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Evaluation of Yolk Sac Diameter, Gestational Sac Diameter, Embryonic Heart Rate as Prognostic Factor of 1st Trimester Outcome

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Abstract

Background: Ultrasound at 5 weeks gestation reveals the yolk sac's hypoechoic centre and echogenic rim. Between 8 and 11 weeks of pregnancy, it expands and then disappears. Larger yolk sacs cause more miscarriages. Normal yolk sacs reduce first-trimester complications. A normal yolk sac predicts a 94% typical result. By 5 weeks, the embryonic heartbeat is visible. The fetal heart rate rose from 118 to 167 beats per minute between 6 and 10 weeks. An embryonic heart rate (EHR) of 100 BPM is abnormal and related to an 83.3% loss rate early in pregnancy (6–9 weeks).

Aim: Does Assessment of gestational sac diameter, yolk sac diameter, and embryonic heart rate could serve as prognostic factor of 1st trimester result?

Subject and methods: This cross-sectional investigation involved 100 pregnant cases who were among 6 and 12 weeks along in their first trimester, in obstetrics outpatient's clinic. Department of Obstetrics and Gynecology, Faculty of Medicine – Al-Azhar University.

Results: By running a Spearman correlation analysis, no significant relationship was found amongst YS & the consequence of pregnancy. The YS diameter was found to be a fair prognostic test where area under the curve (AUC) and P value was 0.086 statistically insignificant. By running a Spearman correlation analysis, a significant association was found among GS & the outcome of pregnancy.

Conclusion: Pregnancy outcomes may be reliably and affordably predicted in the first trimester using the gestational sac diameter & the embryonic heart rate. YSD and pregnancy outcome had no association. Larger cohorts are needed to better predict first trimester outcomes.

Keywords: Yolk sac diameter, Gestational sac diameter, Embryonic heart rate, Trimester outcome

1. Introduction

It is assessed that between 15 and 20 percent of pregnancies end in miscarriage (Cunningham et al., 2010). By 5 weeks of pregnancy, an ultrasound will reveal the yolk sac as a large hypo echoic core and echogenic rim; it will continue to grow until 8–11 weeks of pregnancy, and then it will shrink and vanish by 12 weeks.

Embryonic health has been linked to certain traits of the yolk sac, gestational sac & embryonic heartbeats, as documented in previous research. A

variety of research have looked at the shape, size, and purpose of the yolk sac.

There was an increased risk of miscarriage for pregnancies when the diameter of the yolk sac was more than 5 mm. 37.5 percent of pregnancies with larger yolk sacs & 3.8 percent of pregnancies with irregular yolk sacs ended in miscarriage.

As the first trimester of a pregnancy with a normal yolk sac progresses, the incidence of complications decreases. With a typical yolk sac, the sensitivity for predicting a normal outcome is as high as 94.2%.

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Usually, the heartbeat of an embryo can be recognized with enhanced visual resolution as early as 5 weeks. In this regard, both Doppler studies and motion mode (M-mode) are useful.

Between 6 and 10 weeks of gestation, the fetal heart rate increased from 118 to 167 beats per minute. Studies indicate that a sluggish EHR early in pregnancy (6–9 weeks) is correlated with a great rate of subsequent fetal demise, as EHR 100 BPM is aberrant with a miscarriage rate of 83.3%.

This study sought to determine whether the diameter of the yolk sac, the diameter of the gestational sac & the heart rate of the embryo could serve as a predictor of the fate of the first trimester.

2. Patients and methods

This cross-sectional research involved 100 pregnant cases in their first trimester between 6 and 12 weeks, in obstetrics outpatient's clinic.

2.1. Inclusion criteria for study group

Informed consent form signed, Women between 6 and 12 weeks along in their pregnancies, with a single gestational sac and evidence of a beating heart in the embryo, and Pregnancy age was determined with precision with early ultrasound examination with CRL if the LMP was uncertain.

