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A prospective study of secondary yolk sac diameter measured using transvaginal ultrasound, in anticipation of early pregnancy outcome

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Abstract
Background and Objectives: The secondary yolk sac is the extraembryonic structure, translucent, cyst like within the gestational sac (1).
It is seen the chorionic cavity from 5th week to 11 week 6days of menstrual age at the latest(2). It acts as primary source of exchange between embryo and mother before the establishment of placental circulation during organogenesis (3). Yolk sac functions like, nutritive, endocrine, metabolic, secretory, excretory functions (4).our study is conducted to evaluate the size of yolk sac for predicting early pregnancy outcome.
Methods: In this study 100 women attending their first trimester antenatal visit were included. Women with 5 week and 10 weeks of gestation were evaluated for YSD, MSD, CRL by transvaginal ultrasound. Their regular follow up done, routine investigations done, Nuchal translulescency scan done between 11 week to 13 week 6 days, and TIFFA scan for fetal anomaly done between 18 weeks to 24 weeks. Pregnancy without any complications labelled normal and those with abortion, increased NT and fetal anomaly were labelled as abnormal
Results: There was a significant positive correlation between Yolk Sac Diameter, Crown Rump Length, Gestational Sac and Gestational Age A Normal range of YSD Is established based on normal outcome of each Gestational week YSD >2SD above or below the mean were considered as abnormal YSD(5). With Sensitivity of 90.9% Specificity 96.48% PPV- 55.56%. And NPV -90.96%
Conclusion: We Can Conclude from the present study that measurement of secondary yolk sac diameter between 6th to 10th week of gestation can be used as a valuable tool to predict early pregnancy outcome, even before the detection of embryo. This in turn helps in counseling the parents regarding the risk of miscarriage and need for follow up ultrasound examinations.

Keywords: Yolk sac diameter, abnormal pregnancy outcome, transvaginal sonography, crown rump length, targeted imaging for fetal anomalies

Introduction
Early pregnancy failure/spontaneous abortion is frequent complications of pregnancy [6]. The difficulty is still there in anticipating which pregnancy will land up in abortion. There are many patients with history of threatened or recurrent abortion who still abort In spite of resting on bed for many weeks. So it is important to know the techniques which allow early diagnosis and active management can be pursued if so desired. The yolk sac is the first extra embryonic structure that can be visualised better by trans vaginal ultrasound, can be seen from 5th week to 12 week at the latest [7]. During organogenesis and before placental circulation is established, yolk sac is the primary source of exchange between the embryo and the mother. Yolk sac has nutritive, endocrine, metabolic, immunologic, secretary, excretory and hematopoietic functions. Many studies on the prognostic significance of the Yolk sac for pregnancy outcome have been performed with conventional sonography and more recently with TVS [7]. The results are conflicting. Thus further studies on the measurements of yolk sac size and it's association with normal and abnormal pregnancy outcome could help as an early pregnancy outcome.

Materials and Methods
Source of data Antenal cases attending OPD at A ameen medical college hospital Vijaypura, those consenting for the for the study will be will be included in this study Method of collection

of Data: Sample size: 100 Study design: Prospective cross sectional study With 95% confidence level and margin of error +/-10%, a sample size of 97 (~~100) subjects will be allowed to study the association between increase/decrease in yolk sac diameter >/2SD from the mean, with the early pregnancy outcomes. Ethical clearance was obtained from ethical review board of Al- ameen medical college and hospital. vijaypur Scanning Technique: Patients were reassured before the procedure and an informed consent was taken from the antenatal women for performance of Transvaginal Scan. The Machine used in this study was Logiq P9 by GE Healthcare, With frequency of the probe was 7.8MHz. The scan was done with empty bladder. Procedure was explained to the patient informed written consent taken. The patient was placed in dorsal position and pelvic muscles relaxed [8]. Head of the probe was cleaned, covered with a condom after applying ultrasonic jelly. Tip of the condom smeared with jelly. The probee is inserted slowly into the vagina to obtain the sagital section of the uterus [8]. Probe was rotated from 12 'o'clock position to 9 ט' clock position (anticlockwise) to obtain a transverse section of the uterus [9].Yolk sac diameter was measured using electronic callipers and measuring INNER TO INNER diameter [10].

