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DIAGNOSTIC ACCURACY OF HIGH ALANINE AMINOTRANSFERASE (ALT) LEVELS IN PREDICTING ADVERSE MATERNAL OUTCOME IN PRE-ECLAMPSIA

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ABSTRACT

Introduction: Elevations of the liver enzymes aspartate aminotransferase and alanine aminotransferase (ALT) during the first 20 weeks of pregnancy are associated with an increased chance of experiencing severe preeclampsia in the latter half of pregnancy.

Objectives: The study's goal was to ascertain if elevated levels of ALT could accurately predict unfavorable outcomes for mothers with pre-eclampsia, with severe pre-eclampsia being the gold standard.

Materials & Methods: This descriptive, cross-sectional validation study was conducted at the Department of Obstetrics & Gynecology, BBH, Rawalpindi, from April 30th, 2019, to October 29th, 2019, enrolled 247 pre-eclamptic women aged 18 to 40 years. Patients having several pregnancies, chronic hypertension, renal illness, chronic liver disease, and HELLP syndrome were among those excluded. All subjects had their serum ALT levels measured in the Institutional Pathology laboratory

by a consultant pathologist who had completed at least three post-fellowship years of service. The researcher observed maternal outcomes up until delivery and then managed them as needed after that.

Results: There were 07 False Positive results and 133 True Positive results in that research study. Of the 107 patients who tested negative for ALT, 11 (False Negative) had a poor maternal outcome, while 96 (True Negative) did not (p=0.0001). The total specificity, sensitivity, positive predictive value, negative predictive value, and diagnostic accuracy in predicting an adverse maternal outcome in pre-eclampsia were 92.36%, 93.30%, 95.0%, 89.72%, and 92.71% when high ALT levels were present.

Conclusion: This study found that high ALT levels have a fairly high diagnostic accuracy in predicting a poor maternal outcome in pre-eclampsia.

Keywords: preeclampsia, alanine aminotransferase, adverse maternal outcome.

Introduction

Hypertensive disorders of pregnancy (HDPs) complicate between 3 and 10% of pregnancies [1-3]. One of the leading causes of maternal and fetal mortality and morbidity globally, HDPs are responsible for over 30,000 maternal and 500,000 perinatal deaths annually [2,4]. Eclampsia, stroke, and harm to the liver and kidneys are examples of maternal problems [2]. Forecasting when these issues will arise should help with prompt interventions, which could lower morbidity and death from HDPs. These actions could include greater surveillance, symptom treatment, transfer to a higher care facility, and delivery as needed [5].

One of the most common medical issues during pregnancy is preeclampsia, which often manifests after 20 weeks of gestation and is distinguished by hypertension, proteinuria, as well as edema [1]. Preeclampsia continues to be a major cause of maternal and neonatal death worldwide, with India bearing a particular burden as 7–10% of prenatal hospital admissions are related to preeclampsia [2]. Preeclampsia is thought to be primarily caused by faulty placentation and endothelial dysfunction, while the exact cause of the condition is unknown [3]. This multisystem illness mostly affects the placenta but also affects the brain, liver, kidneys, and coagulation system of the mother [4]. Preeclampsia is a sickness that essentially affects every organ system in a mother, and as such, it is linked to several clinical features, as well as prevention, diagnosis, and treatment, all of which necessitate tight interdisciplinary collaboration [5].

The ability to predict and prevent PE in the near future may be enhanced by the examination of a variety of biochemical markers, particularly those associated with vascular dysfunction, such as elevated uric acid, alanine aminotransferase (ALT), lactate dehydrogenase and aspartate aminotransferase concentrations [6, 7]. The liver enzymes aspartate aminotransferase and ALT have been associated with elevated levels during the first 20 weeks of pregnancy with a greater risk of developing severe preeclampsia in the second half of pregnancy [8]. Negative maternal outcomes were seen in 27.0% of pre-eclamptic women with elevated ALT levels, according a research by Aziz et al. [9]. Furthermore, the research revealed that elevated levels of ALT exhibited a sensitivity as well as a specificity of 55.0% and 25.9%, respectively, in forecasting worse outcomes for mothers with pre-eclampsia.

