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ORIGINAL ARTICLE

Gestational Sac Diameter and Embryonic Heart Rate as Prognostic Factors of First Trimestric Pregnancy Outcome

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Abstract

Background: While the 1st trimester of pregnancy is essential to organogenesis, it also carries the risk of an elevated complication rate. The detection of fetal cardiac activity is the first indication of a healthy pregnancy. The gestational sac is the first detectable sign of pregnancy by ultrasound.

Aim and objectives: To evaluate gestational sac diameter (GSD) and embryonic heart rate (EHR) & to determine if these parameters may be utilized as prognostic indicators for the pregnancy outcome in the 1sttrimester.

Subjects and methods: This prospective observational investigation was conducted at the Obstetrics and Gynecology Department at Al-Hussein University Hospital on 76 cases of singleton pregnancies within gestational age from 6-12 weeks.

Result: Fetal heart rate showed a significant reduction in the miscarriage group contrasted with the normal pregnancy group (p<0.001). Gestational Sac Size showed a substantial decline in the miscarriage group contrasted with the normal pregnancy group (p=0.006).

Regarding Gestational Sac Size (mm), the AUC was 0.741, the Cutoff value was 33, the Sensitivity was 78%, and the Specificity was 76.9%. Regarding Heart Rate (Bpm), the AUC was 0.822, the Cutoff value was 126, the Sensitivity was 81.4%, and the Specificity was 84.6%.

Conclusion: Regardless of maternal risk variables like age, body mass index (BMI), or parity, abnormal GSD (small, inflated, nonexistent, or uneven yolk sac) and embryonic bradycardia have been related to a poor pregnancy outcome

Keywords: Gestational sac diameter (GSD); Embryonic heart rate (EHR); First trimestric pregnancy

1. Introduction

M iscarriage is responsible for the loss of around 15% to 20% of all pregnancies. Several clinical, biochemical, and sonographic variables are linked to the prognosis of very early intrauterine pregnancies. ¹

One of the prognostic indicators in the 1st trimester of pregnancy is the HER. Research throughout the past 15 to 20 years has laid the basis for accurate and repeatable assessment of EHR at <10 weeks of gestation. ^{2,3}

As a possible sign of fetal viability, the mean and distribution of EHRs have been explored by everal researchers about gestational age. The majority of research on early EHR in fertile women has focused on the prognostic importance of either slow or rapid early HER. ²

As early as 5 weeks, with better visual clarity, the heart pulse of an embryo may generally be recognized. In this respect, both Doppler investigations & motion mode (M-mode) are helpful. Among weeks 6 and 10, the fetal heart rate rose significantly, from 118 to 167 BPM.^{4, 5}

Studies have linked a low EHR (100 BPM) between weeks 6 and 9 of pregnancy to an increased risk of miscarriage (83.3 percent). ⁶

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It was shown that between 28 and 35 days following the previous menstrual cycle, the average width of the gestational sac did not vary significantly among healthy pregnancies and those that ended in miscarriage. Nevertheless, spontaneous miscarriage can be predicted if the sac diameter is lower than expected between 36 and 42 days following the previous menstrual cycle. ⁷

To our knowledge, most previous studies focused on yolk sac width as an indicator of 1st-trimester pregnancy outcome ⁸. In contrast, the function of (GSD) was considered in just a few studies.⁹

This investigation aimed to evaluate the predictive value of the EHR and the GSD for the outcome of the first trimester of pregnancy.

2. Patients and methods

This prospective observational research involved 76 cases of singleton pregnancies within gestational age from 6-12 weeks, Obstetrics and Gynecology Department at Al-Hussein University Hospital.

Sample size iustification: The minimum number of cases needed for statistically significant research was 76 utilizing the statistical software MedCalc® version 12.3.0.0, with a 95% confidence interval and 80% power of the Study with an error of 5%. The total number of cases was 76, and that's accounting for a dropout rate of 5%; patients were chosen from pregnant women attending the Obstetrics and Gynecology Department at Al-Hussein University Hospital. The selection of cases was done using a randomized, non-controlled observational study.

Inclusion Criteria: Women between the ages of 20 and 35 who were pregnant, 1st-trimester pregnancies between 6 and 12 weeks along, a single gestational sac, and a heartbeat detected in the embryo.