Inclusion criteria

1. Pregnant women with estimated gestational age of 6 week to 10 week +6 days, attending the antenatal OPD of Al Ameen Medical College Hospital, Vijaypur, Karnataka
2. Wo men sure of dates
3. Singleton gestation
4. Consent given for study
5. Consenting for regular follow-up

Exclusion Criteria

1. Ectopic pregnancy
2. Wo men with structural anomalies of uterus and cervix
3. Medical diseases such as hypertension, SLE, and cardiac diseases
4. Multiple gestation
5. Recurrent Pregnacy Loss
6. Women with known endocrine disorder causing abnormal pregnancy outcome e.g. hypothyroidism and diabetes mellitus

Collection of data

Mean yolk sac diameter will be measured by taking average of the diameter assessed on 3 perpendicular measurements, by placing callipers at inside the yolk sac wall. They were followed up till 24 week of gestation and considerd as normal pregnancy outcome if pregnancy continued beyond 24 week and abnormal outcome if they had spontaneous abortion, missed abortion,an embyonic gestation or demonstrable fetal anomalies.

Duration of study: Jan 2021 to December 2022

Statistical analysis

All the quantitative parameters such as yolk sac diameter, gestational age, CRL, Mean gestational sac diameter, age of women etc. Are described in terms of descriptive statistics such as mean and standard deviation. Bivariate co relation was estimated between different factors such as Yolk sac diameter v/s Gestational age, Yolk sac v/s Crown lunmp length, yolk sac diameter v/s Mean gestational sac diameter. Upper and lower 95% confidence limits were estimated for yolk sac diameter based on normal pregnancy outcomes, for particular gestational age, which was grouped in weeks. Appropriate graphical presentation was out to plot yolk sac diameter with mean +/- 2SD based on Women with normal pregnancy outcome. An abnormal yolk sac diameter was defined as being more than 2SD above or below the mean for particular gestational age. Sensitivity, Specificity, positive predictive value and negative predictive value were calculated for abnormal yolk sac diameter in predicting abnormal pregnancy outcome. These parameters were represented graphically based on gestational age at which measurements were taken. To test for difference in yolk sac diameter between abnormal and normal outcome t-test was employed. The statistical analysis was performed using SPSS package version 2O.Chi square test was used when appropriate. Statistical significance was defined as (p<0.05)

Table 1: Pregnancy outcome in the antenatal cases

Pregnancy outcome	No of antenatal cases	% of antenatal cases
Normal	82	82.00
Abnormal	18	18.00
Total	100	100.00

out of 100 patients in our study 18 patients had abnormal outcome like, incomplete abortion, missed abortions, *anomalous fetus*. L

Table 2: Normal and abnormal outcome with gravidity

Gravidity	Normal	%	Abnormal	%	Total	%
Gravida 1	49	92.45	4	7.55	53	53.00
Gravida 2	19	73.08	7	26.92	26	26.00
Gravida 3	12	80.00	3	20.00	15	15.00
Gravida 4	1	25.00	3	75.00	4	4.00
Gravida 5	1	50.00	1	50.00	2	2.00
Total	82	82.00	18	18.00	100	100.00
Chi-square= 15.5 590				,p=0040*		

*p<0.05

As the gravida increases abnormal pregnancy outcome increases up to gravida 4.

Table 3: Normal and abnormal outcome with number of previous abortions

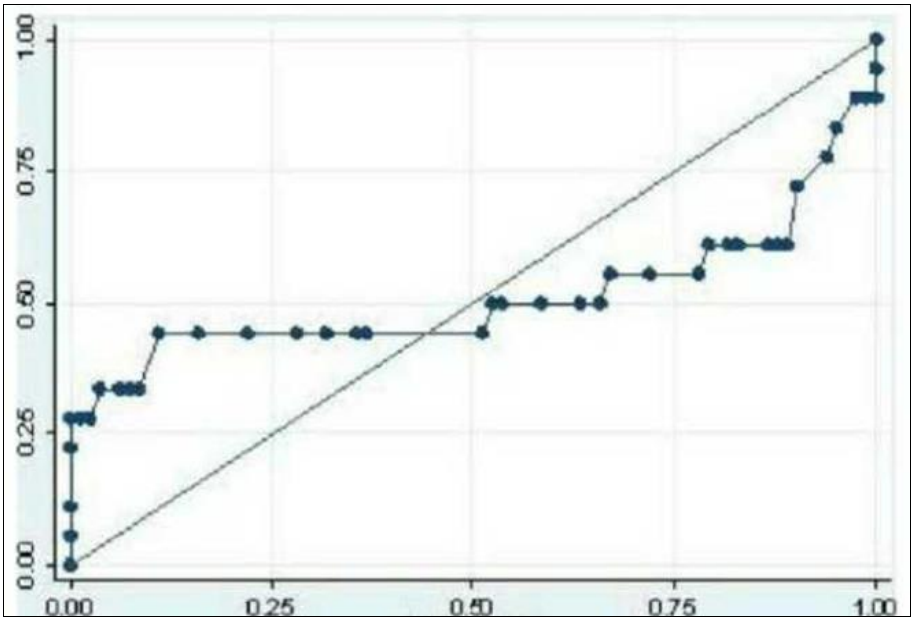
Previous	Normal	%	Abnormal	%	Total	%
0	64	86.49	10	13.51	74	74.00
1	17	85.00	3	15.00	20	20.00
>=2	1	16.67	5	83.33	6	6.00
Total	82	82.00	18	18.00	100	100.00
Chi-square=l8			.4830, p=0	.0001*		

