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Original Research Article

Evaluation of Early Pregnancy Failure with Transvaginal Sonography: A Prospective Observational Study

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Abstract

Background: Spontaneous miscarriage is one of the common complications in pregnancy. It occurs in up to 20% of clinical pregnancies. In the first trimester with transvaginal ultrasonography a series of measurements like embryonic crown-rump length (CRL), embryonic heart rate (EHR), gestational sac diameter (GSD) and yolk sac diameter (YSD) were taken. The objective of this study is to evaluate early pregnancy developmental changes in first trimester ultrasound screening also to identify abnormal ultrasound parameters and correlate the ultrasound findings with the clinical outcomes.

Materials & Methods: The study included 100 pregnant women attending antenatal clinic at 5-12 weeks of gestation fulfilling inclusion and exclusion criteria. They were subjected to TVS. Mean Gestational Sac Diameter (MGSD), Yolk Sac Diameter (YSD), morphology of yolk sac, Crown rump length (CRL), Retroplacental or Perisac Collection, Embryonic Heart Rate (EHR) were noted.

Results: In our study, 34% patients had abnormal pregnancy. Maximum patients belonged to the age group 26-30. Majority of abortions occurred before 12 weeks of gestation. Threatened abortion was noted in 23% of patients. 50% of patients with abnormally large yolk sac, 94% of patients with MSD>25 mm with absent embryo, 100% of patients with CRL>9mm and 100% with EHR<100bpm aborted.

Conclusion: TVS can help in early diagnosis of EPF in asymptomatic patients. Timely appearance of parameters like Gestational Sac, CRL, EHR, Yolk Sac and evaluation of retroplacental and perisac area can be used to predict pregnancy outcome.

Keywords: Ultrasound, first trimester, pregnancy failure.

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Introduction

Early pregnancy units (EPUs) have developed with the aim of providing a one-stop outpatient service to women with abdominal pain, vaginal bleeding or anxiety, as to the location and viability of their pregnancy [1]. In such EPUs the patients are examined both clinically and by pelvic ultrasound for prompt and accurate diagnosis of extrauterine and failed intrauterine pregnancy [2]. However, in the majority of women there is a normal intrauterine pregnancy. In the presence of live embryos, a series of measurements are taken, including embryonic crown-rump length (CRL), embryonic heart rate (EHR). gestational sac diameter (GSD) and yolk sac With transvaginal diameter (YSD). ultrasound, it is possible to identify the sac by 4 weeks and 3 days gestation when the mean diameter is 2 to 3 mm [3]. Approximately 12-24% of all pregnancies suffer miscarriages and 80% of all cases of pregnancy loss occur within the first trimester and most of the early miscarriages are caused by chromosomal abnormalities [3]. Ultrasound has become an essential diagnostic imaging modality in the field of obstetrics and is being extensively used for evaluation of pregnancy [4]. Being noninvasive, safe and without hazards of radiation, USG has gained wide acceptability, as an integral part of basic investigative procedures [4]. Early pregnancy failure may present with vaginal bleeding and (or) abdominal pain. Differential diagnoses include threatened, inevitable, and missed abortion. The latter can be further subdivided into anembryonic pregnancy (blighted ovum) or embryonic demise. Other differential diagnoses include ectopic and pregnancy. TVS findings can be conclusive of early pregnancy failure (EPF) or can be suggestive. This study is aimed to assess the early pregnancy developmental changes in first trimester ultrasound screening also to identify abnormal ultrasound parameters and correlate the ultrasound findings with the clinical outcomes.

Materials & Methods:

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This prospective observational study was carried out in a tertiary health care facility Burdwan Medical College, Burdwan, West Bengal, from June 2018 to June 2019 for a period of one year, after receiving approval from the Ethical Committee of this Institution. The study was conducted for a period of one year. The study included 100 pregnant women attending antenatal clinic of this Institution at 5-12 weeks of gestation fulfilling inclusion and exclusion criteria. They were subjected to TVS after proper informed consent. Normal embryonic development and signs of early pregnancy failure were identified. All the patients were followed up to 20 weeks to see the outcome. Any age, any parity, single pregnancy with intrauterine estimated gestational age of 5-12 weeks with accurate last menstrual period (LMP) with previous history of regular cycle and any subject of threatened abortion were included in this study. Multiple pregnancies, known fetal or uterine abnormalities, chronic diseases in pregnant women like heart disease, diabetes, chronic hypertension etc. womens not willing to participate in study were excluded. Philips HD7 USG machine with transvaginal probe of frequency 5-7.5 MHz was used for study purposes. Mean Gestational Sac Diameter (MGSD), Yolk Sac Diameter (YSD), morphology of yolk sac, Crown rump length (CRL), Retroplacental or Perisac Collection, Embryonic Heart Rate (EHR). All USG was done and reviewed by a single radiologist in sonography to reduce obstetric observational bias. All the cases were subjected to detailed history, general physical, systemic as well as obstetrical examination at the time of their antenatal visit and at the time of admission. Gestational age was calculated by modified Naegele's rule. LMP derived gestational age was compared with ultrasound derived gestational age using CRL and marked discrepancy of one or more

weeks led to exclusion of participants from the study. MGSD was assessed by averaging dimensions (longitudinal, three anteroposterior and transverse). Sac was measured from inside of the sac to the inside of the decidual reaction, excluding the latter in the measurement. Yolk Sac (YS) was determined by placing calipers on the inner limits of the longer diameter. Size of the sac, shape, echogenicity of the rim and centre of sac, its number and degenerative changes such as calcification was evaluated. Yolk Sac having diameter between 3-6 mm, rounded shape, absence of degenerative changes, presence of echogenic rim and hypoechoic centre was considered normal. Any deviation from above parameters was considered abnormal. Crown Rump Length (CRL) was measured in sagittal plane of the embryo avoiding inclusion of YS. CRL >4 mm in TVS who fail to demonstrate heartbeat were judged non-viable and CRL <4 mm without a visible heart beat returned for repeat TVS after 7 days. EHR of less than 100 beats per minute at 8 weeks or earlier was classified as slow. Presence of any perisac collection or haemorrhage in or around sac or placenta were noted. All the patients were followed upto 20 weeks to see whether there was any spontaneous loss or any other early pregnancy complication or if the pregnancy is continued normally as suggested by previous TVS findings.

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Statistical Analysis

Statistical significance of the result was evaluated by Percentage, Predictive value. Comparison of groups was done by using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate. A value of p<0.05 was considered statistically significant.

Results:

This prospective observational study was performed to evaluate the early pregnancy developmental changes in first trimester ultrasound screening and also to identify abnormal ultrasound parameters and correlate the findings with the clinical outcomes.

Table 1: Demography of study subjects

		Age (years)	
	<=20	21-25	26-30
A an Distuilantion	>30		
Age Distribution	15(15%)	23(23%)	39(39%)
	23(23%)	, ,	
	Parity		
	P0+0	P0+1-P0+5	P1+0- P2+0
Devite Distribution	P3+0		
Parity Distribution	49(49%)	22(22%)	21(21%)
	8(8%)	, ,	
	Age (years)		
Total number of abortion in relation to	<=20	21-25	26-30
	>30		
maternal age (n=34)	4(11.76%)	8(23.53%)	11(32.35%)
	11(32.35%)		
	Parity		
Total number of abortion in relation to parity	P0+0	P0+1-P0+5	P1+0-P2+0
(n=34)	P3+0		
	14(41.17%)	11(32.35%)	8(23.52%)
	1(2.94%)		

Total number of abortion in relation to period of	Period of Ges	tation (weeks)	
gestation (n=34)	<8	8-12	
	18(52.94%)	16(47.06%)	

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Table 2: Pregnancy Outcome in the study population

OUTCOME	Frequency	Percent
Ν	66	66.0
EPF/LPF	34	34.0
Total	100	100.0

Table 3: Distribution of patients as per gestational age (in weeks)

GEST AGE(WEEKS)	Frequency	Percent
<8	25	25.0
8-12	75	75.0
Total	100	100.0

Table 4: Incidence of Abnormal Parameters in TVS

Incidence of Abnormal Parameters	Number	%
MSD>25 with No Embryo	14	14.0
YSD > 6 mm	4	4.0
Abnormal Morphology of YS	3	3.0
CRL> 4 mm with No Cardiac Activity	8	8.0
SCH or PGH	4	4.0
EHR <100 bpm	3	3.0

