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Role of Serum CA-125 as a prognostic marker in first-trimester threatened abortion: A prospective observational study

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Abstract
Background: Threatened abortion is a common complication of early pregnancy and is associated with significant maternal anxiety and adverse outcomes. Identifying reliable biochemical markers to predict pregnancy outcome is clinically valuable. Serum cancer antigen-125 (CA-125), a glycoprotein released from decidual and trophoblastic tissue, has been proposed as a prognostic marker in early pregnancy bleeding.
Objectives: To evaluate the role of maternal serum CA-125 as a prognostic marker in threatened abortion and to assess its association with adverse pregnancy and fetal outcomes.
Methods: This prospective hospital-based observational study was conducted in the Department of Obstetrics and Gynecology, SMGS Hospital, GMC Jammu, from May 2024 to April 2025. A total of 225 pregnant women aged 20-40 years with singleton pregnancies of 7-14 weeks' gestation presenting with vaginal bleeding were enrolled. Serum CA-125 levels were measured at presentation using chemiluminescent immunoassay. Participants were followed until pregnancy outcome. Statistical analysis included chi-square test and ROC curve analysis.
Results: Of 225 women, 75 (33.3%) experienced abortion while 150 (66.7%) continued pregnancy beyond the period of viability. Mean serum CA-125 levels were significantly higher in the abortion group (112.4 ± 48.76 U/mL) compared to the non-abortion group (45.1 ± 18.24 U/mL; $p<0.001$). A cutoff value of >65 U/mL predicted abortion with sensitivity 86.7%, specificity 92.6%, and AUC 0.968. Elevated CA-125 levels were also significantly associated with adverse fetal outcomes.
Conclusion: Maternal serum CA-125 is a reliable, non-invasive, and cost-effective prognostic marker for predicting pregnancy outcome in first-trimester threatened abortion.

Keywords: Threatened abortion, CA-125, miscarriage, first trimester, prognostic marker

Introduction

Threatened abortion, defined as vaginal bleeding occurring before 20 weeks of gestation with a closed cervical os and a viable fetus, affects nearly 20% of pregnancies [1]. Despite the presence of fetal cardiac activity, up to half of these pregnancies may subsequently end in miscarriage. Early identification of pregnancies at higher risk of loss remains a challenge in obstetric practice [2].

Serum biochemical markers such as β-human chorionic gonadotropin and progesterone have been used to predict pregnancy viability, but their sensitivity in early gestation is limited. Cancer antigen-125 (CA-125), a high-molecular-weight glycoprotein expressed by tissues derived from the embryonic coelom, including decidua and amnion, rises in conditions associated with decidual disruption. Elevated CA-125 levels have been observed in women with threatened abortion and impending miscarriage, suggesting its potential role as a prognostic biomarker [3].

Given the emotional, physical, and economic burden of early pregnancy loss, a simple and reliable marker such as CA-125 could assist clinicians in counseling, monitoring, and management. This study aims to evaluate the prognostic utility of maternal serum CA-125 in women presenting with first-trimester threatened abortion. The objectives of the study are as below:

1. To study the role of serum CA-125 as a prognostic marker in threatened abortion.
2. To assess the association between CA-125 levels and early pregnancy loss.
3. To evaluate the relationship between elevated CA-125 levels and adverse fetal outcomes such as preterm birth, low birth weight, and small-for-gestational-age infants.

Materials and Methods

This prospective hospital-based observational study was conducted in the Department of Obstetrics and Gynecology, SMGS Hospital, GMC Jammu from May 1, 2024 to April 30, 2025.

Sample Size: A total of 225 participants were included, calculated using OpenEpi software with an expected prevalence of 30%, absolute precision of 6%, $\alpha = 0.05$, and power of 80%.

Inclusion Criteria

- Pregnant women aged 20-40 years
- Gestational age between 7 and 14 weeks
- Singleton intrauterine pregnancy
- History of vaginal bleeding

Exclusion Criteria

- Age >40 years
- Diabetes mellitus or hypothyroidism
- Gynecological conditions affecting CA-125 levels
- Multiple pregnancy
- Antiphospholipid antibody syndrome
- Assisted reproductive pregnancies

Methodology

After informed consent, participants underwent clinical examination, routine antenatal investigations, ultrasonography, and serum CA-125 estimation using chemiluminescent immunoassay. Participants were followed until pregnancy outcome.

