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Original Research Article

Single serum progesterone measurement: a key diagnostic and prognostic tool in threatened abortion

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ABSTRACT

Background: Miscarriage represents a prevalent complication during pregnancy, often leaving both patients and healthcare providers grappling with the anxiety of distinguishing viable from nonviable pregnancies in a timely manner. Identifying a highly sensitive and specific biomarker for this purpose could greatly enhance early intervention strategies. Progesterone has emerged as a significant biomarker for early pregnancy failure. This study aims to assess the effectiveness of a single serum progesterone measurement in cases of threatened abortion and its correlation with pregnancy outcomes.
Methods: Conducted at the Gynaecology and Obstetrics Department of Sir Salimullah Medical College and Mitford Hospital in Dhaka between January and June 2020, this cross-sectional study included 60 women. Group I consisted of 30 patients (6 to 12 weeks of gestation) with vaginal bleeding, while Group II comprised 30 women with normal viable pregnancies of the same gestational age.
Results: The mean age was approximately 24.87±3.79 years in Group I compared to 23.7±4.19 years in Group II. Notably, the mean serum progesterone levels were significantly different, with Group I showing 51.02±30.77 ng/ml versus 80.39±20.68 ng/ml in Group II ($p<0.05$). At 22 weeks of pregnancy, 60.0% of patients in Group I and 100.0% in Group II had viable outcomes, which was statistically significant ($p<0.05$). A serum progesterone cut-off value of ≥61 ng/ml demonstrated an 86.7% sensitivity and 70.0% specificity for predicting threatened abortion.
Conclusions: Serum progesterone levels significantly differentiate between cases of threatened abortion and normal pregnancies, establishing it as a reliable marker for early pregnancy failure.

Keywords: Cut-off level, Miscarriage, Predictive, Progesterone

INTRODUCTION

Threatened abortion presents a significant clinical challenge for obstetricians, characterized by vaginal spotting or bleeding, a closed cervical os, and potential mild uterine cramps in women less than 20 weeks of gestation.[1] This condition may lead to either a viable pregnancy or various forms of abortion, including incomplete, complete, missed, or septic abortion. It is the most common pregnancy complication during the first half of gestation, with approximately 20% of early pregnancies affected.[2,3] While many threatened pregnancies continue to

term, spontaneous abortion affects less than 30% of women in this category.[2]

Steroid hormones, particularly estrogen and progesterone, are pivotal for maintaining pregnancy. Estrogen contributes to the growth and vascularization of the uterine myometrium, while progesterone facilitates uterine quiescence, implantation, and suppresses uterine contractions.[4,5] The corpus luteum predominantly produces progesterone, which decreases around the seventh week of gestation as the placenta takes over its role.[6,7]

The correlation between serum progesterone levels and pregnancy viability is well-established. A notable finding demonstrates that low serum progesterone levels may indicate a higher risk of miscarriage, particularly when HCG is detectable.[8,9] Therefore, measuring serum progesterone has emerged as a reliable diagnostic tool for determining threatened abortion outcomes, potentially allowing for better patient management in clinical settings.

Given that threatened abortion is the most prevalent complication in early pregnancy, identifying reliable predictive measures is crucial. While ultrasound is the gold standard for assessing fetal viability, it often struggles to clarify ambiguous cases of threatened miscarriage.[10] Hormonal assessments have proven beneficial, particularly progesterone levels, in differentiating between healthy and nonviable pregnancies.[11,12]

Despite the established reliability of serum progesterone in predicting pregnancy outcomes, its use remains underutilized in routine clinical practice.[13] This may stem from an absence of universally accepted serum progesterone cut-off levels for risk stratification. Establishing a validated cut-off for serum progesterone could enhance the ability of clinicians to categorize patients by risk effectively.

Overall, this study aims to fulfill the urgent need for a non-invasive, affordable, and effective diagnostic tool, utilizing single serum progesterone measurements to accurately predict outcomes in threatened abortions among Bangladeshi women.