2.2. Exclusion criteria for groups

Pregnant women experiencing any pregnancy-related issues (such as vaginal bleeding or abdominal cramps), Patients expecting a child who have medical conditions that increase their chance of miscarriage, such as diabetes, persistent hypertension, or connective tissue abnormalities. Observation of a patient with a history of uterine abnormalities, the patient has refused transvaginal sonography and further treatment.

The taken time for complete the study was from October 2021 until October 2022.

2.3. Sample size

This study base on study carried out by Abd Ellatif et al. was used to calculate the sample size by considering the following assumptions:- 95% two-sided confidence level, with a power of 80%. & α error of 5%. The final maximum sample size taken from output was 98. Thus, the sample size was increased to 100 subjects to assume any drop out cases during follow up.¹

3. Methods

Patients were subjected to: Complete history taking (Personal history that includes, Exceptional behaviors with medical importance, and Detailed history of obstetrics and gynecology, Menstruation record, Histories of Parity, Current record, Previous history, a familial history of a comparable ailment and allergy history to any medication) & General examination.

3.1. Trans-vaginal ultrasound for fetal assessment

Using a trans-vaginal ultrasound probe, fetus was assessed for the following points: Gestational sac dimensions, fetal heart rate, Yolk sac dimensions, Site of pregnancy (intrauterine or tubal) and Site of the placenta.

We used sonoscape ultrasound device for examination Fig. 1.

3.1.1. Technique

The patient should initially be positioned in the dorsal lithotomy posture with an empty bladder before transvaginal ultrasonography is performed to assess the cervix. The anterior fornix is the spot to insert the vaginal probe without applying any force. A lack of visibility of the cervix may be missed if the



Fig. 1. Sonoscape ultrasound device.

probe is pushed too firmly on the cervix. The sagittal image of the cervix is used as a starting point for orientation.

3.1.2. Follow up

All patients were followed up during the first trimester to assess the outcomes including miscarriage, or continuation of pregnancy or medical abortion.

Table 1. Patient characteristics (N = 50).

| | EPF (N = 50) | Ongoing (N = 50) | P value |
|---------------------------------|-----------------|---------------------|---------|
| Age (years) | 29.2 ± 6.9 | 28.4 ± 5.7 | 0.627 |
| Less than 25 | 9 (36) | 10 (40) | |
| 25 - 35 | 10 (40) | 13 (52) | |
| More than 35 | 6 (24) | 2 (8) | |
| BMI (kg/m²) | 30.5 ± 5.9 | 29 ± 5.5 | 0.375 |
| Normal Weight | 4 (16) | 6 (24) | |
| Overweight | 7 (28) | 6 (24) | |
| Obesity Grade I | 6 (24) | 6 (24) | |
| Obesity Grade II | 5 (20) | 5 (20) | |
| Obesity Grade III | 3 (12) | 2 (8) | |
| Gravidity | 3.4 ± 1.5 | 3.8 ± 1.3 | 0.322 |
| Primigravida | 4 (16) | 2 (8) | |
| Multigravida | 21 (84) | 23 (92) | |
| Parity | 1.5 ± 1.1 | 2.1 ± 1.1 | 0.088 |
| Nullipara | 6 (24) | 3 (12) | |
| Primipara | 6 (24) | 5 (20) | |
| Multipara | 13 (52) | 17 (68) | |
| Recurrent Pregnancy Loss | 7 (28) | 5 (20) | 0.508 |
| Mode of Conception | | | 0.684 |
| Normal Delivery | 22 (88) | 21 (84) | |
| Assisted Delivery | 3 (12) | 4 (16) | |
| Gestational Age (wk) | 8.9 ± 1.8 | 8.8 ± 1.7 | 0.840 |
| 6–8 weeks | 10 (40) | 8 (32) | |
| 8–10 weeks | 7 (28) | 10 (40) | |
| 10–12 weeks | 8 (32) | 7 (28) | |

EPF: Early pregnancy failure.