Statistical Analysis: Data were analyzed using SPSS version 20. Continuous variables were expressed as mean ± SD. ROC curve analysis determined diagnostic accuracy. A p-value <0.05 was considered statistically significant.

Results: Mean age was 28.9 ± 5.48 years (range 20-40 years). The majority belonged to the 25-29 year age group. Mean gestational age at presentation was 10.6 ± 2.32 weeks (table 1).

Table 1: Baseline characteristics of the study participants

Age (years)	Number (n=225)	Percentage
20-24	56	24.9
25-29	68	30.2
30-34	54	24.0
≥35	47	20.9
Gravida		
Primigravida	74	32.9
Multigravida	151	67.1
Previous abortion		
Yes	64	28.4
No	161	71.6
Gestational age (weeks)		
<8	27	12.0
8-10	72	32.0
10-12	45	20.0
12-14	81	36.0

Table 2: Pregnancy outcomes

Outcome	Number	Percentage
Term pregnancy	120	53.3
Abortion	75	33.3
Preterm birth	12	5.3
Low birth weight	11	4.9
Small for gestational age	7	3.1
Total	225	100

Table 3: Age and pregnancy outcome

Age (years)	Abortion n (%)	No abortion n (%)	P-value
20-24	18 (24.0)	38 (25.3)	0.237
25-29	21 (28.0)	47 (31.3)	
30-34	17 (22.7)	37 (24.7)	
≥35	19 (25.3)	28 (18.7)	

Table 4: Gravida and pregnancy outcome

Gravida	Abortion n (%)	No abortion n (%)	P-value
Primigravida	22 (29.3)	52 (34.7)	0.422
Multigravida	53 (70.7)	98 (65.3)	

Table 5: Previous abortions and outcome

Previous abortion	Abortion n (%)	No abortion n (%)	P-value
Yes	26 (34.7)	38 (25.3)	0.114
No	49 (65.3)	112 (74.7)	

Table 6: Comparison of mean CA-125 levels

Outcome	N	Mean (U/mL)	SD	P-value
Abortion	75	112.4	48.76	<0.001
No abortion	150	45.1	18.24	

Table 7: Diagnostic accuracy of CA-125 (>65 U/mL)

Parameter	Value
Sensitivity	86.7%
Specificity	92.6%
PPV	85.5%
NPV	93.3%
Accuracy	90.7%
AUC (ROC)	0.968

Table 8: Association of CA-125 levels with pregnancy outcome

CA-125 (U/mL)	Abortion n (%)	No abortion n (%)	P-value
>65	65 (86.7)	11 (7.3)	<0.001
≤65	10 (13.3)	139 (92.7)	

Discussion

The present prospective observational study was conducted to evaluate the prognostic significance of maternal serum CA-125 levels in women presenting with first-trimester threatened abortion. The findings of this study clearly demonstrate that elevated CA-125 levels are strongly associated with an increased risk of miscarriage and adverse fetal outcomes. These results are in agreement with a substantial body of published literature, reinforcing the role of CA-125 as a reliable biochemical marker in early pregnancy complications.

Comparison with Previous Studies

In the present study, 33.3% of women with threatened abortion experienced miscarriage, while 66.7% continued pregnancy beyond the period of viability. This abortion rate is comparable to that reported by Ayaty *et al* [4]., Sweed *et al* [5]., and Gupta *et al* [6]., who documented miscarriage rates ranging from 20% to 42% among women presenting with first-trimester vaginal bleeding.