Precise diagnostic and therapeutic criteria are necessary for pre-eclampsia since it is a very hazardous form of hypertension illness in pregnancy that has major risks for both the mother and the fetus [10,11]. Regarding the diagnostic efficacy of elevated ALT levels in predicting a poor maternal outcome in pre-eclampsia, there is a lack of information available locally. Moreover, research of this type is necessary to determine whether pre-eclampsia influences the vascular anatomy and physiology of expectant individuals. We will be able to identify high-risk women for unfavorable maternal outcomes using the straightforward strategy we will discover during this study. In order to forecast the unfavorable maternal outcome in pre-eclampsia, my study will present baseline and current local

information on the diagnostic accuracy of elevated ALT levels. Additionally, it will assist in determining if all pre-eclamptic women should follow the recommendations about high ALT levels. As a result, this research will be crucial for developing therapeutic and preventative methods in the clinic.

Research Objective

The study's goal was to ascertain if elevated levels of ALT could accurately predict unfavorable outcomes for mothers with pre-eclampsia, with severe pre-eclampsia being the gold standard.

Material and Methods

Study design and Settings

The predictive usefulness of serum ALT levels in pre-eclamptic women was assessed using a descriptive, cross-sectional validation methodology in this study. It took place from April 30 to October 29, 2019, in the BBH, Rawalpindi, Department of Obstetrics & Gynecology.

Sample Size

The study used non-probability, sequential sampling with a 95% confidence level and a 10% desired precision to select the sample size, which came out to be 247 cases. It has been shown that in pre-eclamptic women who have elevated ALT levels, there is a 55.0% sensitivities and a 25.9% specificity to forecast an unfavorable maternal result, and a prevalence of adverse maternal outcome of 27.0% in these women.

Inclusion and Exclusion Criteria

The study's inclusion criteria included pre-eclamptic women who were between the ages of 18 and 40 and whose last menstrual period (LMP) indicated a gestational age more than 20 weeks. Moreover, singleton pregnancies with cephalic presentation ascertained by ultrasonography and parity ranging from 0 to 5 were included. On the other hand, patients with a history of persistent hypertension, persistent liver illness as shown by blood bilirubin levels higher than 2 mg/dl, and multiple pregnancies as identified by ultrasonography were excluded based on predetermined criteria. In addition, women who had a history of renal illness and Serum creatinine concentrations exceeding 1.5 mg/dl was excluded. Last but not least, participation was also prohibited for those who had HELLP syndrome, which is defined by a platelet count of fewer than 100,000/mm3.

Data Collection

This study's findings were recorded on a structured proforma that was specially made. The study included 247 women in total who attended the outpatient department (OPD) of the gynecological department at BBH, Rawalpindi, and who satisfied the inclusion criteria. The ethical committee of the institution approved. Written informed permission from the patients was acquired. A specialized pathologist evaluated the serum ALT levels from each patient's blood sample, which was forwarded to the Institutional Pathology laboratory. Every woman was closely observed by the researcher until delivery to make sure the mother would not have any negative consequences and to make any necessary adjustments to the care.

Statistical Analysis

SPSS-20 made data input and analysis easier by using percentage distributions for qualitative features and descriptive statistics for quantitative aspects. With further research utilizing likelihood ratios and ROC curves, a 2x2 contingency table determined the sensitivity, specificity, predictive values, and diagnostic accuracy of increased ALT levels in predicting poor maternal outcomes in pre-eclampsia. Age, gestational age, parity, and past history of pre-eclampsia were used to stratify the data. Overall diagnosis accuracy was evaluated and significance was verified using post-stratification chi-square tests with a threshold of $p < 0.05$.