The objective of this study is to estimate serum progesterone levels for diagnosing threatened abortion and predicting pregnancy outcomes. This includes evaluating serum progesterone in study subjects, monitoring pregnancy outcomes until the age of viability (24 weeks gestation), determining the cutoff value of serum progesterone for diagnosing threatened abortion, and establishing the cutoff value of progesterone in the first trimester to differentiate between viable and non-viable pregnancies.

METHODS

A cross-sectional study was conducted over a six-months period from January to June 2020 at the Department of Obstetrics and Gynaecology, Sir Salimullah Medical College and Mitford Hospital in Dhaka. The study population consisted of 60 women, divided into two groups: Group I included 30 women with vaginal bleeding and a single intrauterine pregnancy between 6 to 12 weeks of gestation, while Group II comprised 30 women with normal viable pregnancies of the same gestational age. Purposive sampling was employed for participant selection.

The sample size was determined using a formula derived from previous studies.[14] Based on mean progesterone levels (62.3 ng/ml for Group I and 89.7 ng/ml for Group II), standard deviations (12.0 ng/ml for Group I and 33.2 ng/ml for Group II), along with Z-values for two-tailed (1.96) and one-tailed (0.85) significance levels, a total sample size of 60 was established, with 30 women in each group.

Inclusion criteria

Inclusion criteria mandated that women have single intrauterine pregnancies confirmed by ultrasound between 6 to 12 weeks of gestation and experience vaginal bleeding.

Exclusion criteria

Exclusion criteria accounted for women with prior bleeding episodes, those treated with progesterone during the current pregnancy, diagnosed inevitable or missed abortions, local causes of bleeding (such as cervical polyp, cervical cancer, trauma), or women who had planned terminations of pregnancy.

Serum progesterone levels were defined as critical for implantation and maintaining pregnancy, typically rising in early pregnancy (ranging from 12–20 ng/ml by 6 weeks and 11.2–90 ng/ml from 6 to 12 weeks of gestation). A viable pregnancy was classified as one likely to survive beyond 24 weeks, whereas a non-viable pregnancy was identified as one without cardiac activity before 24 weeks.

Data collection involved detailed histories and physical examinations of all patients. Pregnant women diagnosed with threatened abortion were followed until 24 weeks gestation to assess viability. Blood samples for progesterone assays were collected upon admission.

Statistical analysis

Statistical analysis was conducted using SPSS software, version 11.0. Results were presented as mean values with standard deviations for normal distributions and median values for non-normal distributions. Receiver Operating Characteristic (ROC) curve analysis was performed to

determine optimum progesterone cut-off values, while Chi-square tests and unpaired t-tests were utilized to evaluate outcomes, establishing significance at $p<0.05$.

Quality assurance was integrated into data collection and analysis, adhering to strict protocols with assistance from statisticians to ensure accuracy and reliability. Ethical clearance was obtained from the local Ethical Committee, and informed consent was secured from all subjects, ensuring a thorough explanation of the study's aims, procedures, risks, and benefits while maintaining participant confidentiality throughout the process.

RESULTS

Table 1 shows the distribution of demographic characteristic of the study patients. It was observed that majority (86.6%) patients belonged to age 20-30 years in group I and 23(76.6%) in group II. Almost half (43.3%) patients educations levels were primary in group I and 14 (46.7%) in group II. Almost two third (63.3%) patients were unemployed in group I and 24 (80.0%) in group II. The differences were statistically not significant ($p>0.05$) between two groups.

Table 1: Distribution of demographic characteristics of the study patients (n=60).

