

ORIGINAL RESEARCH ARTICLE

Prediction of early pregnancy failure by use of first trimester ultrasound screening

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ABSTRACT

Background: Spontaneous miscarriage is defined as an involuntary termination of pregnancy before 20th week of gestation or spontaneous expulsion of fetus below a fetal weight of 500 gm. The introduction of ultrasound into the obstetrical practice has been extremely useful in providing better understanding of the etiology of the first trimester spontaneous abortion and a basis for its clinical classification and management. **Aims :** The aims of assess the early pregnancy developmental changes in first trimester ultrasound screening, to identify any abnormal ultrasound parameters, to correlate abnormal ultrasound findings with clinical outcome measured in terms of spontaneous or missed abortion. **Materials and Methods:** This prospective observational analytical study was conducted in Department of Obstetrics and Gynaecology, R.G. Kar medical college and hospital, Kolkata. Study was conducted from

February 2020 to July 2021. During the period 150 patients were included in the study as per inclusion criteria Thorough history taking and clinical examination was done. Template was generated in MS excel sheet and analysis was done on SPSS software. **Results:** The mean age in the present study was 23.9800 ± 2.8906 . In the study, 24 (16.0%) patients were Alcoholic, 20 (13.3%) patients were Smokers and 12 (8.0%) patients had Stress. In co-relation of age with Early pregnancy failure, 6 (10.9%) patients were 15-20 years of age, 30 (54.5%) patients were 21-25 years of age and 19 (34.5%) patients were 26-30 years of age. In co-relation with Early pregnancy failure, 30 (54.5%) patients were Booked Association of mean Age with Early pregnancy failure was not statistically significant. In patients with Early pregnancy failure, the mean USG UA RI (mean \pm s.d.) of patients was $.3945 \pm .0699$. Association of mean USG UA RI with Early pregnancy failure was not statistically significant **Conclusion:** We concluded that ultrasound screening in early pregnancy gave a reliable and accurate differentiation between a viable normal pregnancy and an abnormal/ pathological pregnancy.

Keywords: Early pregnancy failure, First trimester, Spontaneous abortion, Ultrasonographic screening

Introduction :

Spontaneous miscarriage is involuntary termination of pregnancy before 20th week of gestation or spontaneous expulsion of fetus below fetal weight of 500 gram¹. Approximately 12-24% of all pregnancies suffer miscarriages and most of the early miscarriages are caused by chromosomal abnormalities, and the risk of which increases with maternal age. Antenatal ultrasonography (USG) has revolutionized the management of early pregnancy failure. First trimester of pregnancy is the most important period of human development in which single cell transforms into a recognizable human being. USG plays an important role in assessing establishment and evaluation of early pregnancy. It also helps in diagnosing any untoward events in early pregnancy and may guide its appropriate management. Therefore, USG is an easily available tool to differentiate normal from abnormal pregnancy².

This study is aimed to assess the accuracy of first trimester USG markers as mean gestational sac diameter (MGSD), Yolk sac diameter (YS), Crown rump length (CRL), MGSD-CRL, Embryonic heart rate (EHR), Fetal pole, Yolk Sac morphology, Gestational Sac morphology, Decidual reaction, presence or absence of Subchorionic hematoma, Umbilical Artery Doppler RI in first trimester of pregnancy to predict the risk of early pregnancy failure (EPF). Also to assess the early pregnancy developmental changes in first trimester ultrasound screening, to identify any abnormal ultrasound parameters, to correlate abnormal ultrasound findings with clinical outcome measured in terms of spontaneous or missed abortion. This study also aims to analyse the success of conservative management on patients presented with threatened abortion on the basis of early ultrasound findings and to analyse the outcome of pregnancy up to 20 weeks.