High serum alanine amino transferase		Adverse maternal outcome	
		Yes	No
	Yes	**True Positive (a)**	**False Positive (b)**
	No	**False Negative (c)**	**True negative (d)**

Sensitivity: a / a+c x 100
Specificity: d / b+d x 100
Positive predictive value: a / a+b x 100 **Negative predictive value:** d / c+d x 100 **Diagnostic accuracy:** a+d / a+b+c+d x 100

Ethical Approval
The Institutional Review Board granted ethical approval for the study "Diagnostic Accuracy of High ALT Levels in Predicting Adverse Maternal Outcome in Pre-eclampsia," guaranteeing compliance with ethical standards such as informed consent, participant confidentiality, and respect for ethical norms. The goals and procedures of the research were fully explained to the participants, and they were given the assurance that they might withdraw at any time. Furthermore, regardless of their participation in the study, every subject was given access to medical treatment, emphasizing their health at every stage of the research process.

Results
Table 1 lists the participants' demographic details and obstetric history in the study examining the predictive power of elevated ALT levels for unfavorable maternal outcomes in pre-eclampsia. The age distribution of the patients is shown, with 19.14% of them being between the ages of 31 and 40 and 70.85% being between the ages of 18 and 30. 35.63% of patients have a gestational age of ≤32 weeks, whereas 64.37% have a gestational age of >32 weeks. 43.32% of the sample have parity ≤2, whereas 56.62% have parity >2. Furthermore, 24.70% of participants reported having pre-eclampsia in the past, whereas 75.30% did not.

Table 1: Demographic information and obstetric history of those participating in the study on the prognostic power of high ALT levels for unfavorable pregnancy outcomes in pre-eclampsia

Variable	**Category**	**No. of Patients**	**%age**
Age (years)	18-30	175	70.85
	31-40	72	19.14
	Total	247	100.0
Gestational Age (weeks)	≤32	88	35.63
	>32	159	64.37
	Total	247	100.0
Parity	≤2	107	43.32
	>2	140	56.62
	Total	247	100.0
History of Previous PE	Yes	61	24.70
	No	186	75.30
	Total	247	100.0

Table 2 shows that elevated levels of alanine ALT are a reliable indicator of poor maternal outcomes in cases of pre-eclampsia, with severe cases serving as the gold standard. For positive ALT results, it shows the number of true positive (133) and FP (7) cases, and for negative ALT results, the number of false negative (11) and true negative (96) cases. Calculations show that the following values are obtained: 92.36% for sensitivity, 93.30% for specificity, 95.0% for positive predictive value (PPV), 89.72% for negative predictive value (NPV), 13.59 for likelihood ratio for positive test results, 0.08

for likelihood ratio for negative test results, and 92.71% for diagnostic accuracy. ROC curve, however, is displayed in Figure I.

Table 2: Diagnostic accuracy of high ALT levels in forecasting adverse maternal result in pre-eclampsia, taking severe pre-eclampsia as gold standard.

Parameter	Positive Adverse Prenatal Result	Negative Adverse Prenatal Result	P value
favorable ALT outcome	133 (TP)*	07 (FP)***	0.0001
Unfavorable ALT outcome	11 (FN)**	96 (TN)****	
Sensitivity	92.36%		
Specificity	93.30%		
PPV	95.0%		
NPV	89.72%		
Likelihood ratio for positive test result	13.59		
Likelihood ratio for negative test result	0.08		
Diagnostic Accuracy	92.71%		
*-TP=True positive **-FP=False positive ***-FN=False negative ****-TN=True negative			

