

## A Study Evaluate the Embryonic Fetal Heart Rate as Prognostic Factor of First Trimester Pregnancy Outcome: Prospective Observational Study

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### Abstract

**Aim:** to evaluate the heart rate as prognostic factor of first trimester pregnancy outcome.

**Materials and Method:** This prospective observational study was performed in the department of Obstetrics and Gynecology, Lady Hardinge Medical College, New Delhi. This study was conducted in 230 pregnant women who had satisfied inclusion and exclusion criteria. Detailed history like chief complaints, past history, present history, and family history was taken. After that detailed examination- general physical examination, systemic examination, per speculum, and per vaginal examination was done. Gestational age was calculated by last menstrual period. Each participant was subjected to transvaginal ultrasonography. Philips HD 11xE model ultrasound machine was used which had transvaginal probe of frequency 6-9MHz. All scans were performed by a single sonographer. All scans were performed by a single sonographer. On sonography embryonic fetal heart rate was estimated by M-mode

**Results:** Total subjects participated in the study were 230, minimum and maximum ages were 19 years and 38 years respectively. Mean age was  $27.68 \pm 4.38$ -year, maximum number of woman 128/230 (55.7%) were in the age group of 23-30 year. Based on ROC analysis cut off value of Heart Rate that predict the abortion was  $<110$ b/m. Out of 230 women small yolk sac ( $<3.5$ mm) was observed in 17(7.39%) women. Out of 230 subjects 23 (10%) women were found to have decreased embryonic heart rate ( $<110$ ) and out of these 23 women 14 (60.8%) women had abortion and remaining 9 (39.1%) women had continued the pregnancy.

**Conclusion:** Suggested that abnormal embryonic heart rate is associated with poor outcomes.

**Keywords:** heart rate, outcome, sonography

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**Introduction**

The cardiovascular system is the first system to function in the embryo. Contractions of the heart begin by day 21 after conception, so the detection of embryonic heart rate and measurement of it are the earliest functional parameters that can be assessed in embryonic life, probably informing us about the normal development and physiological maturation of the cardiovascular system and reported to be useful in the prediction of the pregnancy outcome.[1]

A normal fetal heart rate (FHR) usually ranges from 120 to 160 beats per minute (bpm) in the in utero period. It is measurable sonographically from around 6 weeks and the normal range varies during gestation, increasing to around 170 bpm at 10 weeks and decreasing from then to around 130 bpm at term.[2,3]

The embryonic heartbeat can usually be identified at prenatal ultrasonography (US) by 6 weeks gestation, and the heart rate can be measured via M mode. Several studies have demonstrated that a slow embryonic heart rate early in pregnancy, 6.0–7.0 weeks gestation, is associated with a high rate of subsequent fetal demise by the end of the first trimester. It is demonstrated that a heart rate below 80 beats per minute at 6.0–6.2 weeks gestation or below 100 beats per minute at 6.3–7.0 weeks is associated with a very high rate of first-trimester demise, a heart rate of 80–89 beats per minute at 6.0–6.2 weeks or 100–109 beats per minute at 6.3–7.0 weeks is associated with a moderately high rate of demise, and a heart rate of 90–99 beats per minute at 6.0–6.2 weeks or 110–119 beats per minute at 6.3–7.0 weeks is associated with a mildly elevated rate of demise. When there is a demise of pregnancy following a slow embryonic heart rate early in pregnancy, the demise often occurs within 1 week after the slow heart rate is first detected and almost always occurs by the end of the first trimester.[4,5] The study was done to

evaluate the embryonic fetal heart rate as prognostic factor of first trimester pregnancy outcome.

**Materials and Methods**

This prospective observational study was performed in the Department of Obstetrics and Gynecology, New Delhi. This study was conducted in 230 pregnant women who had satisfied inclusion and exclusion criteria.

**Sample size estimation**

(Researchers have reported the abortion figures in Indian population to lie between 9.8% (Sebastian et al., 2014)<sup>6</sup> to 20% (Abortion: Facts and Figures, 2011)<sup>7</sup>. Therefore, assuming 15% as the incidence of abortion and 5% margin of error, the minimum required sample size at 5% level of significance was 196 patients).

**Inclusion Criteria:**

- Singleton pregnancy.
- With period Gestation  $\leq$  10week on ultrasonography.
- Embryo with positive cardiac activity on ultrasonography.

**Exclusion Criteria**

- Women having bleeding per vagina with pregnancy of  $\leq$ 10week were excluded from study.

**Methodology**

This prospective observational study was conducted in the department of Obstetrics and Gynecology, Lady Hardinge Medical College, New Delhi. Cases were selected out of a cohort of women attending the Gynae OPD who had early pregnancy. 230 women with pregnancy  $\leq$ 10week were included in the study. Detailed history like chief complaints, past history, present history, and family history was taken. After that detailed examination- general physical examination, systemic examination, per speculum and per vaginal examination was

done. Gestational age was calculated by last menstrual period. Each participant was subjected to transvaginal ultrasonography. Philips HD 11xE model ultrasound machine was used which had transvaginal probe of frequency 6-9MHz. All scans were performed by a single sonographer. On sonography embryonic fetal heart rate was estimated by M-mode. Women were followed till the end of 14 week of pregnancy. Result of ultrasonography was correlated with pregnancy outcome in first trimester of pregnancy.