Table 2. Gestational sac diameter.

| | EPF (N = 50) | | Ongoing (N = 50) | | P value |
|-----------------|--------------|-----|------------------|-----|---------|
| | Mean | SD | Mean | SD | |
| First Trimester | 3.28 | 1.5 | 4.3 | 1.3 | 0.011 |
| 6–8 weeks | 1.8 | 0.4 | 3.0 | 0.8 | 0.003 |
| 8–10 weeks | 3.1 | 0.4 | 4.3 | 0.7 | 0.001 |
| 10–12 weeks | 5.2 | 0.4 | 6.0 | 0.4 | 0.002 |

EPF: Early pregnancy failure.

Table 3. Prognostic value of gestational sac diameter.

| | Cut-off | Sensitivity | Specificity | AUC | P value | Confidence Interval | |
|-----------------|---------|-------------|-------------|-------|---------|---------------------|-------------|
| | | | | | | Upper Limit | Lower Limit |
| First Trimester | 3.55 | 68% | 76% | 0.709 | 0.011 | 0.564 | 0.854 |
| 6–8 wk | 2.15 | 90% | 87.5% | 0.913 | 0.003 | 0.776 | 1.000 |
| 8–10 wk | 3.45 | 85.7% | 90% | 0.921 | 0.004 | 0.770 | 1.000 |
| 10–12 wk | 5.65 | 87.5% | 71.4% | 0.929 | 0.005 | 0.801 | 1.000 |

EPF: Early pregnancy failure.

3.1.3. Ethical consideration

The protocol for the study had been presented to the Institutional Review Board at Al-Azhar University for consideration and approval. The decision was made to accept the permission of the Ethical Committee of the Al-Azhar Faculty of Medicine. Consent in writing had been gained from every participant in the study before they were allowed to take part. At every stage of the investigation, both participants' right to privacy and confidentiality were protected.

3.2. Data management and statistical analysis

Using the Microsoft Excel program, the data were coded, entered, and evaluated after being collected during the history, basic clinical examination, laboratory investigations, and outcome measurements. After that, the information was prepared for analysis by being imported into the program recognized as Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences). The following tests were utilized to evaluate whether or not the differences were statistically significant: correlation by Pearson's correlation or Spearman's. Concerning the kind of data, qualitative data are shown by numbers and percentages, while quantitative data continue groups are shown by means ± SD. The threshold for significant results was set at <0.05, while the threshold for very significant findings at <0.001.

4. Results

Table 1.

There was no statistically significant variance was observed among groups in terms of age, BMI. Parity, gravidity, rate of pregnancy loss, mode of conception either normal or assistant, and gestational age ($P>0.05$) (Table 2)

EPF group had significantly lower GS diameter in the first trimester and at different gestational age categories (Independent sample t test, $P < 0.05$) (Table 3).

A receiver operating characteristic (ROC) analysis was done to demonstrate the prognostic value of GS

diameter. The GS diameter was found to be a good prognostic test where AUC equaled 0.709 ± 0.074 (CI, 0.564; 0.854), and P value was 0.011 (statistically significant). At a cut-off point of 3.55 mm, the test was found to have a sensitivity of 68% and a specificity of 76% (Table 4).

A ROC analysis was done to demonstrate the prognostic value of YS diameter. The YS diameter was found to be a fair prognostic test where AUC equaled 0.642 ± 0.082 (CI, 0.480; 0.803), and P value was 0.086 (statistically insignificant). At a cut-off point of 6.35 mm, the test was found to have a sensitivity of 48% & a specificity of 99% (Table 5).

A ROC analysis was performed to demonstrate the prognostic value of FHR. The FHR was found to

be a very good prognostic test where AUC equaled 0.865 ± 0.051 (CI, 0.764; 0.965), and P value was less than 0.001 (statistically significant). At a cut-off point of 133 bpm, the test was found to have a sensitivity of 96% and a specificity of 60%.

Figure 2 shown that the mean GA was 8.9 ± 1.8 weeks (range, 6.4–11.9) in the RPF group, and 8.8 ± 1.7 weeks (range, 6–11.7) in the ongoing group. And also it illustrates the ROC curve at first trimester and at different GA categories.

