

Original Research Article

A Hospital Based Prospective Study to Assess the Correlation of First Trimester Pregnancy Outcome Using Yolk Sac Measurements and Embryonic Heart Rate at Newly Established Tertiary Care Centre**Balgopal Singh Bhati^{1*}, Nooren Mirza², Neha Grover³, Ipsa Chauhan⁴**¹Assistant Professor & Unit Head, Department of Obstetrics & Gynaecology, Government Medical College, Pali, Rajasthan, India²Associate Professor & Head, Department of Obstetrics & Gynaecology, Government Medical College, Pali, Rajasthan, India³Senior Resident, Department of Obstetrics & Gynaecology, Government Medical College, Pali, Rajasthan, India⁴Junior Resident, Department of Obstetrics & Gynaecology, Government Medical College, Pali, Rajasthan, India

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Abstract

Background: Ultrasound is the primary imaging modality in obstetrics over the last three decades. The advent of high-resolution transvaginal ultrasound (TVS) has revolutionized our understanding of the pathophysiology and the management of early pregnancy failure. This prospective correlation study is conducted to assess the correlation of first trimester pregnancy outcome using yolk sac measurements and embryonic heart rate. **Materials & Methods:** This is a prospective study done on 80 women attending routine antenatal check up in the out-patient department of gynecology were subjected to scan at Government Medical College, Pali, Rajasthan, India. A thorough general, physical, systematic and obstetric examination was carried out. After obtaining informed consent the women between 6-12 weeks of gestation were subjected to transvaginal ultrasound (using linear array real time B scan with 7.5 MHz transducer). The chi-square test and student paired t test were used for qualitative data. A *P* value of <.05 indicated statistical significance. Data were analyzed using SPSS (v 22.0; IBM). **Results:** Our study showed that age at the time of pregnancy and first Sonogram correlates with the first trimester pregnancy outcome. Mean age was 23.38 years with minimum 16 years and maximum of 36 years. There was a linear correlation ($p=0.026^*$) between the age at time of pregnancy and miscarriage. The Yolk sac size varied between 2.5 to 7.0 with a mean of 4.725 mm. The Yolk sac size has significant correlation with the first trimester pregnancy outcome. (*T-test* $p=0.001^{**}$). The heart rate of the fetus ranged between 100 and 180, with a mean of 153.86. The heart rate of the fetus predicted the first trimester pregnancy outcome significantly (*T-test* $p=0.035^*$). The area under the curve was 0.708. Yolk sac (mm) has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased. **Conclusion:** We concluded that the yolk sac size and the embryonic heart rate is a reliable, cost effective and beneficial in predicting first trimester pregnancy outcome especially in patients who conceive following IVF.

Keywords: Yolk Sac, Heart Rate, Embryonic, Transvaginal Ultrasound, Miscarriage.

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Introduction

Ultrasonography as a technique for determining the foetal gestational age was introduced in the nineteen fifties. In a surprisingly short span of time, development and improvisations in newer technology and research methodology has led to a mind-boggling improvement in assessment of foetal gestation using various parameters[1]. Human placentation is more complex than that of other mammalian species, including the higher primates. Abnormalities of placentation are associated with diseases that are almost unique to the human species, such as preeclampsia or hydatidiform mole, or rare in other

species, such as miscarriage. Abnormally high or rapidly fluctuating concentrations of oxygen have a harmful effect on tissue and in particular on trophoblastic tissue. There is increasing evidence to indicate that failure of placentation is associated with an imbalance in reactive oxygen species (ROS), which will further affect placental development and function and may subsequently have an influence on both the fetus and its mother[1].

The emergence of three-dimensional (3D) ultrasound in obstetrics provided an opportunity to revisit previously abandoned or disregarded obstetric ultrasound parameters, particularly in early pregnancy. 3D assessment of gestational sac volume in the first trimester has been found to be a sensitive indicator of pregnancy outcome, with a smaller than expected gestational sac volume being predictive of failing early pregnancy. It has not, however, proved useful in determining the outcome of expectant management or in predicting the success of medical treatment and appears to add little to the diagnostic or prognostic value of two-dimensional imaging[2].