Diagnostic ultrasound is a sophisticated electronic technology, which utilises pulses of high frequency sound to produce an image. A transducer which is moved across the area to be examined emits pulses of ultrasound which propagate through the tissues. Some pulses are

reflected back to the transducer which converts these returning echoes into electronic signals. The strength of the returning echo is determined by tissue interface characteristics. Returning signals are processed by a computer which displays each echo in both strength and position as an image on a screen. The quality of ultrasound imaging is dependent not only on the technical capabilities of the ultrasound equipment but also on the experience and expertise of the operator and standards are variable. Diagnostic ultrasound examination may be employed in a variety of specific circumstances during pregnancy, such as: after clinical complications (e.g. bleeding in early pregnancy); where the fetus is perceived to be at particularly high risk of malformation; and where there are concerns regarding fetal growth. Because adverse outcomes may also occur in pregnancies without clear risk factors, assumptions have been made that the routine use of ultrasound in all pregnancies will prove beneficial. The rationale for such screening would be the detection of clinical conditions which place the fetus or mother at high risk, which would not necessarily have been detected by other means such as clinical examination, and for which subsequent management would improve perinatal outcome. Routine screening examinations may be planned for early pregnancy, late gestation, or both. The focus of this review is routine early pregnancy ultrasound, late pregnancy screening will be addressed in another review.

The advent of high-resolution trans-vaginal ultrasound (TVS) has corroborated trans-abdominal ultrasonography (TAS) and went further to revolutionize our understanding of the pathophysiology and management of pregnancy³. First trimester pregnancy is defined as twelve weeks after the last menstrual period⁴. It is known to be the important period of organogenesis but could be fraught with high complication rate. This calls for a lot of dedication and circumspection on ultrasonographic evaluation in this crucial period. First and foremost, first trimester ultrasonography must establish the existence of pregnancy before any other meaningful assessment could continue. This assessment will then aim at visualizing viability, dating pregnancy, detecting multiple pregnancy, evaluating normal embryonic/foetal development, evaluating foetal gross anomaly, assessing nuchal translucency/ other markers, observing adnexal structures, observing uterine/ cervical lesions and detecting other special indications⁴. Therefore mastery of the spectrum of sonographic findings in the normal and abnormal first-trimester pregnancy equips the radiologist with the potentials to make accurate diagnoses and assists in appropriately guiding patient management⁵

The present study is aimed on first trimester Ultrasound Screening to find out whether there is any significant predictors which can give us a clue to the continuation of normal pregnancy or abnormal pregnancy resulting in Spontaneous abortion or Missed abortion or any other Early Pregnancy Failure

Materials and Methods

- **Study design / experimental design:** Prospective Observational Analytical Study
- **Study setting:** Hospital based study in R. G. Kar Medical College and Hospital, Kolkata among the patients admitted in Department of Obstetrics and Gynaecology.
- **Study Timeline:** February 2020 - July 2021(Total 18 months)

- **Place of study:** Department of Obstetrics and Gynaecology, R.G.Kar Medical College and hospital, Kolkata
- **Period of study:** February 2020 - July 2021 (Total 18 months)
- **Study population:** Catchment area of R.G Kar Medical College and Hospital
- **Sample size:** The trial conducted by Kumari et al, Tuladhar AS, Tuladhar AG, Karki DB, Shrestha A, Pradhan S Showed that the incidence of Early pregnancy failure was more in those patients with abnormal USG parameters as compared to those With normal USG parameters (Abnormal Vs Normal: 15% vs. 8.8%) Using these results as guidance data a sample size of 137 will be sufficient for a power 80% and α error = 0.05. A further 10% was included to account for missing data/technical failures or loss to follow up. Therefore, the Sample Size came as 150.

The formula used for calculation of Sample Size :

$$n = \frac{(Z_{\alpha} \sqrt{2p(1-p)} + Z_{\beta} \sqrt{P1(1-P1) + P2(1-P2)})^2}{(P1 - P2)^2}$$

- **Inclusion criteria :** All age, any parity, single intrauterine pregnancy, pregnant women with estimated gestational age of 5-12 weeks, subjects with accurate last menstrual period (LMP) with previous history of regular cycle and any subject of threatened abortion. 28 .Patients with past history of abortion are also included in the study.
- **Exclusion criteria :** Patient's refusal, multiple pregnancies, known uterine abnormalities, chronic diseases in pregnant women like; heart disease, diabetes, chronic hypertension, renal diseases, bronchial asthma, etc. Also patients who terminated their pregnancy electively or who lost to follow up were excluded from their study.⁶

Independent study variables like Age, BMI, Booking Status, Gravida, Parity, Gestational Age, Chief Complaints and Risk Factors like Smoking, Alcohol, Stress were recorded. Dependent variables like Mean gestational sac diameter, Yolk sac diameter, Morphology of yolk sac, Crown rump length, MGSD-CRL difference, Embryonic heart rate, Presence or Absence of Fetal Pole, Decidual Reaction, Subchorionic Hematoma, Morphology of Gestational sac, Umbilical Artery Doppler RI, On Progesterone Support and Early Pregnancy Failure Outcome were also recorded.