Demographic characteristics	Group I (n=30)		Group II (n=30)		P value
	N	%	N	%	
Age (in years)					
<20	2	6.7	5	16.7	
20-30	26	86.6	23	76.6	
>30	2	6.7	2	6.7	
Mean±SD	24.87	±3.79	23.7	±4.19	[a]0.261[ns]
Range (Min, Max)	18	33	16	32	
Education					
Nil	0	0.0	3	10.0	[b]0.254[ns]
Primary	13	43.3	14	46.7	
SSC	13	43.3	7	23.3	
HSC	3	10.0	5	16.7	
Graduate	1	3.3	1	3.3	
Occupation					
Service holder	10	33.3	6	20.0	[b]0.275[ns]
Business	1	3.3	0	0.0	
Unemployed	19	63.3	24	80.0	

ns=not significant; [a]p value reached from Unpaired t-test; [b]p value reached from Chi-square test; Group I: Threatened abortion; Group II: Normal pregnancy

Table 2: Distribution of the study patients according to parity (n=60).

Parity	Group I (n=30)		Group II (n=30)		P value
	N	%	N	%	
Primi	10	33.3	10	33.3	1.000[ns]
Multi	20	66.7	20	66.7	

ns=not significant; p value reached from Chi-square test

Table 3: Distribution of serum progesterone level of the study patients (n=60).

	Group I (n=30)	Group II (n=30)	P value
	Mean ±SD	Mean±SD	
Serum progesterone level (ng/ml)	51.02±30.77	80.39±20.68	0.001[s]
Range (min-max)	(13.8±120)	(46±120)	

s=significant; p value reached from Unpaired t-test

Table 2 shows the distribution of the study patients according to parity. In both Group I and Group II 10 (33.3%) patients were primigravida. The difference was statistically not significant ($p>0.05$) between two groups.

The mean serum progesterone level was 51.02±30.77 (ng/ml) in group I and 80.39±20.68 ng/ml in group II. The difference was statistically significant ($p<0.05$) between two groups.

Table 4 shows the distribution of study patients according to outcome at 22 weeks of pregnancy. It was observed in USG that almost two third (60.0%) patients' outcome at 24 weeks of pregnancy continued to be viable in group I. The difference was statistically significant (p<0.05) between two groups.

Table 4: Distribution of study patients according to outcome after 24 weeks of pregnancy (n=60) by USG.

Outcome at 22 weeks of pregnancy	Group I (n=30)		Group II (n=30)		P value
	N	%	N	%	
Viable	18	60.0	30	100.	0.001[s]
Non-viable	12	40.0	0	0.0	

s= significant; p value reached from Chi-square test

The mean serum progesterone level was 69.59±25.78 (ng/ml) in viable and 23.15±7.55 ng/ml in non-viable pregnancy. The difference was statistically significant (p<0.05) between two groups (Table 5).

Table 5: Serum progesterone in viable and non-viable pregnancy (n=30) in Group I.

Outcome of pregnancy	Serum progesterone level (ng/ml)		P value
	Mean±SD	Min-Max	
Viable (n=18)	69.59±25.78	(33-120)	0.001[s]
Non-viable (n=12)	23.15±7.55	(15-38)	

s=significant; p value reached from Unpaired t-test

The area under the receiver-operator characteristic (ROC) curves for the Serum progesterone level is depicted in the above table 6. Based on the receiver-operator characteristic (ROC) curves constructed using serum progesterone level with a best combination of sensitivity and specificity which gave a cut off value of ≥61 with 86.7% sensitivity and 70.0% specificity as the value and for diagnosing threatened abortion which is presented in the table 6.

Table 6: Receiver-operator characteristic (ROC) curve of serum progesterone level for prediction of threatened abortion.

	Cut off value	Area under the ROC curve	95% Confidence interval (CI)		P value	Sensitivity	Specificity
			Lower bound	Upper bound			
Serum progesterone level	61	0.786	0.663	0.908	0.001	86.7	70.0

Table 7: Receiver-operator characteristic (ROC) curve of serum progesterone level for prediction of non-viability.