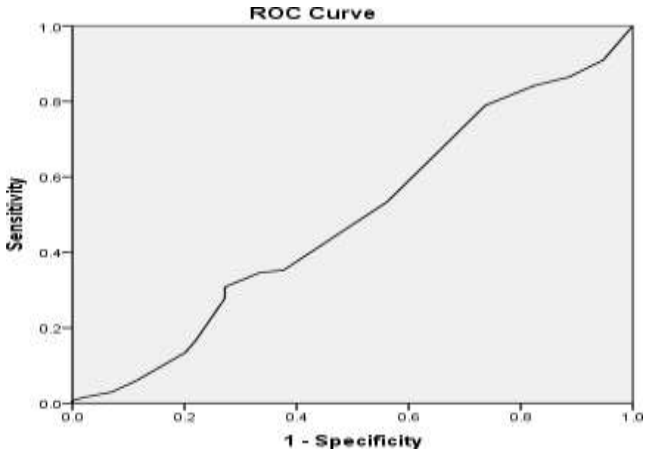

Figure I: ROC Curve

The diagnostic accuracy of pre-eclampsia in predicting unfavorable maternal outcomes is assessed by grouping individuals (18–30) based on their ALT levels (Table 3). It shows true positive (TP), FP, false negative (FN), and true negative (TN) scenarios for both positive and negative ALT levels. The test yields results with a sensitivity of 92.0%, or the percentage of true positives among women who have adverse maternal outcomes, and a specificity of 93.33%, or the percentage of true negatives among women who do not have adverse outcomes. The PPV, which stands for the likelihood of an accurate positive test result, is 94.85%. On the other side, the NPV, which is 89.75%, indicates the likelihood of an accurate negative test result. The diagnostic accuracy in this age group is 92.57%, and the stratification has a similar p-value of 0.001.

Table 3: Diagnostic precision stratification according to a patient's age 18–30 years (n=175).

Parameter	Positive Adverse Prenatal Result	Negative Adverse Prenatal Result	P value
favorable ALT outcome	92 (TP)	05 (FP)	0.001
Unfavorable ALT outcome	08 (FN)	70 (TN)	
Sensitivity			92.0%
Specificity			93.33%
NPV			89.75%
PPV			94.85%
Diagnostic Accuracy			92.57%

The research shows that among individuals with a positive result on ALT testing, there were 41 TP cases and 2 FP instances in Table 4, which stratifies diagnostic accuracy for the age range of 31–40 years (n=72). In contrast, 3 false negative (FN) and 26 TN instances were found among individuals who had a negative result on the ALT test. The test's sensitivity is 93.18%, meaning it shows the percentage of true positives among mothers who have unfavorable outcomes, and its specificity is 92.86%, meaning it shows the percentage of true negatives among those who do not. Furthermore, the probability that a negative test result is correct is shown by the NPV of 89.66% and the potential of a positive test result being accurate is indicated by the PPV of 95.35%. The test's overall diagnostic accuracy in this age range is 93.06%, and the p-value for the relationship is 0.001.

Table 4: Stratification of Diagnostic Accuracy with Respect to Age 31-40 years (n=72)

Parameter	**Positive Adverse Prenatal Result**	**Negative Adverse Prenatal Result**	**P value**
favorable ALT outcome	41 (TP)	02 (FP)	0.001
Unfavorable ALT outcome	03 (FN)	26 (TN)	
Sensitivity			93.18%
Specificity			92.86%
PPV			95.35%
NPV			89.66%
Diagnostic Accuracy			93.06%

The research, which stratifies diagnostic accuracy based on gestational age of ≤32 weeks (n=88), reveals that among those with a positive result on ALT tests, there were 40 TP and 4 FP occurrences. Conversely, people who had a negative result on the ALT test included 10 false negatives (FN) and 34 true positives (TN). The test indicates the number of true positives among moms who have poor outcomes with an estimated sensitivity of 80.0% and the number of true negatives among those who do not with a specificity of 89.47%. Additionally, it is evident that the NPV denotes the likelihood that a negative test result would be correct, whilst the PPV stands for the chance that a positive test result will be accurate. 90.91% and 77.27%, respectively, are these figures. The test's diagnostic accuracy in this gestational age range is 84.09%, and the p-value for the relationship is 0.001.