Statistical Analysis: Data was entered into Microsoft Excel data sheet and analysed using SPSS 22 version software. Categorical data was represented in the form of frequencies and proportions. Chi- square was used as test of significance. P value <0.05 was considered statistically significant. Ethical clearance was obtained through proper channel from the review and ethics committee of the institution

Results

This institutional based Prospective Observational Analytical Study was conducted in R. G. Kar Medical College and Hospital, Kolkata, West Bengal, India. Study was conducted from February 2020 to July 2021. During the period 150 Patients were included in the study as per inclusion criteria.

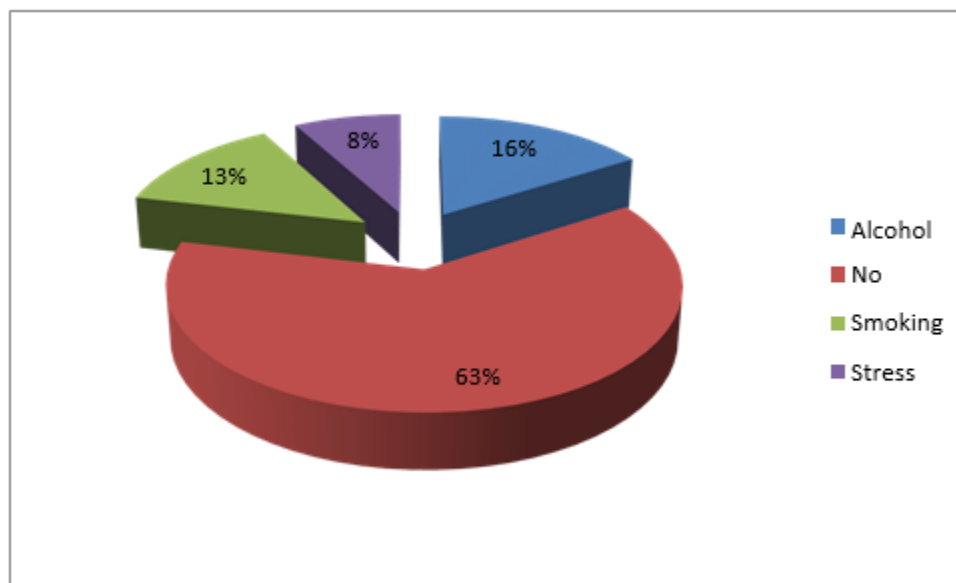
Table 1: Distribution according to independent study variables

Age Group	Frequency	Percentage (%)	Booked Status	Frequency	Percentage (%)
15-20	15	10.0%	No	66	44.0%
21-25	84	56.0%	Yes	84	56.0%
26-30	51	34.0%	Parity		
Total	150	100.0%	P0+0	81	54.0%
Gravida			P0+1	45	30.0%
G1	88	58.7%	P0+2	12	8.0%
G2	44	29.3%	P0+3	6	4.0%
G3	12	8.0%	P1+0	6	4.0%
G4	6	4.0%	Gestational age		
Chief complaint			>8 weeks	44	29.3
Bleeding	44	29.3%	8-12 weeks	100	66.7
Pain	62	41.3%	>12 weeks	6	4
Spotting	44	29.3%	Previous EPL		
Spontaneous/MART			No	93	62.0%
MART	31	20.7%	Yes	57	38.0%
Spontaneous	119	79.3%	Yolk sac morphology		
Fetal pole			Calcified	14	9.7%
Absent	38	25.3%	Irregular	6	4.2%
Present	112	74.7%	Round	124	86.1%
Subchorionic hematoma			SAC Morphology		
62ml	6	4.0%	Irregular	12	8.0%
65ml	6	4.0%	Regular	138	92.0%
68ml	6	4.0%	Early pregnancy failure		
Absent	132	88.0%	No	95	63.3%
Progesterone support			Yes	55	36.7%
No	58	38.7%			
Yes	92	61.3%			