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Ultrasound imaging has rapidly replaced all other techniques used to study normal human development in the first trimester, and ultrasound features of the early gestational sac have corroborated anatomical studies showing that the first structures to appear are the coelomic cavity and the secondary yolk sac. No single ultrasound measurement of the different anatomical features in the first trimester has been shown to have a high predictive value for determining early pregnancy outcome[3]. This prospective correlation study is conducted to assess the correlation of first trimester pregnancy outcome using yolk sac measurements and embryonic heart rate.

Materials & Methods

This is a prospective study done on 80 women attending routine antenatal check up in the out-patient department of gynecology were subjected to scan at Government Medical College, Pali, Rajasthan, India.

Inclusion Criteria

1. Antenatal patients with single gestation and live embryo
2. Age < 30yrs.
3. Primigravida & Multigravida women

Exclusion Criteria

1. Pregnancy from infertility treatment
2. Cases without embryonic heart rate, anembryonic pregnancy, subchorionic haemorrhage and inconsistency between gestational sac size and CRL.
3. Women who has used any abortive or teratogenic drugs.

Methods

A detailed history was elicited with special reference to the last menstrual period, its regularity and other associated risk factors like diabetes mellitus, hypertension, hypothyroidism, cardiac disease and bronchial asthma. Then a thorough general, physical, systematic and obstetric examination was carried out. After obtaining informed consent the women between 6-12 weeks of gestation were subjected to transvaginal ultrasound (using linear array real time B scan with 7.5 MHz transducer).

Measurement of Yolk Sac

The yolk sac appears as a transonic mass within the gestational sac and it is measured by placing the caliper on the inner limits of longer diameter. Any yolk sac with totally smooth and no deformed margins was defined as having regular shape. The yolk sac with mainly wrinkled margins, indented walls was identified as having irregular shape.

Measurement of Embryonic Heart Rate

Heart rate – in the first trimester the measurement of heart rate should be performed using turnover M-mode. The heart rate increases rapidly from six to eight weeks and then remains relatively stable afterwards.

Statistical Analysis

The following descriptive variables were calculated: mean, standard deviation, median, range, frequency, and percentage. The chi-square test and student paired t test were used for qualitative data. A *P* value of <.05 indicated statistical significance. Data were analyzed using SPSS (v 22.0; IBM).

Results

Our study showed that age at the time of pregnancy and first Sonogram correlates with the first trimester pregnancy outcome. Mean age was 23.38 years with minimum 16 years and maximum of 36 years. There was a linear correlation ($p=0.026^*$) between the age at time of pregnancy and miscarriage. Out of 80 cases, 68 cases were without medical illnesses and about 12 cases with associated one of the medical illnesses. Medical illnesses were Systemic hypertension, polycystic ovary disease (PCOD), Diabetes Mellitus, Bronchial Asthma, Anemia and Hypothyroidism. Medical illness doesn't have correlation with pregnancy outcome (Pearson Chi-Square test $p=0.306$) (Table 1).

The Yolk sac size varied between 2.5 to 7.0 with a mean of 4.725 mm. The Yolk sac size has significant correlation with the first trimester pregnancy outcome. (*T-test* $p=0.001^{**}$) (Table 2). The heart rate of the fetus ranged between 100 and 180, with a mean of 153.86. The heart rate of the fetus predicted the first trimester pregnancy outcome significantly (*T-test* $p=0.035^*$) (Table 3).

The area under the curve was 0.708. Yolk sac (mm) has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased (Fig. 1).