Statistical methods:

The quantitative variables were evaluated using unpaired t-test. The qualitative variables were compared using Chi-square test. ROC curves were made to find the critical values of quantitative variables to predict abortion. Sensitivity, specificity, PPV, NPV was calculated for the critical values. A p-value < 0.05 was assumed statistically significant. Statistical Package for Social Sciences (SPSS) version 15.0 was used for analysis.

## Results

**Table 1: Age distribution**

Age group	Number of subjects	Percentage
< 20 YEARS	4	1.7
20-30 YEARS	128	55.7
>30 YEARS	98	42.6
Total	230	100.0

Total subjects participated in the study were 230, minimum and maximum age were 19 years and 38 years respectively. Mean age was  $27.68 \pm 4.38$  years, maximum number of woman 128/230 (55.7%) were in the age group of 23-30 year.

**Table 2: Distribution based on fetal indices**

Indices	N	Minimum	Maximum	Mean	Std. Deviation
POG (weeks)	230	6	10	7.98	1.019
CRL( cm)	230	0.40	4.80	2.3197	.92318
FHR(b/m)	230	78	176	152.70	25.735
Yolk sac(mm)	230	2.07	8.2	5.1132	.91213

Period of gestation varied from 6 week to 10 week with mean of  $7.8 \pm 1.02$  week. Fetal Heart rate  $152.70 \pm 25.735$

**Table 3: ROC analysis to predict abortion using Heart Rate**

Area under the curve (AUC)	Standard error	Asymptotic 95% Confidence Interval		P value
		Lower Bound	Upper Bound	
0.863	0.049	0.767	0.960	<0.001

Based on ROC analysis cut off value of Heart Rate that predict the abortion was <110b/m.

**Table 4: Validity of heart rate in predicting abortion**

Validity	Values (95% Confidence interval)
Sensitivity (%)	60.86 (61.43 – 92.29)
Specificity (%)	94.20 (85.56 – 94.18)
PPV (%)	53.84 (44.27 – 66.76)
NPV (%)	95.58 (93.64 – 98.41)
Accuracy (%)	90.86 (84.37 – 92.84)

Sensitivity in prediction was 60.86%, specificity 94.2%, positive predictive value 53.84%, negative predictive value 95.58% and accuracy was 90.86%.

**Table 5: Total adverse outcome as per embryonic heart rate**

EHR	CONTINUING		TOTAL	P VALUE
	YES	NO		
< 110/MIN	<b>9</b>	<b>14</b>	23	<0.001
	39.1%	60.9%	100.0%	
>/= 110/MIN	<b>195</b>	<b>12</b>	207	
	94.2%	5.8%	100.0%	
TOTAL	204	26	230	
	88.7%	11.3%	100.0%	

Out of 230 subjects 23 (10%) women were found to have decreased embryonic heart rate (<110) and out of these 23 women 14 (60.8%) women had abortion and remaining 9 (39.1%) women had continued the pregnancy.

### Discussion

Contractions of the heart begin by day 21 after conception, so the detection of embryonic heart rate and measurement of it are the earliest functional parameters that can be assessed in embryonic life, probably informing us about the normal development and physiological maturation of the cardiovascular system and reported to be useful in the prediction of the pregnancy outcome.[7,8]

In present study out of 230 subjects 23(10%) women were found to have decreased embryonic heart rate (<110) and out of these 23 women, 14(60.8%) women had abortion and remaining 9 (39.1%) women had continued the pregnancy. Mean value of embryonic heart rate in women who had abortion was  $119.31 \pm 39.716$  as compared to  $156.96 \pm 19.793$  in women who had continued the pregnancy. The difference between two groups was statistically significant ( $p < 0.001$ ) with a sensitivity of 60.86%, specificity of 94.20%, positive predictive value of 53.84%, negative predictive value of 95.58% suggesting that abnormal embryonic heart rate is associated with poor pregnancy outcomes. These results were consistent with a study done by Neemat

Mohamed et al reporting that embryonic heart rate at less than 110 bpm was associated with a high likelihood of pregnancy loss. The sensitivity, specificity, positive and negative predictive value, and accuracy were 43.1%, 86%, 40.7%, 87.2%, and 78.2%, respectively.[9] Embryonic heart rate can be an independent predictor of the outcome of pregnancy in women with intrauterine pregnancy complaining of first trimester bleeding. Similarly in a study conducted by Doubilet PM1, et al where they reported that the short- and long-term outcomes were significantly different from those of the control group of embryos with normal early heart rates ( $p > 0.20$ , Fisher's exact test). Pregnancies in which the embryo has a rapid early heart rate have a good prognosis, with a high likelihood of normal outcome.[4] Similar study done by Stefos, et al. explained that a heart rate between 116 and 125 beats/min was associated with the fewest losses in the age group between 42-45 days and in 46-49 days of gestations. However fewest losses of fetuses in age group between 50-52 days and 53-56 days were related with heart beat of 146 beats/min. Heart rate below 85 beats/min in age group of 6-8 weeks did not survive.[10]

### Conclusion

Mean value of embryonic heart rate in women who had abortion was  $119.31 \pm 39.716$  as compared to  $156.96 \pm 19.79$  in women whom the pregnancy continued, with a sensitivity of

60.86%, specificity of 94.20%, positive predictive value of 53.84%, and negative predictive value of 95.58% suggesting that abnormal embryonic heart rate is associated with poor outcomes.

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