In the present study, 15 (10.0%) patients were 15-20 years of age, 84 (56.0%) patients were 21-25 years of age and 51 (34.0%) patients were 26-30 years of age. In the study, 84

(56.0%) patients had Booked. In the study, 88 (58.7%) patients were G1, 44 (29.3%) patients were G2, 12 (8.0%) patients were G3 and 6 (4.0%) patients were G4. In the study, 81 (54.0%) patients were P0+0, 45 (30.0%) patients were P0+1, 12 (8.0%) patients were P0+2, 6 (4.0%) patients were P0+3 and 6 (4.0%) patients were P1+0 in Parity. In our study, gestational age of 44 (29.3%) patients were >8 weeks, 100 (66.7%) patients were 8-12 weeks and 6 (4%) patients were >12 weeks. In our study, 44 (29.3%) patients had Bleeding, 62 (41.3%) patients had Pain and 44 (29.3%) patients had Spotting. In our study, 31 (20.7%) patients conceived through MART and 119 (79.3%) patients conceived Spontaneously. In our study, 57 (38.0%) patients had Previous EPL. In our study, in 112 (74.7%) patients Fetal pole appeared. In our study, 14 (9.7%) patients had Calcified yolk sacs, 6 (4.2%) patients had Irregular yolk sacs and 124 (86.1%) patients had Round yolk sac in morphology. In our study, 6 (4.0%) patients had a Subchorionic hematoma measuring 62ml, 6 (4.0%) patients had a Subchorionic hematoma measuring 65ml, 6 (4.0%) patients had a Subchorionic hematoma measuring 68ml. In our study, 12 (8.0%) patients had Irregular G-SAC Morphology, 138 (92.0%) patients had Regular G-SAC Morphology. In our study, 92 (61.3%) patients were on Progesterone support. In our study, 55 (36.7%) patients had Early pregnancy failure. (Table 1)

Figure 1: Distribution on the basis of risk factors



In our study, 24 (16.0%) patients were Alcoholic, 20 (13.3%) patients were Smokers and 12 (8.0%) patients had Stress in the form of very poor financial status, domestic violence and due to past history of Early Pregnancy loss. Also, in a few patients with pregnancy occurring after some infertile period, stress factor was present. (Figure 1)

Table 2: Distribution of mean findings of different parameters

Parameters	Number	Mean	SD	Minimum	Maximum	Median
Age	150	23.9800	2.8906	18.0000	30.0000	24.0000
BMI	150	22.0480	1.8665	17.5000	26.0000	22.3000
Embryonic heart rate	150	130.7410	10.1820	98.0000	142.0000	136.0000
MSD	150	28.1400	5.3408	18.0000	40.0000	29.0000
MSD-CRL	112	9.9691	3.2987	3.0000	14.0000	12.0000
YSD	144	5.3750	1.3937	4.0000	9.0000	5.0000
Decidual reaction	150	4.9400	1.1941	3.0000	8.0000	5.0000
USG UA doppler RI	150	.3917	.0631	0.3200	0.5900	0.3900

In above table showed that the mean Age (mean±s.d.) of patients was 23.9800± 2.8906. Mean BMI (mean±s.d.) of patients was 22.0480± 1.8665. Mean Embryonic heart rate (mean±s.d.) of patients was 130.7410± 10.1820. Mean MSD (mean±s.d.) of patients was 28.1400± 5.3408. Mean MSD-CRL (mean±s.d.) of patients was 9.9691±3.2987. Mean YSD (mean±s.d.) of patients was 5.3750± 1.3937. Mean Decidual reaction (mean±s.d.) of patients was 4.9400± 1.1941. Mean USG UA doppler RI (mean±s.d.) of patients was .3917±.0631. (Table 2)

Table 3: Association between different parameters and early pregnancy failure.