Table 1: Age and Pregnancy outcome

	Pregnancy outcome	Mean ± Sd	SE	t	df	P-value	Mean difference	95% CI
Age (yrs)	Normal (N=68)	23.38±3.52	0.356	-2.210	108	0.026*	-2.07	-3.843 to -0.224
	Miscarriage (N=12)	24.41±3.13	0.723	-2.321	23.410	0.026*	-2.07	-3.828 to -0.239

Table 2: Yolk Sac and Pregnancy outcome

	Pregnancy outcome	Mean ± Sd	SE	t	df	P-value	Mean difference	95% CI
Yolk sac (mm)	Normal (N=68)	4.725±0.721	0.7202	-	118	0.001**	-0.635	-0.9508 to -0.2190
	Miscarriage (N=12)	5.321±0.68	0.1592	-	23.415	0.002**	-0.527	-0.9460 to -0.2245

Table 3: Embryonic heart rate and Pregnancy outcome

	Pregnancy outcome	Mean ± Sd	SE	t	df	P-value	Mean difference	95% CI
Embryonic heart rate (bpm)	Normal (N=68)	153.86±14.312	1.367	1.984	118	0.035**	8.23	0.06254 to 16.823
	Miscarriage (N=12)	148.53±22.205	5.234	1.334	18.943	0.214	8.23	-4.765 to 20.268