Figs. 3 and 4 shown that the YS diameter was found to be a fair prognostic test where area under the curve (AUC) equaled 0.642 ± 0.082 (CI, 0.480; 0.803), and P value was 0.086 (statistically insignificant). At a cut-off point of 6.35 mm, the test was found to have a sensitivity of 48% and a specificity of

Table 4. Prognostic value of yolk sac diameter.

| | Cut-off | Sensitivity | Specificity | AUC | P value | Confidence Interval | |
|-----------------|---------|-------------|-------------|-------|---------|---------------------|-------------|
| | | | | | | Upper Limit | Lower Limit |
| First Trimester | 6.15 | 48% | 96% | 0.642 | 0.086 | 0.480 | 0.803 |
| 6–8 wk | 5.90 | 80% | 87.5% | 0.900 | 0.004 | 0.751 | 1.000 |
| 8–10 wk | 5.65 | 71.4% | 50% | 0.657 | 0.283 | 0.333 | 0.981 |
| 10–12 wk | 4.30 | 37.5% | 57.1% | 0.402 | 0.524 | 0.103 | 0.700 |

EPF: Early pregnancy failure.

Table 5. Prognostic value of feta heart rate.

| | Cut-off | Sensitivity | Specificity | AUC | P value | Confidence Interval | |
|-----------------|---------|-------------|-------------|-------|---------|---------------------|-------------|
| | | | | | | Upper Limit | Lower Limit |
| First Trimester | 133 | 96% | 60% | 0.865 | 0.000 | 0.764 | 0.965 |
| 6–8 wk | 128 | 90% | 50% | 0.794 | 0.037 | 0.583 | 1.000 |
| 8–10 wk | 142 | 85.7% | 90% | 0.971 | 0.001 | 0.901 | 1.000 |
| 10–12 wk | 122 | 87.5% | 85.7% | 0.946 | 0.004 | 0.839 | 1.000 |



Fig. 2. Gestional sac diameter.



Fig. 3. Yolk sac diameter.

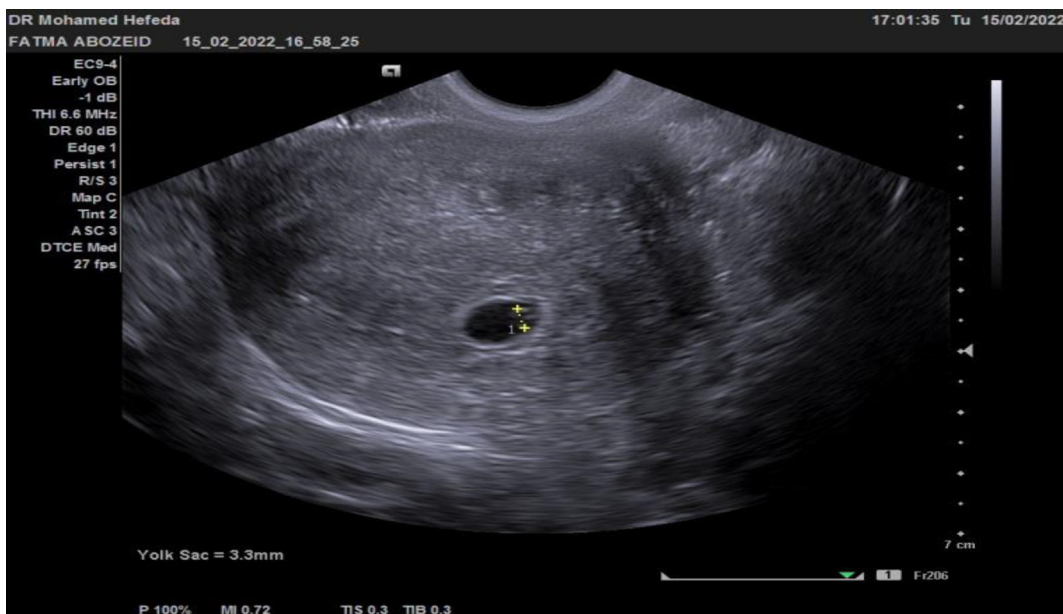


Fig. 4. Yolk sac diameter.