Table 5: Diagnostic Accuracy Stratification according to Gestational Age ≤32 weeks (n=88)

Parameter	**Positive Adverse Prenatal Result**	**Negative Adverse Prenatal Result**	**P value**
favorable ALT outcome	40 (TP)	04 (FP)	0.001
Unfavorable ALT outcome	10 (FN)	34 (TN)	
Sensitivity			80.0%
Specificity			89.47%
PPV			90.91%
NPV			77.27%
Diagnostic Accuracy			84.09%

Table 6 presents a stratified analysis of diagnosis accuracy based on gestational age (n = 159) exceeding 32 weeks. There were 93 TP and 3 FP instances among those who tested positive for ALT, while there was only 1 false negative (FN) case and 62 TN cases among those who tested negative for ALT. At 98.94%, the test's sensitivity is very high, suggesting that a significant percentage of true positives among those with poor maternal outcomes really occur. At 95.38%, the specificity is also strong, indicating a large percentage of genuine negatives among those without unfavorable results. The test has great accuracy in predicting unfavorable maternal outcomes, with a PPV of 96.88% and a NPV of 98.41%. This results in an overall diagnostic accuracy of 97.48%.

Table 6: Arrangement of Diagnostic Precision according to Gestational Age >32 weeks (n=159)

Parameter	**Positive Adverse Prenatal Result**	**Negative Adverse Prenatal Result**	**P value**
favorable ALT outcome	93 (TP)	03 (FP)	0.001
Unfavorable ALT outcome	01 (FN)	62 (TN)	
Sensitivity			98.94%
Specificity			95.38%
PPV			96.88%
NPV			98.41%
Diagnostic Accuracy			97.48%

A comparison of the diagnostic accuracy for parity ≤2 (n=107) is shown in Table 7. The table shows that among those with a positive ALT test result, there were 63 true positive (TP) and 5 FP instances; among those with a negative ALT test result, there was only one false negative (FN) case and 38 TN occurrences. The test's sensitivity is very high at 98.44%, suggesting a significant percentage of true positives among those with bad maternal outcomes. Its specificity is 88.37%, indicating a significantly lesser number of genuine negatives among those without poor outcomes. Despite this, the test yields a 94.39% overall diagnostic accuracy with a 92.65% PPV and a 97.44% NPV.

Table 7: Grouping Diagnostic Precision according to Parity ≤2 (n=107)

Parameter	**Positive Adverse Prenatal Result**	**Negative Adverse Prenatal Result**	**P value**
favorable ALT outcome	63 (TP)	05 (FP)	0.001
Unfavorable ALT outcome	01 (FN)	38 (TN)	
Sensitivity			98.44%
Specificity			88.37%
PPV			92.65%
NPV			97.44%
Diagnostic Accuracy			94.39%

Table 8 assesses the diagnostic accuracy of n = 140 in relation to parity > 2. The research found that among those with a positive ALT test result, there were 70 TP and 2 FP cases; among those with a negative ALT test result, there were 10 false negative (FN) and 58 TN cases. The test's specificity is higher at 96.67%, but its sensitivity is somewhat lower at 87.50% when compared to parity ≤2. Despite this, the test has an excellent 91.43% overall diagnostic accuracy, 97.22% PPV, and 85.29% NPV.

Table 8: Grouping Diagnostic Precision according to Parity >2 (n=140)

Parameter	**Positive Adverse Prenatal Result**	**Negative Adverse Prenatal Result**	**P value**
favorable ALT outcome	70 (TP)	02 (FP)	0.001
Unfavorable ALT outcome	10 (FN)	58 (TN)	
Sensitivity			87.50%
Specificity			96.67%
PPV			97.22%
NPV			85.29%
Diagnostic Accuracy			91.43%

A stratified diagnostic accuracy based on pre-eclampsia history in the n=61 individuals is shown in Table 9. Among individuals who tested positive for ALT, there were 38 TP occurrences and no FP

cases, indicating a high specificity of 100.0%. Conversely, among individuals who had a negative result from the ALT test, there were 6 false negatives (FN) and 17 TN cases. The test's sensitivity, calculated at 86.36%, represents the proportion of true positives among individuals with adverse maternal outcomes. There is a high probability that a positive test result is correct when the PPV is 100.0%. The NPV of 73.91%, on the other hand, indicates that a negative test result has a lower likelihood of being correct. The test's overall diagnostic accuracy in this group is 90.16%..