Pregnancy age was determined with precision with early ultrasound examination with CRL if the LMP was uncertain.

Exclusion Criteria: Pregnant ladies experiencing any discomfort, whether it be vaginal bleeding, stomach cramping, or anything else; diabetes, chronic hypertension, and antiphospholipid syndrome are all conditions that might put a pregnant woman at risk of miscarriage. In women who were diagnosed with uterine abnormalities, the patient declined transvaginal sonography and was hesitant to participate further in the trial or get follow-up care.

2.1.Methods

Patients were subjected to Complete history taking, Examination (General examination and Abdominal and local clinical examination),

Scanning technique: All pregnant women had their bladders emptied before their ultrasound examinations using a seminars Axon x300 ultrasonography equipment and a 7.5 MHz vaginal probe. TVS was carried out methodically. EHRs and the gestational sac were located. Following recording 6-10 heartbeat cycles transvaginally with M-mode sonography, EHRs were acquired. Auscultation was used to determine the heart rate by determining how long it took for two cardiac cycles to complete.

Follow-up of cases: After 12 weeks of pregnancy had passed, an ultrasound was performed to check the status of all pregnancies.

Ethical Consideration

Once the faculty's ethical committee approved the protocol, it was implemented. The investigation was done on 76 cases in their first trimetric pregnancy, and they were assigned to by ultrasound.

2.2.Data Management and Statistical Analysis: Data acquired throughout the history, basic clinical, laboratory investigations, and outcome evaluations were coded, processed, and evaluated with Microsoft Excel software. The data were then prepared for analysis by being loaded into the program known as Statistical Package for the Social Sciences (SPSS version 20.0). The following tests were employed to determine whether or not there was a significant variance among the groups: correlation by Pearson's correlation Spearman's. Based on the kind of data, qualitative data are shown by numbers & percentages, while quantitative data continue groups are represented by mean and standard deviation. A p-value of less than 0.05 was chosen for significant findings, while a p-value of less than 0.001 was considered very important. A statistical examination has been done of the data gathered and presented. The following statistical tests and characteristics were utilized: mean, standard deviation (SD), sensitivity specificity predictive value, and ROC curve.

3. Results

Table 1. Demographic characteristics among the examined population

EXAMINED POPULATION (N = 76)

AGE (YEARS)	
$MEAN \pm SD$.	27.5 ± 3.62
MEDIAN (IQR)	27 (25 - 30)
RANGE (MIN-MAX)	15 (20 - 35)

SD: standard deviation IQR: interquartile range

Table 1. showed demographic characteristics amongst the examined population. Age in the examined population varied from 20 to 35 with mean \pm SD = 27.5 \pm 3.62.

Table 2. Measurements of Gestational Sac Size among the examined population

EXAMINED
POPULATION
(N = 76)

	$(1\mathbf{V} - 7\mathbf{O})$
GESTATIONAL SAC SIZE	
(MM)	
$MEAN \pm SD.$	38.92 ± 14.4
MEDIAN (IQR)	39 (26 - 50)
RANGE (MIN-MAX)	55 (12 - 67)

Table 2. showed Measurements of Gestational Sac Size among the examined population. Gestational Sac Size in the examined population varied from 12 to 67 with mean ± SD = 38.92 ± 14.4.

Table 3. Pregnancy outcome among the examined population

	EXAMINED			
	POPULATION			
	(N = 76)			
	n	%		
PREGNANCY				
OUTCOME				
NORMAL				
N (%)	62	81.57%		
MISCARRIAGE				
N (%)	14	18.42%		

Table 3. showed Pregnancy outcome amongst the examined population. Number of patients that had Normal Pregnancy outcome in the examined population was 62 (81.57%). Number of patients that experienced Miscarriage as a Pregnancy outcome in the examined population was 14 (18.42%).