99%. Figure illustrates the ROC curve at first trimester and at different GA categories.

5. Discussion

Pregnancy complications are more likely to occur in the first trimester, despite the fact that this is the crucial time for organogenesis. Prediction of spontaneous abortion is useful in advising and managing

pregnancies with a high risk of a negative outcome. Therefore, a risk assessment model is needed that can estimate the likelihood of an abortion occurring throughout a pregnancy.²

Concerning demographic data of the examined patients, we found no statistically significant variance was discovered to exist in terms of age, BMI. Gravidity, parity, rate of pregnancy loss, mode of conception, and gestational age ($P > 0.05$).

The mean age in our study was 29.2 ± 6.9 years (range, 19–38) in the Early pregnancy failure (EPF) group and 28.4 ± 5.7 years (range, 18–38) in the ongoing group.

Our study was in agreement with Elsyed et al. who aimed to see if measuring embryonic heart rate (EHR) and yolk sac diameter (YSD) might help predict pregnancy outcomes. 52 pregnant cases were enrolled, with their average gestational age being 6–12 weeks. The ages of the participants varied from 21 to 40, with a mean age of 25.8 ± 3.1 .

As regard BMI in our study, the mean BMI was 30.5 ± 5.9 kg/m² (range, 20–40) in the Early pregnancy failure (EPF) group & 29 ± 5.5 kg/m² (range, 20–39) in the ongoing group.³

Our study was in agreement with Elsyed et al. as BMI varied from 22.6 to 30 with a mean of 25.4 ± 2.4 kg/m².³

In the current research, the mean gravidity was 3.4 ± 1.5 in the Early pregnancy failure (EPF) group and 3.8 ± 1.3 in the ongoing group. The mean parity was 1.5 ± 1.1 in the EPF group, and 2.1 ± 1.1 in. No statistically significant variance was existed amongst groups concerning gravidity and parity (Independent sample t test, $P > 0.05$).

In the EPF group, we found that four (16%) were primigravida, and 21 (84%) were multigravida. Six (24%) were nullipara, 6 (24%) were primipara, and 13 (52%) were multipara. In the ongoing group, two (8%) were primigravida, and 23 (92%) were multigravida. Three (12%) were nullipara, five (20%) were primipara, and 17 (68%) were multipara.

This was in line with Jaiswal et al. According to the researcher, of the 50 study participants, 21 (42 percent) were primigravidae and 29 (58 percent) were multigravidae. The statistical significance of demographic variables such as maternal age, location, education, and socioeconomic status on the outcome of pregnancy was lacking. There was no statistically significant distinction among miscarriage rates based on the patient's gestational age.⁴

As regard GA in our study, the mean GA was 8.9 ± 1.8 weeks (range, 6.4–11.9) in the RPF group, and 8.8 ± 1.7 weeks (range, 6–11.7) in the ongoing group. Pregnancies were classified according to GA into three categories, including: 6–8 weeks, 8–10 weeks, and 10–12 weeks. No statistically significant variance was exist among groups concerning GA (Independent sample t test, $P = 0.840$).

In line with our results, Aseri, S. reported that Gestational age varied among 6.0–11.5 weeks with a mean of 8.426 weeks.⁵

Also, in the same line Singh et al. demonstrated the gestational period ranged from 6 to 10 weeks, with a mean of 7.8 ± 1.02 weeks.⁶

In the present research, the rate of recurrent pregnancy loss was 28% in the EPF group, and 20% in the ongoing group. No statistically significant difference was found among groups regarding recurrent pregnancy loss. As regard to Patterns of EPF (20%) patients had blighted ovum, 8 (16%) had missed miscarriage, four (8%) had incomplete miscarriage, and three (6%) had complete miscarriage.

