* who stated that the second trimester detailed anatomy scan was markedly better than in the first and early-second in terms of organs and systems visualization. This was also agreed by *Ebrashy et al. (2010)* in a 5-year period prospective study.

The results of the current study regarding the heart details were the same as *Allan (2010)* who concluded that adequate views of the heart, to include the four-chamber view and the great arteries, can be obtained in the majority of patients by most ultra-sonographers at around 20 weeks of gestation.

On the other hand, *Becker and Wegner (2010)* conducted a prospective study and concluded that an anomaly scan at 11–13 gestational weeks by expert operators provides the chance of detecting the majority of fetal anomalies around the transition from the first to the second trimester.

O ur study showed that detailed anatomy scan of the fetus at 14-16 weeks has no statistically significant difference in comparison with scan of the fetus at 18-22 weeks regarding head details including (Intact cranium, Midline falx and Thalami), neck details including (Absence of cystic Hygroma and Nuchal fold thickness), heart and chest including (Presence of heart activity and Absence of diaphragmatic hernia), abdomen including (Stomach in normal position and Bowel not dilated), all spine and skeletal details, placenta and fetal genitalia, but current study showed that detailed anatomy scan of the fetus at 14-16 weeks has a statistically significant difference in comparison with scan of the fetus at 18-22 weeks regarding in head details including (Cavum septi pellucidi, Cerebral ventricles, Cerebellum and Cisterna magna), face details including (Both orbits present, Mouth present and upper lip intact), heart and chest including (four chamber view and aortic and pulmonary outflow tracts), abdomen including (presence of both kidneys) and umbilical cord vessels.

The current study concluded that detailed transabdominal fetal anatomy scan at 14-16 weeks versus 18-22 weeks was statistically insignificant in most fetal details' parameters, but none of the two

periods has an advantage over the other as both are of same importance.

That agreed by *Westin et al. (2010)* who conducted a randomized controlled study to compare the antenatal detection rate of malformations in chromosomally normal fetuses between a strategy of offering one routine ultrasound examination at 12 gestational weeks and a strategy of offering one routine examination at 18 gestational weeks concluded that none of the two strategies for prenatal diagnosis is clearly superior to the other. The 12-week strategy has the advantage that most lethal malformations were detected at <15 gestational weeks, enabling earlier pregnancy termination. The 18-week strategy seems to be associated with a slightly higher detection rate of major malformations, although the difference was not statistically significant.

The points of strength in this study, that all patients were examined by the same examiner, same ultrasound machine and results were evaluated with those recorded during the study and this was attended by candidate of study all high-risk pregnancy cases.

CONCLUSION

None of both gestational ages (14-16 weeks and 18-22) was clearly superior to the other. As at 14-16 weeks has the advantage that most lethal malformations are detected early in pregnancy allowing early termination and at 18-22 weeks is associated with a slightly higher detection rate of major malformations.

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إستخدام الموجات فوق الصوتية ثنائية الأبعاد في الفترة ما بين الأسبوع الرابع عشر والسادس عشر من الحمل لإكتشاف العيوب الخلقية للجنين

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خلفيــة البحــث: تحــدث التشــوهات الخلقيــة فــي 2-3٪ مــن جميــع الــولادات. وهــي ســبب للمراضــة والوفيــات فــي الفتــرة المحيطــة بــالولادة, وتمثــل 20-30٪ مــن وفيــات الفتــرة المحيطــة بــالولادة. والكشــف عــن تشــوه الجنــين قبــل الــولادة عــن طريــق الفحــص المبكــر بالموجــات فــوق الصــوتية يقلــل مــن وفيــات الفتــرة المحيطــة بــالولادة مــن خــلال الســماح بالإنهاء الاختياري للأجنة المشوهة.

الهــدف مــن البحــث: الكشــف عــن دقــه نتــائج المســح التشــريحى المفصــل للجنــين بالموجــات فــوق الصــوتيه عــن طريــق جــدار الــبطن فــي 14-16 أســبوع بالمقارنــة مــع النتائج في 18-22 أسبوع.