Table 5: Relationship between TVS parameters and pregnancy outcome

TVS parameters	Live	Dead	Total	p value
MGSD > 25 mm and Embryo Absent	0	14	14	
MGSD > 25 mm and Embryo Present	50	13	63	< 0.001
CRL > 4 mm and Cardiac Activity Absent	2	6	8	< 0.001
CRL > 4 mm and Cardiac Activity Present	60	13	73	
YSD>6 mm	0	4	4	
YSD<=6 mm	66	30	96	< 0.001
EHR <= 100 min	1	2	3	
EHR > 100 min	57	11	68	0.067
SCH or PGH Present	2	2	4	
SCH or PGH Absent	64	32	96	0.513

Table 6: Inter-relationship of different TVS parameters and prediction value (n=34)

TVS Parameters	TP	TN	FP	FN	PPV	NPV	Diagnostic
							accuracy
MSD > 25 mm and Embryo Absent	14	50	0	13	100.00	79.37	83.12
CRL >4 mm and Cardiac Activity	6	60	2	13	75.00	82.19	81.48
Absent							
YSD>6 mm	4	66	0	30	100.00	68.75	70.00
EHR <= 100 min	2	57	1	11	66.67	83.82	83.10
SCH (subchorionic) or PGH	2	64	2	32	50.00	66.67	66.00
(perigestational hemorrhage) Present							
Abnormal USG: Threatened Abortion	19	7	4	0	82.61	100.00	86.67
Predictive	13	12	0	19	100.00	38.71	56.82
Abnormal USG	32	54	12	2	72.73	96.43	86.00

Table 7: Relationship of TVS parameters with Pregnancy Outcome in Threatened Abortion

TVS parameters	Live	Dead	Total	P value
MGSD > 25 mm and Embryo Absent	0	8	8	0.020
MGSD > 25 mm and Embryo Present	4	11	15	
CRL > 4 mm and Cardiac Activity Absent	1	4	5	0.867
CRL > 4 mm and Cardiac Activity Present	3	15	18	
Abnormal Yolk Sac	0	5	5	0.023
Not	4	14	18	
SCH or PGH	2	2	4	0.129
Neither	2	17	19	

Table 8: Inter-relationship between different abnormal parameters in threatened abortion and prediction value

TVS Parameters	TP	TN	FP	FN	PPV	NPV	Diagnostic Accuracy
MSD > 25 mm and	8	4	0	11	100	26.67	52.17
Embryo Absent							
CRL > 4 mm and Cardiac	4	3	1	15	80	16.67	30.43
Activity Absent							
Abnormal Yolk Sac	5	4	0	14	100	22.22	39.13
SCH or PGH	2	2	2	17	50	10.53	17.39

Discussion:

The study was conducted for one year. One hundred pregnant women attending antenatal clinic of this Institution at 5-12 weeks of gestation were included. In this study, 34% patients had abnormal pregnancy. Maximum patients belonged to the age group 26-30

which is 39. There were equal number of patients in the age group 21-25 and >30 which is 23 and there were 15 patients from ≤20 yrs. The increased risk with advancing maternal age has been attributed to the increasing risk of aneuploidies [5,6]. Buss L et al also reported that increasing maternal age has been found to be a risk factor for