EARLY PREGNANCY FAILURE				
Age in group	NO	YES	TOTAL	P-value
15-20	9 (9.5%)	6 (10.9)	15 (10%)	Chi-square: .1122; p-value:0.9455
21-25	54 (56.8%)	30 (54.5%)	84 (56%)	
26-30	32 (33.7%)	19 (34.5%)	51 (34%)	
TOTAL	95 (100%)	55 (100%)	150 (100%)	
Booked				Chi-square: 0.0746; p-value:0.7848 Odds ratio:0.9111 (0.4670,1.7774)
No	41 (43.2%)	25 (45.5%)	66 (44%)	
Yes	54 (56.8%)	30 (54.5%)	84 (56%)	
Chief complaint				Chi-square: 17.8552; p-value:0.0001
Bleeding	19 (20.0%)	25 (45.5)	44 (29.3%)	
Pain	38 (40%)	24 (43.6%)	62 (41.3%)	

Spotting	38 (40%)	6 (10.9%)	44 (29.3%)	Chi-square: 5.0430; p-value:0.0247 Odds ratio:2.9167 (1.1135,7.6397)
Spontaneous/mart				
Art	25 (26.3%)	6 (10.9%)	31 (20.7%)	
Spontaneous	70 (73.7%)	49 (89.1%)	119 (79.3%)	Chi-square vlue: 2.0483; p-value:0.1523 Odds ratio:1.6406 (0.8310,3.2392)
Previous EPL				
No	63 (66.3%)	30 (54.5%)	93 (62%)	
Yes	32 (33.7%)	25 (45.5%)	57 (38%)	

In co-relation of age with Early pregnancy failure, 6 (10.9%) patients were 15-20 years of age, 30 (54.5%) patients were 21-25 years of age and 19 (34.5%) patients were 26-30 years of age. Association of Age in group with Early pregnancy failure was not statistically significant ($p=0.9455$). In co-relation with Early pregnancy failure, 30 (54.5%) patients were Booked. Association of Booked with Early pregnancy failure was not statistically significant ($p=0.7848$). In patients with Early pregnancy failure, 25 (45.5%) patients had Bleeding, 24 (43.6%) patients had Pain and 6 (10.9%) patients had Spotting. Association of Chief complaint with Early pregnancy failure was statistically significant ($p<0.0001$). In patients with Early pregnancy failure, 6 (10.9%) patients conceived through ART and 49 (89.1%) patients conceived Spontaneously. Association of Spontaneous conception/MART with Early pregnancy failure was statistically significant ($p=0.0247$). In patients with Early pregnancy failure, 25 (45.5%) patients had Previous EPL. Association of Previous EPL with Early pregnancy failure was not statistically significant ($p=0.1523$). (Table 3)

Table 4: Association between different mean parameters and early pregnancy failure.

Mean parameters		Number	Mean	SD	Minimum	Maximum	Median	p-value
Age	No	95	24.0105	2.8565	19.0000	30.0000	24.0000	0.8657
	Yes	55	23.9273	2.9743	18.0000	30.0000	24.0000	
BMI	No	95	21.9979	1.7895	17.5000	26.0000	22.3000	0.6672
	Yes	55	22.1345	2.0067	18.5000	26.0000	22.0000	
Embryonic heart rate	No	95	135.8095	5.1850	122.0000	142.0000	137.5000	≤ 0.0001
	Yes	55	124.2244	11.2852	98.0000	138.0000	124.0000	
MSD	No	95	27.6526	6.5392	18.0000	40.0000	29.0000	0.1424
	Yes	55	28.9818	1.7690	26.0000	32.0000	28.0000	

MSD-CRL	No	95	10.4761	3.4588	3.0000	14.0000	12.0000	0.9654
	Yes	55	10.5535	3.1048	3.0000	14.0000	12.0000	
YSD	No	95	5.2697	1.2132	4.0000	9.0000	5.0000	0.2500
	Yes	55	5.5455	1.6422	4.0000	9.0000	5.0000	
Decidual reaction	No	95	5.2316	1.1710	4.0000	8.0000	5.0000	<0.0001
	Yes	55	4.4364	1.0674	3.0000	7.0000	4.0000	
USG UA doppler RI	No	95	.3900	.0591	0.3200	0.5900	0.3800	0.6721
	Yes	55	.3945	.0699	0.3200	0.5700	0.4000	