In harmony with our results, Elsyed et al. reported The number of previous abortions varied from three to five, with a mean of 3 ± 0.7 , and 76 percent of patients had more than three abortions. In addition, the last abortion week varied from 6 to 13 weeks, with a mean of 10.1 ± 3.1 weeks.³

The GS diameter was found to be a good prognostic test where AUC equaled 0.709 ± 0.074 (CI, 0.564; 0.854), and P value was 0.011 (statistically significant). At a cut-off point of 3.55 mm, the test was found to have a sensitivity of 68% and a specificity of 76%.

The average size of our gestational sacs was 3.2, which agrees with the findings of Aseri, S., who found a strong correlation between sac size and first-trimester outcomes ($p = .007^{**}$). In normal pregnancies, it averaged 3.3 mm, but in miscarriage cases, it was 2.6 mm. The large variation in estimates of the volume of the gestational sac in 'normal' early pregnancy has been known for some time. The existence of embryonic heart activity does not rule out the possibility that a gestational sac that is smaller than predicted is an indicator of a negative outcome for the pregnancy.⁵

In the current study, no significant relation was exist among YS & the outcome of pregnancy ($r = 0.246$, $P = 0.086$). EPF group had significantly higher YS diameter in the first trimester and at GA ranging between 6 and 8 weeks (Independent sample t test, $P < 0.05$). The YS diameter was found to be a fair prognostic test where AUC equaled 0.642 ± 0.082 (CI, 0.480; 0.803), and P value was 0.086 (statistically insignificant). At a cut-off point of 6.35 mm, the test was found to have a sensitivity of 48% and a specificity of 99%.

However, Singh et al. found that the mean value of yolk sac size was 3.5487 ± 1.27 mm in women who had abortions, but it was 5.3126 ± 0.619 mm in women who carried their pregnancies to term. It was found that there was a statistically significant ($p < .001$) distinction among the two groups, with pregnant women who had a large yolk sac having a normal fetal outcome and cases who had a small yolk sac having a higher rate of missed or spontaneous abortion based on the test's sensitivity (76.47 percent) and specificity (93.89 percent). A smaller,

more irregularly shaped yolk sac was associated with a worse outcome.⁶

Regarding FHR in our research, A significant relation was exist among FHR & the outcome of pregnancy ($r = 0.632$, $P = 0.000$). EPF group had significantly lower FHR in the first trimester and at different gestational age categories (Independent sample t test, $P < 0.05$). The FHR was found to be a very good prognostic test where AUC equaled 0.865 ± 0.051 (CI, 0.764; 0.965), and P value was less than 0.001 (statistically significant). At a cut-off point of 133 bpm, the test was found to have a sensitivity of 96% and a specificity of 60%.

Contrasting the EHRs of women who miscarried with those who continued their pregnancies revealed a statistically significant distinction (bradycardia). Fetal bradycardia is an indication of a malfunction in the circulatory system and is a predictor of fetal mortality. Possible causes include a chromosomal abnormality associated with fetal bradycardia.⁷

Our findings were corroborated by a research by Abdulkadhim, who found that, when looking at embryonic heart rate (EHR), the majority of patients with a poor first trimester outcome (group B) had an EHR of 100 or below in 6 of 9 cases.⁸

6. Conclusion

Pregnancy outcomes may be reliably and affordably predicted in the first trimester using the gestational sac diameter and the embryonic heart rate. YSD and pregnancy outcome had no association. Larger cohorts are needed to better predict first trimester outcomes.

7. Recommendation

Larger cohort is required for finding out the further correlation between first trimester outcome and characteristics of yolk sac, gestational sac diameter and the embryonic heart rate and for better prediction. Further multicenter studies are

needed to confirm the current results. We recommend the combination between yolk sac, gestational sac diameter and the embryonic heart rate and other diagnostic methods for better accuracy. Avoid occurrence of vaginal bleeding.

Conflict of interest

The authors declared that there were no conflicts of interest.

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