The most significant finding of this study was the markedly elevated mean serum CA-125 level among women who aborted (112.4 ± 48.76 U/mL) compared to those with ongoing pregnancies (45.1 ± 18.24 U/mL), with a highly significant p-value (<0.001). Similar observations were reported by Fiegler *et al* [7]., who demonstrated mean CA-125 levels of 69.6 IU/mL in aborted pregnancies compared to 20.3 IU/mL in normal pregnancies. Sweed *et al* [5]. reported mean CA-125 levels of 58.17 ± 7.52 IU/mL in aborted cases and 30.89 ± 2.93 IU/mL in

ongoing pregnancies, while Gupta *et al* [6]. observed significantly higher CA-125 levels (89.44 U/mL) in pregnancies ending in abortion compared to ongoing pregnancies (44.69 U/mL). These consistent findings across multiple studies strongly support the prognostic role of CA-125.

The cutoff value of serum CA-125 identified in the present study was >65 U/mL, which predicted miscarriage with a sensitivity of 86.7% and specificity of 92.6%. This cutoff is in close agreement with the thresholds proposed by several previous studies. Ocer *et al* [8]. reported a significantly increased risk of abortion when CA-125 levels exceeded 65 U/mL, with a relative risk of 4.2. Sweed *et al* [5]. identified an optimal cutoff of 58 U/mL with sensitivity of 78% and specificity of 97%. Kumar *et al* [9]. and Gidwani *et al* [10]. also reported cutoff values around 60 U/mL, demonstrating high diagnostic accuracy. The high area under the ROC curve (0.968) in the present study is comparable to that reported by Gupta *et al* [6]. (AUC 0.916) and confirms the excellent discriminative power of CA-125.

In contrast, some studies such as Adeku *et al* [11]. and Barooti *et al* [12]. reported lower cutoff values (approximately 30-36 U/mL) with moderate sensitivity and specificity. These variations may be attributed to differences in study design, assay methods, gestational age at sampling, population characteristics, and inclusion criteria. Nevertheless, all studies consistently demonstrated significantly higher CA-125 levels in pregnancies that ended in miscarriage, regardless of the cutoff used.

Demographic and Obstetric Variables

In the present study, maternal age, gravidity, history of previous abortions, and gestational age at presentation showed no statistically significant association with pregnancy outcome. These findings are consistent with those of Shabana *et al* [13]., Ramezampour *et al* [14]., and Sweed *et al* [5]., who similarly reported no significant correlation between CA-125 levels and maternal age, parity, or gestational age. This suggests that CA-125 acts as an independent biochemical marker of trophodecidual damage rather than being influenced by baseline demographic factors.

Pathophysiological Correlation

The elevation of CA-125 in threatened abortion is thought to result from decidual and trophoblastic disruption, leading to increased release of CA-125 into maternal circulation. The decidual trauma theory and tubal reflux theory provide plausible explanations for this phenomenon. Studies by Kobayashi *et al* [15]. and Schmidt *et al* [16]. support the concept that CA-125 reflects the extent of decidual destruction, which directly correlates with pregnancy outcome. The significantly higher CA-125 levels observed in aborted pregnancies in the present study further strengthen this hypothesis.

Association with Adverse Fetal Outcomes

In addition to miscarriage, the present study demonstrated a significant association between elevated CA-125 levels and adverse fetal outcomes such as preterm birth, low birth weight, and small-for-gestational-age infants ($p < 0.001$). Similar associations have been reported by Karaman *et al* [17]. and Mukherjee and Das [18], who observed negative correlations between CA-125 levels and birth weight and gestational age at delivery. These findings suggest that elevated CA-125 may serve as a marker of underlying placental dysfunction, which can adversely affect fetal growth and pregnancy continuation.

Clinical Implications

The consistent evidence from the present study and previous research highlights the clinical utility of serum CA-125 as a non-invasive, cost-effective, and readily available prognostic marker in threatened abortion. When used alongside ultrasonography and clinical evaluation, CA-125 can aid in early risk stratification, patient counseling, and individualized management. However, due to its nonspecific nature and elevation in various benign conditions, CA-125 should be interpreted cautiously and in conjunction with other diagnostic modalities.

Limitations

- Single-center design
- Lack of serial CA-125 measurements
- Possible influence of unrecognized confounding conditions

Conclusion

Serum CA-125 is a valuable, non-invasive, and cost-effective prognostic marker for predicting pregnancy outcome in first-trimester threatened abortion. Incorporation of CA-125 testing into routine evaluation may facilitate early risk stratification and improved clinical management.

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