In patients without Early pregnancy failure, the mean Age (mean± s.d.) of patients as 24.0105± 2.8565. In patients with Early pregnancy failure, the mean Age (mean± s.d.) of patients was 23.9273± 2.9743. Association of mean Age with Early pregnancy failure was not statistically significant (p=0.8657). In patients without Early pregnancy failure, the mean BMI (mean± s.d.) of patients was 21.9979± 1.7895. In patients with Early pregnancy failure, the mean BMI (mean± s.d.) of patients was 22.1345± 2.0067. Association of mean BMI with Early pregnancy failure was not statistically significant (p=0.6672). In patients without Early pregnancy failure, the mean Embryonic heart rate (mean± s.d.) of patients was 135.8095± 5.1850. In patients with Early pregnancy failure, the mean Embryonic heart rate (mean± s.d.) of patients was 124.2244± 11.2852. Association of mean Embryonic heart rate with Early pregnancy failure was statistically significant (p≤0.0001). In patients without Early pregnancy failure, the mean MSD (mean± s.d.) of patients was 27.6526± 6.5392. In patients with Early pregnancy failure, the mean MSD (mean± s.d.) of patients was 28.9818± 1.7690. Association of mean MSD with Early pregnancy failure was not statistically significant (p=0.1424). In patients without Early pregnancy failure, the mean MSD-CRL (mean± s.d.) of patients was 10.4761± 3.4588. In patients with Early pregnancy failure, the mean MSD-CRL (mean± s.d.) of patients was 10.5535± 3.1048. Association of mean MSD-CRL with Early pregnancy failure was not statistically significant (p=0.9654). In patients without Early pregnancy failure, the mean YSD (mean± s.d.) of patients was 5.2697± 1.2132. In patients with Early pregnancy failure, the mean YSD (mean± s.d.) of patients was 5.5455± 1.6422. Association of mean YSD with Early pregnancy failure was not statistically significant (p=0.2500). In patients without Early pregnancy failure, the mean Decidual reaction (mean± s.d.) of patients was 5.2316± 1.1710. In patients with Early pregnancy failure, the mean Decidual reaction (mean± s.d.) of patients was 4.4364± 1.0674. Association of mean Decidual reaction with Early pregnancy failure was statistically significant (p<0.0001). In patients without Early pregnancy failure, the mean USG UA RI (mean± s.d.) of patients was .3900± .0591. In patients with Early pregnancy failure, the mean USG UA RI (mean± s.d.) of

patients was $.3945 \pm .0699$. Association of mean USG UA RI with Early pregnancy failure was not statistically significant ($p=0.6721$).

DISCUSSION

This Prospective Observational Analytical Study was conducted in R. G. Kar Medical College and Hospital among the patients admitted in Department of Obstetrics and Gynaecology from February 2020 - July 2021.

Patients of all age, any parity, single intrauterine pregnancy, pregnant women with estimated gestational age of 5-12 weeks, subjects with accurate last menstrual period (LMP) with previous history of regular cycle and any subject of threatened abortion were included in this study.

In the present study, 15 (10.0%) patients were 15-20 years of age, 84 (56.0%) patients were 21-25 years of age and 51 (34.0%) patients were 26-30 years of age. The mean Age of patients was 23.9800 ± 2.8906 years. In our study, 84 (56.0%) patients were Booked. It was found that, 88 (58.7%) patients had G1, 44 (29.3%) patients had G2, 12 (8.0%) patients had G3 and 6 (4.0%) patients had G4. 81 (54.0%) patients had P0+0, 45 (30.0%) patients had P0+1, 12 (8.0%) patients had P0+2, 6 (4.0%) patients had P0+3 and 6 (4.0%) patients had P1+0 in Parity. As per Table 5, Our study showed that, 19 (12.7%) patients were 10+2wks, 6 (4.0%) patients were 10+3wks, 13 (8.7%) patients were 11+2wks, 6 (4.0%) patients were 12+4wks, 8 (5.3%) patients were 6+1wks, 6 (4.0%) patients were 6+2wks, 6 (4.0%) patients were 6+3wks, 6 (4.0%) patients were 6+4wks, 6 (4.0%) patients were had 7+1wks, 6 (4.0%) patients were 7+3wks, 6 (4.0%) patients were 7+5wks, 12 (8.0%) patients were 8+2wks, 18 (12.0%) patients were 8+3wks, 14 (9.3%) patients were 8+4wks, 6 (4.0%) patients were 9+4wks and 12 (8.0%) patients were 9+5wks in Gestational age.