المريضــات وطــرق البحــث: هــذه الدراســة البحثيــة التــي أجريــت فــي وحــدة العنايــة الخاصــة للجنــين فــي مستشــفى جامعــة عــين شــمس للنســاء والتوليــد فــي الفتــرة مــن ينــاير 2016 حتــي ديســمبر 2019، والتــي شــملت 150 امــرأة حامــل لــديهن الخصــائص المــذكورة ســالفا, واللائــي كــن يحضــرن وحــدة الموجــات فــوق الصــوتية للحصــول علــى رعايــة مــا قبــل الــولادة الروتينيــة التــي تهــدف لمســح تشــريحى مفصــل لأجنــتهن بواســطة الموجــات فــوق الصــوتية بطريــق جــدار الــبطن خــلال الفتــرة مــن 14-16 أســبوعا مــن الحمــل, ثــم إعــادة فحصــهن خــلال 18-22 أســبوعا مــن الحمــل مســتهدفا مســح الأجهــزة المســتهدفة التــى تشــمل فحــص الجهــاز العصــبى المركــزى للجنــين (الجمجمــة، البطينــات الجانبيــة، الضــفيرة المشــيمية، المخــيخ، والحفــرة الخلفيــة), والوجــه (الأنــف والشــفة العليــا) والقلــب (تخطــيط صــدى القلــب كاملــة، دوبلــر الملــون) والجهــاز الهضــمي (المعــدة والمــرارة، والأمعــاء) وجــدار الــبطن, والحبــل الســري, والجهــاز

البــولي (اليمــين واليســار الكلــى والمثانــة), والهيكــل العظمــي (العمــود الفقــري والعظــام الطويلة), والأعضاء التناسلية والمشيمة.

نتـــائج البحــث: أظهــرت هــذه الدراســة أن المســح التشــريحي المفصــل فــي بدايــة الثلــث الثــاني مــن الحمــل أقــل دقــة بشــكل ملحــوظ مــن الــذى فــي منتصــف الثلــث ذاتــه مــن الحمــل فيمــا يتعلــق بتفاصــيل القلــب وجهــة نظــر أربعــة غــرف القلــب حيــث أنهــا شــوهدت بشــكل جيــد فــي 18-22 أســبوعا فــي 144 إمــرأه حامــل (96٪)، ولكــن شــوهدت فقــط فــي 14-16 أســبوعا فــي 127 إمــرأه حامــل (84.7٪)، وكــذلك فــي الأوعيــة الدمويــة الكبــرى شــوهدت مســاحات تــدفق أفضــل فــي 18-22 أســبوعا فــي 141 إمــرأه حامــل (94٪)، وكــان ينظــر فقــط فــي 119 إمــرأه حامــل (79.3٪) فــي 14- 16 أســابيع، وعــلاوة علــى ذلــك الكلــى وتصــور بشــكل جيــد فــي 18-22 أســبوعا فــي 144 إمــرأه حامل (96٪)، وتصور فقط في 127 إمرأه حامل (84.7٪) في 14-16 أسابيع.

الأســتنتاج: أيــا مــن كــلا أعمــار الحمــل (14-16 أســبوعا و18-22 أســبوعا) لا يتفــوق بشــكل واضــح علــي الاخــر حيــث أن المســح بالموجــات الصــوتية فــي فتــرة الحمــل مــن 14-16 أســبوع يكشــف عــن التشــوهات المميتــه ممــا يســمح بالإنهــاء المبكــر للحمــل . بينمــا المســح بالموجــات الصــوتيه فــي فتــرة الحمــل مــن 18-22 أســبوع ارتــبط بمعــدل إكتشــاف أعلــى قلــيلا مــن التشــوهات الكبيــرة. هــذا علــى الــرغم مــن أن الفــرق لــم يكــن كبيرا من الناحية الإحصائية.

الكلمــات الدالــة: التشــوهات الهيكليــة للجنــين، الموجــات فــوق الصــوتية ثنائيــة الأبعــاد، الفحــص المبكــر فــي الثلــث الثــاني مــن الحمــل، الموجــات فــوق الصــوتية التوليديــة، المسح المستهدف للأعضاء.