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miscarriage [7]. In our study 49% patients were primigravida and rests were parous. In their study Kumari et al³ reported 30 % were primigravida patient and 32% of abortion occur in more than 30 years. There were increases tendency of early miscarriage (40%) among those who had previous history of abortion. Maximum abortion ocurred before 12 weeks (72% between 8-12weeks) and <4% abortion occurred after 12 weeks of gestation. 50% of patients with abnormally large yolk sac, 94% of patients with MSD>25 mm with absent embryo, 100% of patients with CRL>9mm and 100% with EHR<100bpm aborted. Brigham S et al [8] reported that initial period of conception is most vital as majority of the abortions occur before 12 weeks gestational age and fewer than 5% occur after identification of fetal heart activity. Second trimester loss, between 12-24 weeks, occurs less frequently and constitutes <4% of pregnancy outcomes [9]. Gestational sac (GS) is the first definitive landmark of pregnancy which is consistently visible by 5 weeks of gestation, even with TAS (Transabdominal Pregnancy), GS should be at least 10 mm larger than the CRL [10]. Higher rate of pregnancy loss is noted with a difference of less than 5 mm between GS and CRL [10]. In our study those who have abnormally large yolk sac aborted. In their study Jarjour et al.[11] reported 100% of patients with empty gestational sac aborted. We showed relationship between MGSD and pregnancy outcome. The p value is <0.001 which is significant. Hence this shows positive correlation with MSD>25 mm with absent embryo with early pregnancy failure. Embryo should be present where MSD is >25 mm. Approximately 94% of EPF occur in MSD>25 mm without an embryo [12]. Our study showed 100% abortion rate with MSD >25 mm without an embryo which signifies a very high positive correlation between MSD >25 mm without an embryo and incidence of early abortion. Fetal cardiac activity is the earliest proof of a viable pregnancy. The

cutoff CRL for detecting cardiac activity by TVS is 4 mm and by TAS is 9 mm [12, 13]. Our study showed relationship between CRL and pregnancy outcome. The p value was < 0.001 which was significant. Therefore, CRL >4mm with no embryo is an important predictive factor of early pregnancy failure. In our study 75% with CRL>4mm with absent cardiac activity aborted. The findings were correlated with study done by Pennell RG et al and Levi CS et al [12,13]. Chittacharoen A et al documented that a slow EHR at 7-9 weeks gestation is associated with high rate of first trimester pregnancy demise [14]. In our study 66.67% with EHR<100bpm aborted. So, evaluation of EHR as soon as possible in all pregnancies because regardless of the presence of symptoms, it is a consistent parameter in the outcome of pregnancy. Study done by Nuaim LA et al on the effects of intrauterine hemorrhage on pregnancy outcome showed that out of 92 (8.5%) patients with IUH, 20.70% patients aborted in the late first and early 2nd trimester of pregnancy [15]. In our study out of 4, where subchorionic and perigestational hemorrhage present 2 suffered from EPF and out of 96 where SCH and PGH absent 32 were aborted. We have not measured the size of hematoma in this study. But when outcome was assessed in relation to size of hematoma, 7 of 37 patients (19%) who had small hematoma (13.1cm2) aborted, compared with (21.8%) of 55 patients with large hematoma $(13.2 \text{cm}^2)^{15}$. In their study Preisler et al. 16 reported 100% specificity of MSD>25 mm with no embryo, 100% with CRL>7mm with absent cardiac activity. In this study PPV of MSD>25mm with absent embryo is 100% and CRL>4mm with absent cardiac activity is 75%.

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In our study out of 100 patients 23 suffered from threatened abortion and we have also shown the relationship between MGSD, CRL, morphology of yolk sac, PGH and pregnancy outcome in cases of threatened abortion. In cases of threatened abortion, there was 100%

PPV of MSD>25mm with no embryo, 80% of CRL>4mm with absent cardiac activity, 100% of abnormal yolk sac which was in association with study done by Kumari et al [3]. In this study 82.6% (19 out of 23) of patients with threatened abortion with abnormal TVS parameters aborted. In study done by Chritiansen et al [17], larger yolk sac was associated with increased odds of spontaneous abortion (OR=4.37, 95% CI 1.33-14.32; p=0.0149). In this study 100% of patients with large yolk sac aborted (p<0.001) and 100% of patients with abnormal morphology of yolk sac aborted (p=0.023). [18]

Conclusion

The first trimester of pregnancy is very important as 80% pregnancy loss occurs during this period. Transvaginal Sonography (TVS) with high resolution is superior to Transabdominal Sonography (TAS). TVS can help in early diagnosis of EPF in asymptomatic patients. Timely appearance of parameters like Gestational Sac, CRL, EHR, Yolk Sac and evaluation of retroplacental and perisac area can be used to predict pregnancy outcome. It can also help in taking decision whether to continue, abort or follow conservative management. TVS is important diagnostic tool in diagnosis and management of EPF. It can reduce the number of unnecessary terminations of pregnancy in patients with symptoms of EPF and can diagnose EPF in asymptomatic patients.

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