Jurkovic D et al⁷ found that most miscarriages resolve spontaneously and expectant management should be offered as the first line management strategy. Emergency surgery is indicated in women presenting with severe pain or bleeding and in those with signs of infection. **Bottomley** C et al⁸ found that limitation is the absence of information on either bleeding or pain in 18% of women. Caution should be exercised before implementation of this scoring system prior to further external validation studies.

In the present study, 44 (29.3%) patients had Bleeding, 62 (41.3%) patients had Pain and 44 (29.3%) patients had Spotting. 31 (20.7%) patients conceived through ART and 119 (79.3%) patients conceived Spontaneously. 57 (38.0%) patients had Previous EPL. Present study showed that in patients with Early pregnancy failure, 25 (45.5%) patients had Bleeding, 24 (43.6%) patients had Pain and 6 (10.9%) patients had Spotting. This was statistically significant ($p<0.0001$). We observed that, 24 (16.0%) patients were Alcoholic, 20 (13.3%) patients had a habit of Smoking and 12 (8.0%) patients had Stress. In our study, 112 (74.7%) patients had Fetal pole appearance on Ultrasound. As per Table 11, It was found that, 14 (9.7%) patients had Calcified, 6 (4.2%) patients had Irregular and 124 (86.1%) patients had Round Yolk sac morphology. In our study, 6 (4.0%) patients had Subchorionic hematoma measuring 62ml, 6 (4.0%) patients had Subchorionic hematoma measuring 65ml, 6 (4.0%) patients had

Subchorionic hematoma measuring 68ml. We found that, 12 (8.0%) patients had Irregular G-SAC Morphology, 138 (92.0%) patients had G-SAC Morphology. 92(61.3%) patients were on Progesterone support. In our study 55(36.7%) patients had an outcome of Early pregnancy failure. We found that the mean BMI (mean±s.d.) of patients was 22.0480±1.8665. The mean Embryonic Heart Rate (mean±s.d.) of patients was 130.7410±10.1820. The mean MSD (mean±s.d.) of patients was 28.1400± 5.3408. The mean MSD-CRL (mean±s.d.) of patients was 9.9691±3.2987. The mean YSD(mean±s.d.) of patients was 5.3750± 1.3937. The mean Decidual reaction(mean±s.d.) of patients was 4.9400± 1.1941. The mean USG UA doppler RI (mean±s.d.) of patients was .3917± .0631. Our study showed that in patients with Early pregnancy failure, 6 (10.9%) patients were 15-20 years of age, 30 (54.5%) patients were 21-25 years of age and 19 (34.5%) patients were 26-30 years of age. This was not statistically significant (p=0.9455).

was found that in patients with Early pregnancy failure, 31 (56.4%) patients had G1,18 (32.7%) patients had G2 and 6 (10.9%) patients had G3 which was not statistically significant (p=0.1861). We also found that in patients with Early pregnancy failure, 24 (43.6%) patients had P0+0, 19 (34.5%) patients had P0+1,6 (10.9%) patients had P0+2and 6 (10.9%) patients had P1+0 in Parity. This was statistically significant (p=0.0019). Our study showed that in patients with Early pregnancy failure, 6 (10.9%) patients conceived through ART and 49 (89.1%) patients conceived Spontaneously which was statistically significant (p=0.0247).

Deti L et al⁹ found that in the pregnancies which failed, all the parameters showed significant changes, with different temporal onsets: GS and YS were the first to become abnormal, deviating from normality as early as 6 weeks' gestation (OR 0.01, 95% CI 0.0– 0.09, and OR 3.36, 95% CI 1.53–7.34, respectively), followed by changes in HR, and CRL, which became evident at 7 and 8 weeks (OR 0.96, 95% CI 0.92–1.0, and OR 0.59, 95% CI 0.48–0.73, respectively). Their observations showed that, after 5 complete weeks' gestation, a small GS and a large YS reliably predicted pregnancy loss. The YS reliably identified the occurrence of a miscarriage at least 7 days prior its occurrence. CRL and HR became abnormal at a later time in pregnancy and closer to the event.

In the present study in patients with Early pregnancy failure, 49 (89.1%) patients had Fetal pole and this was statistically significant (p=0.0019). It was found that In patients with Early pregnancy failure, 6 (10.9%) patients had Irregular Yolk sac morphology and 49 (89.1%) patients had Round Yolk sac morphology. This was statistically significant (p<0.0001).