	Cut off value	Area under the ROC curve	95% Confidence interval (CI)		P value	Sensitivity	Specificity
			Lower bound	Upper bound			
Serum progesterone level	35.5	0.995	0.980	1.000	0.001	94.4	91.7

The area under the receiver-operator characteristic (ROC) curves for the serum progesterone level is depicted in the above table 7. Based on the receiver-operator characteristic (ROC) it was observed in the present study that the area under curve for progesterone was 0.995 (95% CI, 0.980-1.00) with a best combination of sensitivity and specificity with a cut off value 35.5 having 94.4% sensitivity and 91.7% for identifying non-viability pregnancy in patients having threatened abortion.

DISCUSSION

Bleeding during the first trimester of pregnancy is a prevalent occurrence, with less than half of these instances leading to miscarriage. It is notable that about 80% of all miscarriages happen in this early stage (2018). The hormone progesterone, produced by the granulosa cells of the ovary, plays a crucial role in maintaining pregnancy. It induces secretory changes in the uterine lining, essential for successful embryo implantation. Following fertilization, progesterone from the corpus luteum supports early pregnancy until the placenta takes over this function around the 7th to 9th week of gestation. Additionally, progesterone modulates the maternal immune response to prevent embryo rejection and enhances uterine quiescence while suppressing uterine contractions, underscoring its importance as a predictor of pregnancy outcomes in natural conception (2018).

Studies, including those by Elson et al (2003), and Phipps et al (2000), assert that measuring serum progesterone in early pregnancy is a powerful predictor of pregnancy outcomes.[10,15] This study aimed to estimate serum progesterone levels among subjects and identify a cut-off value to differentiate between viable and non-viable pregnancies and track outcomes until approximately 22 weeks of gestation (2018).

The study included 60 patients with confirmed single intrauterine pregnancies who presented at the Gynaecology and Obstetrics department of Sir Salimullah Medical College and Mitford Hospital, Dhaka, from January to June 2020. Group I comprised women experiencing per vaginal bleeding between 6 to 12 weeks of gestation, while Group II included those with normal pregnancies at the same gestational age.

The results showed that 86.6% of patients in Group I and 76.6% in Group II were aged 20-30 years, with mean ages of 24.87±3.79 years in Group I and 23.7±4.19 years in Group II, revealing no statistically significant difference between the two groups ($p>0.05$). This is consistent with previous studies by Kadam et al (2019), Hanita and Hanisah (2012), and Kant et al (2015), which reported similar age distributions.[16-18] Additionally, some literature, such as that by Lek et al (2017) and Abdelazim et al (2012), indicated higher mean maternal ages, potentially attributed to geographical, racial, or ethnic variations influencing the study populations.[19,20]

Educational levels showed that 43.3% and 46.7% of patients in Groups I and II had primary education, respectively, with no significant difference noted ($p>0.05$). The study by Lek et al (2017) indicated a higher educational attainment within their patient groups, which may be due to the differing socio-economic context of a developed country.[19]

Regarding occupational status, 63.3% of participants in Group I were unemployed compared to 80.0% in Group II, with no significant differences also reported between groups ($p>0.05$). Similarly, the parity of patients was consistent, with both groups having 66.7% categorized as multiparous, echoing findings from other studies where most patients belonged to lower parity categories.

A significant finding pertains to serum progesterone levels, with mean values of 51.02±30.77 ng/ml in Group I and 80.39±20.68 ng/ml in Group II. This represented a notable decrease in serum progesterone levels in Group I compared to Group II ($p<0.05$). The observed mean serum progesterone levels in viable pregnancies (69.59±25.78 ng/ml) contrasted sharply with those in non-viable cases (23.15±7.55 ng/ml), supporting assertions made by Kadam et al (2019) regarding higher progesterone levels in viable pregnancies.[16] Elewa et al (2016) corroborated these findings by noting mean serum progesterone levels reflecting similar disparities between viable and non-viable groups.[21]

This research aligns with earlier studies that advocate for serum progesterone as a diagnostic tool, such as that of Hanita and Hanisah (2012), which reported a range of viable pregnancy progesterone levels compared to non-viable ones.[17] Al Jufairi (2000) highlighted serum progesterone as a reliable predictor of early pregnancy failure.