Table 4. Comparison between normal pregnancy and miscarriage according to Gestational Sac Size

NORMAL	MISCAR	TEST	P-
PREGNA	RIAGE	VALUE	VALUE
NCY	(N = 14)		
(N = 62)	,		

GESTATION				
AL SAC				
SIZE (MM)				
MEAN \pm SD.	41.02 ±	$28.85 \pm$	T=2.82	P=0.006
	14.0	14.5		
MEDIAN	41 (35 -	25 (23 -		
(IQR)	52)	33)		
RANGE	54 (13 -	54 (12 -		
(MIN-MAX)	67)	66)		

P value< 0.05 is significant, P value< 0.01 is highly significant, T: Student T test

Table 4. showed that Gestational Sac Size showed significant decline in miscarriage group contrasted with to normal pregnancy group (p=0.006).

Table 5. Comparison between normal pregnancy and miscarriage according to Gestational Sac diameter

	NORMAL PREGNANCY (N = 62)	$\begin{aligned} & \text{MISCARRIAGE} \\ & (N=14) \end{aligned}$	TEST VALUE	P- VALUE
GESTATION AL SAC DIAMETER AT 6 WEEKS MEAN ± SD.	2.74±0.43	1.81±0.43	16.2	<.001
AT 9 WEEKS MEAN \pm SD.	3.89 ± 0.79	2.63±0.45	12.6	<.001
AT 12 WEEKS MEAN ± SD	5.95 ± 0.36	4.85 ± 0.46	3.21	.015

Table 5. showed that there was a statistically significant difference between the studied groups regarding gestational sac diameter at 6 weeks, 9 weeks and 12 weeks.

Table 6. Comparison between normal pregnancy and miscarriage according to fetal heart rate

	NORMAL PREGNANCY (N = 62)	MISCARRIAGE (N = 14)	TEST VALUE	P- VALUE
FETAL				
HEART				
RATE				
(BPM)				
MEAN ±	143.46 ± 16.1	123.23 ± 14.1	T=4.188	P<0.001
SD.				
MEDIAN	145 (131 -	124 (112 - 126)		
(IQR)	154)			
RANGE	63 (111 - 174)	52 (100 - 152)		
(MIN-				
MAX)				

Table 6. showed that Fetal heart rate showed significant reduction in miscarriage group contrasted with normal pregnancy group (p<0.001).

Table 7. Cut-off value, Sensitivity and Specificity of Gestational Sac Size (mm) and Heart Rate (Bpm) to predict first trimestric pregnancy outcome

DIAGNOSTIC PARAMETERS

	AUC	Cutoff value	Sensitivity	Specificity	PPV	NPV	P- value
GESTATIONAL SAC SIZE (MM)							
	0.741	33.0	78%	76.9%	77.2%	78%	0.003
HEART RATE (BPM)							
	0.822	126.0	81.4%	84.6%	84.1%	82%	< 0.001

OR: Odds ratio CI: Confidence Interval p: p value Table 7. showed Cut-off value, Sensitivity and Specificity of Gestational Sac Size (mm) and Heart Rate (Bpm) to predict first trimestric pregnancy outcome. Regarding Gestational Sac Size (mm), AUC was 0.741, Cutoff value was 33, Sensitivity was 78% and Specificity was 76.9%. Regarding

Heart Rate (Bpm), AUC was 0.822, Cutoff value was 126, Sensitivity was 81.4% and Specificity was 84.6%.

4. Discussion

In this study, we found that age in the examined population varied from 20 to 35 with mean \pm SD = 27.5 \pm 3.62, & Gestational Age in the examined population varied from 6 to 11 with mean \pm SD = 8.76 \pm 1.22.

This was consistent with the research by Lebda et al., which involved 52 cases in their 1st trimester from Week 6 to Week 12 of Pregnancy, where their mean age was 27.9 ± 2.3 years, with a range from 25 to 31 years. ³

In this thesis, we illustrated that 62 (81.57%) patients had Normal Pregnancy outcomes in the examined population, and 14 (18.42%) experienced miscarriage as a pregnancMiscarriageConsistent with the findings of the research by Suguna and Sukanya, which surveyed the outcomes of pregnancies amongst 478 cases who went to a prenatal clinic, 393 of them had a positive result and 85 of them did not have an abortion. 9

After the 1st trimester, 50 individuals (20%) of the Shahin et al. research had an early pregnancy loss, but the other 200 cases (80%) did not. ¹⁰

In this thesis, we explained that Gestational sac size in normal pregnancy ranged from 13 to 67 mm with a mean \pm SD = 41.02 \pm 14.0 mm, while gestational sac size in the miscarriage group ranged from 12 to 66 mm with a mean \pm SD = 28.85 \pm 14.5mm. Gestational Sac Size showed a significant decline in the miscarriage group compared with the normal pregnancy group (p=0.006).