Jauniaux E et al¹⁰ found that the maternal circulation inside the placenta starts at the periphery at around 9 weeks of gestation and that this is associated with a physiological oxidative stress which could be the trigger for the formation of the placental membranes.

In the present study patients with Early pregnancy failure, 6 (10.9%) patients had Subchorionic hematoma measuring 68ml. patients with Early pregnancy failure, 6 (10.9%) patients had Irregular G-SAC Morphology, 49 (89.1%) patients had Regular G-SAC Morphology. In patients with Early pregnancy failure, 26 (47.3%) patients were on Progesterone support and it was statistically significant (p<0.0001).

DeVilbiss EA et al¹¹ found that total of 64 women experienced a clinical pregnancy loss following the first ultrasound (10.4%), 7 were lost to follow-up (1.1%), and 546 women (88.5%) had a live birth. Low fetal heart rate and small crown-rump length (≤ 122 , 123, and 158 bpm; ≤ 6.0 , 8.5, and 10.9 mm for gestational weeks 6, 7, and 8, respectively) were independent predictors of clinical pregnancy loss, with greatest risks observed for pregnancies having both characteristics (relative risk, 2.08; 95% confidence interval, 1.24–2.91).

Shah KH et al¹² showed that significant association of age, symptoms like bleeding per vagina, suprapubic pain, and low GSD, CRL, HR, and difference of GSD CRL with EPL ($p < 0.05$). Detection of EPL was highest for HR below 5th centile (57%).

Present study showed that in patients without Early pregnancy failure, the mean MSD (mean \pm s.d.) of patients was 27.6526 ± 6.5392 . In those with Early pregnancy failure, the mean MSD (mean \pm s.d.) of patients was 28.9818 ± 1.7690 . patients without Early pregnancy failure, the mean MSD-CRL (mean \pm s.d.) of patients was 10.4761 ± 3.4588 . In those with Early pregnancy failure, the mean MSD-CRL (mean \pm s.d.) of patients was 10.5535 ± 3.1048 .

Datta MR et al¹³ found that among 800 women, 140 (17.5%) experienced early spontaneous abortion. CRL, GSD, and FHR values below the 5th percentile (odds ratio [OR] 26.48, 26.94, and 100.63, respectively), and YSD above the 95th percentile (OR 1.04) were predictors of early abortion.

Bottomley C et al⁸ found that the scoring system using significant demographic variables alone (maternal age and amount of bleeding) to predict ongoing viability gave an AUC of 0.724 (95% CI = 0.692–0.756) in the training set and 0.729 (95% CI = 0.684–0.774) in the test set.

Küçük T et al¹⁴ found that yolk sac diameter out of two standard deviations of the mean for the menstrual age allowed prediction of an abnormal pregnancy outcome with a sensitivity of 65 %, a specificity of 97 %, a positive predictive value of 71 %, and a negative predictive value of 95%.

Our study showed that in patients without Early pregnancy failure, the mean YSD (mean \pm s.d.) of patients was 5.2697 ± 1.2132 and in those with Early pregnancy failure, the mean YSD (mean \pm s.d.) of patients was 5.5455 ± 1.6422 which was not statistically significant ($p=0.2500$). Without Early pregnancy failure, the mean Decidual reaction (mean \pm s.d.) of patients was 5.2316 ± 1.1710 and in those with Early pregnancy failure, the mean Decidual reaction (mean \pm s.d.) of patients was 4.4364 ± 1.0674 which was statistically significant ($p < 0.0001$).

Limitations of the study :

In spite of every sincere effort my study has lacunae. The sample size was small. A larger sample size will be more accurate regarding conclusion of the study points. The study has been done in a single centre. Multicentric trial will be more conclusive. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out. Ongoing COVID 19 pandemic and lockdown has further hampered the study.

Conclusion :

We concluded that ultrasound screening in early pregnancy gave a reliable and accurate differentiation between a viable normal pregnancy and an abnormal/ pathological pregnancy. We also concluded that Incidence of Early Pregnancy failure was seen more in those patients with Abnormal Ultrasound parameters as compared to those with normal ultrasound parameters.

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