Follow-up assessments at 24 weeks illustrated that 60% of patients in Group I remained viable, whereas 40% did not ($p<0.05$). Comparative studies like that of Kadam et al (2019) found similar percentages of viable outcomes, lending credence to the predictive capability of serum progesterone levels throughout pregnancy.[16]

The receiver-operator characteristic (ROC) curve analysis illustrated a significant ability of serum progesterone to differentiate between viable and non-viable pregnancies, with an area under the curve (AUC) of 0.786 (95% CI, 0.663-0.908) at a cut-off value of 61 ng/ml, providing 86.7% sensitivity and 70% specificity for predicting threatened abortion. More notably, the present study observed an AUC of 0.995 (95% CI, 0.980-1.00) when utilizing 35.5 ng/ml as a cut-off for identifying non-viability in pregnancies with threatened abortion, demonstrating an impressive 94.4% sensitivity and 91.7% specificity.

The ROC analysis by Hanita and Hanisah (2012) similarly identified serum progesterone as a significant marker, reporting an AUC of 0.95.[17] The variability in cut-off values across studies may be attributed to differences in methodology, participant characteristics, and potential confounders influencing serum progesterone levels. While some studies suggest lower cut-off values, our findings reflect a need for tailored assessments that suit individual clinical scenarios better.

Finally, the present study underscores the pivotal role that serum progesterone levels play as reliable indicators of pregnancy viability in early gestation-a crucial tool that healthcare professionals can utilize in anticipating pregnancy outcomes and managing women at risk of miscarriage effectively. Frequent evaluations and further comprehensive studies are warranted to refine these diagnostic frameworks and better assist clinical decision-making.

The study presents several limitations that need to be acknowledged. Firstly, the participant population was exclusively sourced from a single hospital in Dhaka city, which may compromise the results' ability to accurately reflect the national demographic. The specific context and patient population of one healthcare facility may not provide a comprehensive understanding of the issues at hand across a broader spectrum.

Secondly, the research was conducted over a relatively short timeframe, which may have limited the extent of data collection and analysis. This limitation could influence the robustness of the findings and their applicability to ongoing clinical practices.

Additionally, the small sample size represents another critical limitation of the study. A smaller participant pool can weaken the statistical power and the reliability of the conclusions drawn, reducing the ability to generalize the findings to the larger population.

Lastly, while the serum progesterone cut-off value proposed in the ROC curve is relevant for women presenting with threatened miscarriage in early pregnancy, its applicability may not extend to those within low-risk populations. This raises questions about the universality of the findings and highlights a need for further investigation into various populations to validate the results.

CONCLUSION

Threatened abortion is a prevalent complication in early pregnancy, making accurate and timely risk assessment crucial for optimizing patient care. This study evaluated the predictive value of a single serum progesterone measurement in determining pregnancy viability among women experiencing threatened abortion.

Findings revealed that viable pregnancies were associated with an average serum progesterone level of 69.59±25.78 ng/ml, while non-viable pregnancies had significantly lower levels (23.15±7.55 ng/ml). Moreover, approximately 60% of patients in Group I continued to have viable pregnancies beyond 24 weeks of gestation. A serum progesterone threshold of 61 ng/ml was established for diagnosing threatened abortion, while a cut-off value of 35.5 ng/ml demonstrated high sensitivity (94.4%) and specificity (91.7%) for identifying non-viable pregnancies.

These results highlight the effectiveness of serum progesterone as a reliable, non-invasive diagnostic tool for predicting pregnancy outcomes. Integrating progesterone assessments into routine clinical practice could enhance risk stratification, improve patient counseling, and facilitate timely medical interventions. Establishing universally accepted cut-off values may further streamline its application, ultimately leading to better management strategies for patients with threatened abortion.

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