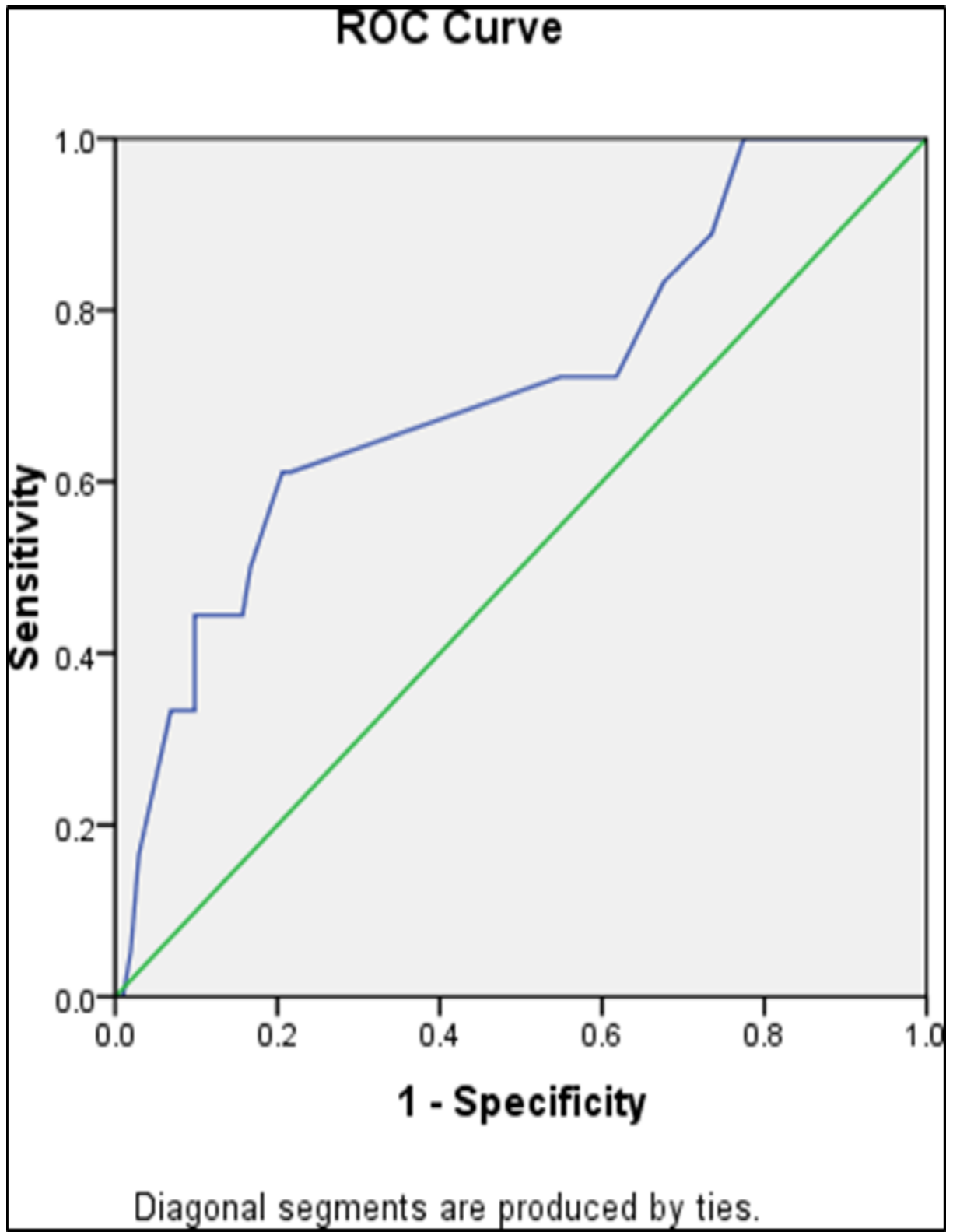


Fig 1: ROC curve

Discussion

Miscarriage occurs in approximately 30–40% of implanted pregnancies, is the commonest complication of pregnancy[4]. Numerous studies have examined the potential value of demographic characteristics and various ultrasonographic parameters in the prediction of those pregnancies that will miscarry. These studies have reported an association between increased risk for miscarriage and advanced maternal age, previous history of miscarriage, vaginal bleeding, fetal bradycardia, early onset fetal growth restriction, small gestational sac volume and large yolk sac. However, most of these studies included small numbers of patients, were retrospective or were carried out in highly selected populations, including women presenting with vaginal bleeding or abdominal pain and in pregnancies achieved using assisted reproduction techniques[5]. There was a linear correlation ($p=0.026^*$) between the age at time of pregnancy and miscarriage. Our study supports the fact that as the maternal age increases, chances of spontaneous abortion also increase. Studies have also shown that the rate of spontaneous abortion following cardiac activity is influenced by maternal age. So, a cardiac activity is not necessarily a reassuring sign in the older patient[6].

In our study medical illness in the mother does not correlate with the pregnancy outcome ($p=0.306$). This is accordance with the previous studies. So, the women with previous medical illness like systemic hypertension, PCOD, Diabetes Mellitus, Hypothyroidism may have good outcome of first trimester provided the fetal cardiac rate and Yolk sac size are within normal range.

The increase in yolk sac diameter during the first trimester and its correlation with advancing gestational age lie in agreement with most of the previous studies[2], although some researchers support that the growth of yolk sac during the first trimester is not constant[7]. We demonstrated that the pregnancies with mean yolk sac diameter ≥ 5 mm on early ultrasound require monitoring and counseling. About a threefold increased risk for first-trimester loss independent of maternal risk factors such as age, body mass index, polycystic ovary syndrome, smoking, and diabetes and we agree with recent studies that support the negative predictive value of the absence of yolk sac[3,8]. We studied only the yolk sac size and not its shape; therefore we cannot comment on previous articles that associate abnormal shapes of the yolk sac with poor pregnancy outcome[9]. In addition, enlarged yolk sac diameter may be associated with an increased risk of preterm delivery[10].

Embryonic heart rate has significant correlation with the first trimester outcome in our study ($p=0.035^*$). FHR has been studied extensively and numerous studies have demonstrated a strong association between pathological FHR and fetal loss. Fetal bradycardia is a sign of impending fetal death reflecting the forthcoming collapse of the cardiovascular system. Another possible cause for the high miscarriage rate in fetuses with abnormal FHR is that there may be an underlying chromosomal abnormality, such as trisomy 18 or triploidy, which is associated with fetal bradycardia[11]. But tachycardia is a feature of trisomy 21 (Down Syndrome)[12].

The limitation of ultrasound examination depends on the machine type, operator factors and timing of scan and our study also has limitation of low volume. In spite of all these limitations we postulate that measurement of yolk sac size and embryonic heart rate in early pregnancy may predict the first trimester outcome and plan for timing of follow up; also to counsel the patient about the short term and long term outcomes.

Conclusion

We concluded that the yolk sac size and the embryonic heart rate is a reliable, cost effective and beneficial in predicting first trimester pregnancy outcome especially in patients who conceive following IVF.

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