Wie et al. also showed that there was significant variation in gestational sac (p= < .001) among the groups that experienced a miscarriage and those that continued to carry a pregnancy. This investigation found that a small size of the gestational sac was strongly related to a subsequent miscarriage. The most likely explanation for an abnormally small gestational sac is a problem with placentation. An abnormal yolk sac size has been linked to early fetal loss, according to previous research. ¹¹

Bamniya et al. discovered that the fetal and maternal outcomes were normal when the gestational sac was large but that there was an increased risk of missed or spontaneous abortion & abruption placentae in cases with a small gestational sac (14.28 and 14.28 percent, respectively), compared to controls with normal growth of the gestational sac (7.7 and 1.4 percent, respectively). As a result, it was revealed that a small gestational sac is correlated with an elevated hazard of pregnancy loss & a poorer prognosis. ¹²

In this study, we demonstrated that Fetal heart rate in normal pregnancy ranged from 111 to 174 bpm with mean \pm SD = 143.46 \pm 16.1 bpm, while fetal heart rate in the miscarriage group ranged from 100 to 152 with mean \pm SD = 28.85 \pm 14.5 bpm. Fetal heart rate showed a significant reduction in the miscarriage group contrasted with the normal pregnancy group (p<0.001).

According to research conducted by Abdulkadhim et al., patients in group B who had a negative result during the 1st trimester had an EHR of less than 100 BPM in 6 of 9.13

Regarding the EHR, Abdulkadhim et al. discovered that 6 out of 9 individuals with a poor 1st-trimester result (group B) had an EHR of less than 100 BPM. Tawfik enlisted 100 instances of women who were 7-13 weeks pregnant and at risk of having a miscarriage.18 There was a significant variance (p< 0.001) in FHR among women who miscarried and those who went on to have a healthy pregnancy. Those who went on had a mean FHR of 156.9±20 bpm, whereas those who miscarried averaged 122±9 bpm. ¹⁴

Slow heart rates in the fetus have been associated with abortion. While it would be unreasonable to define a cutoff value for fetal bradycardia without considering gestational age, multiple investigations have stated a reference value of 110 to 120 BPM for predicting miscarriage. There have been a lot of studies on the 7, 19 FHR gene, and miscarriage studies have revealed a correlation between faulty FHR and miscarriage. Fetal bradycardia is a warning indicator of impending fMiscarriageity since it indicates a failing circulatory system. ¹⁵

This study found that regarding Gestational Sac Size (mm), AUC was 0.741, the Cutoff value was 33, Sensitivity was 78%, and Specificity was 76.9% to predict the first-trimester pregnancy outcome.

Soliman et al. found that GSD was 91 percent sensitive, 80.5 percent specific, 85.2 percent PPV, and 81.4 percent NPV in terms opredictingtion of miscarriage.

In this thesis, we illustrated that regarding Heart RateMiscarriage was 0.822, Cutoff value was 126, Sensitivity was 81.4 percent, and Specificity was 84.6 percent to predict first trimestric pregnancy outcome. ¹⁶

The research conducted by Lebda et al. showed that EHR had a sensitivity of 97.5% and a specificity of 100% in predicting the outcome of the 1st trimester of pregnancy, with an overall accuracy of 98.1%. 3

The limited sample size and challenging followup of the patients were limitations of this research, which may be attributable to the lack of a specialized early pregnancy evaluation clinic. This clinic's creation is therefore suggested.

5. Conclusion

Regardless of maternal risk variables, including age, BMI, or parity, abnormal GSD (small, inflated, nonexistent, or irregular yolk sac) and embryonic bradycardia have been related to poor pregnancy outcomes.

5.1 Recommendations

Gestational sac diameter and embryonic heart rate can guide everyday clinical practice, especially if gestational age is considered. In cases with poor ultrasonographic prognostic factors (abnormal gestational sac diameter and embryonic bradycardia), we should not prematurely reassure the couple but arrange a repeat ultrasound scan.

Disclosure

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Authorship

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