*p<0.05

women with history of previous 2 abortions had 83.33% abnormnal outcome compared to only 13% abnormal outcome in those who were not having any abortions history. The association was very very significant with P value being O.OOO1|

Table 4: Yolk Sac Diameter as a predictor of pregnancy outcome (Sensitivity and specificity)

	Sensitivity	Specificity	PPV	NPV	AUC
Overall	55.56	84.00	20.00	84.00	51.02
5.5-6.0weeks	66.67	44.44	28.57	85.71	55.56
6.1-7.0	66.67	65.52	16.67	95.00	63.22
7.1-8.0weeks	40.00	54.17	15.38	81.25	58.30
9.1-9.Oweeks	50.00	54.55	28.57	75.00	45.45
>=9.1 weeks	33.33	44.44	16.67	66.67	31 8



Graph 1: ROC of Yolk sac diameter as a predictor of pregnancy outcome (total)

Discussion and Conclusion

We can conclude from the present study that measurements of the secondary YSD between v6th to 10th week of gestation can be used as a valuable tool to predict early pregnancy outcome. As the yolk sac is the first structure to appear in the Gestational sac, confirming an intra-uterine Pregnancy, using yolk sac measurements as a tool to evaluate pregnancy outcome, provides a mode of early prediction of pregnancy outcome. Even before the detection of the embryo. Thos in turn helps in counseling the parents regarding the risk of miscarriage and the need for follow up ultrasound sex aminations. lt is particularly helpful to counsel patient with history pdf threatened or recurrent abortion who abort despite resting in the hospital for many weeks. It also helps in pursuing a more active line of management if required. Based on the results of this study and data available from the literature.it is certain that abnormal yolk sac diameter is associated with poor pregnancy outcome [11]. But there is uncertainty regarding the causality of the poor pregnancy outcome associated with abnormal yolk sac size. Very few authors suggest association of abnormalities with abnormal yolk sac size, some negate this association Some suggest association of endocrine abnormalities such as diabetes mellitus with enlarged yolk sac. Further studies are required to establish causality of poor pregnancy outcome with abnormal YSD, so that a line of management can be planned for such patients, which may include karyotyping of the couple, karyotyping of abortus, investigations for detecting any possible endocrine factors associated with such outcome and to plan further line of treatment for such patients.

This study was conducted to evaluate the role of yolk sac diameter in predicting pregnancy outcome

In this study 100 women who presented to the Antenatal OPD of Al-ameen Medical College Hospital Vijaypur Karnataka, between 5 and 10 weeks of gestation were evaluated with Transvaginal sonography and measurements such as MSD.CRL and YSD were taken. Patients were followed up to 24 weeks of gestational age and classified as normal outcome if pregnancy continues beyond 24 weeks and no anomalies of the fetus was noted. The mean age of the study population was 24 and 77.08% of the study population belonged to the age group of 21-25 years. 53% of the study population were primigravidae. We had 18% incidence of Abnormal Pregnancy Outcome Table -1.The probability of abnormal pregnancy outcome did not change with maternl age (p=0.2090). The probability of Abnormal outcome increased with the increase in gravidity of the patient (P=0.0040), with significant increase in the risk of abortions with gravida 4 (75%) table-2. History of previous abortion increased the risk of abnormal outcome in subsequent pregnancies (p<0.0001). With no previous no abortions. The risk of abnormal outcome was 13.5%.which increased to 15.0% with history of previous 1 abortion history and 83.3% with 2 or more previous abortions table-3

There was significant positive correlation between YSD and CRL (r=0.423.Pand CRL (r=0.423.p<0.0001).MSD (r=0,355.P= 0.0003) and GA (r=0.1973.P=0.0491) A Normal range of yolk sac diameter was established based on normal outcome for each gestational week. YSD more than 2 SD above or below the mean were considered as abnormal yolk sac diameter [12]. Using these criteria of abnormal YSD to predict abnormal pregnancy outcome, sensitivity was 90.91%, Specificity of 91.01% positive predictive value was 55.56% and negative predictive value was 98.78%.(P=0.0390).table-4 & graph.

Conflict of Interest

Not available

Financial Support

Not available

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