Table 9: Arrangement of Diagnostic Precision according to Past Pre-eclampsia History (n=61)

Parameter	**Positive Adverse Prenatal Result**	**Negative Adverse Prenatal Result**	**P value**
favorable ALT outcome	38 (TP)	00 (FP)	0.001
Unfavorable ALT outcome	06 (FN)	17 (TN)	
Sensitivity			86.36%
Specificity			100.0%
PPV			100.0%
NPV			73.91%
Diagnostic Accuracy			90.16%

The diagnostic accuracy of patients (n = 186) who have never had pre-eclampsia is assessed in Table 10. The research found that among individuals with a positive ALT test result, there were 95 TP and 7 FP instances, while among those with a negative ALT test result, there were 5 false negative (FN) and 79 TN cases. Given the test's exceptional sensitivity of 95.0%, there may be a significant proportion of true positives among women who have poor maternal outcomes. The proportion of true negatives among those without negative findings is somewhat smaller, with a specificity of 91.86%. The test has a 93.55% overall diagnostic accuracy with a 93.14% PPV and a 94.05% NPV..

Table 10: Grouping Diagnostic Precision according to Lack of Prior Pre-eclampsia History (n=186)

Parameter	**Positive Adverse Prenatal Result**	**Negative Adverse Prenatal Result**	**P value**
favorable ALT outcome	95 (TP)	07 (FP)	0.001
Unfavorable ALT outcome	05 (FN)	79 (TN)	
Sensitivity			95.0%
Specificity			91.86%
PPV			93.14%
NPV			94.05%
Diagnostic Accuracy			93.55%

Discussion

One of the main diseases affecting pregnant women is hypertensive illness, which may have serious consequences for both the mother and the fetus [12]. Preeclampsia, which causes 10-15% of the 500,000 maternal deaths that occur annually, is one of the most serious and possibly deadly hypertensive disorders in the world for both mothers and infants [13, 14]. Aspartate aminotransferase (AST), ALT, lactate dehydrogenase (LDH), bilirubin, and albumin levels are among the liver function test (LFT) values that are routinely determined for women with preeclampsia. Since there are conflicting findings in the literature regarding the relationship between these parameters and the severity of preeclampsia, we conducted this study to determine the diagnostic accuracy of high ALT levels in predicting adverse maternal outcome in pre-eclampsia, using severe pre-eclampsia as the gold standard [15].

In our study, there were 133 genuine positives and 07 false positives. Eleven (False Negative) out of the 107 patients with negative ALT tests had a bad maternal outcome, whereas 96 (True Negative) did not (p=0.0001). In predicting a worse maternal outcome in pre-eclampsia, high ALT levels were linked to an overall 92.36%, 93.30%, 95.0%, 89.72%, and 92.71% sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy. According to Aziz et al.'s research [9], 27.0% of pre-eclamptic women with elevated ALT levels had unfavorable maternal outcomes. Furthermore, the research discovered that in pre-eclampsia, elevated ALT levels were predictive of unfavorable maternal outcomes with a sensitivity and specificity of 55.0% and 25.9%, respectively.

Burwick and Feinberg (2013) found that liver enzyme levels were considerably raised in preeclampsia patients and showed that elevated levels of AST and ALT may be utilized to categorize preeclampsia severity [16]. Kozic JR et al. [15] examined LFT results as a possible indicator of poor maternal outcomes in preeclamptic women in 2008. It was shown that a greater likelihood of adverse maternal outcomes was present in 53% of individuals who had at least one aberration in their LFT values. The prediction accuracy of LFT as the best intermediate indicators of maternal and fetal difficulties in women with preeclampsia for adverse maternal and fetal outcomes was studied by Thangaratinam S et al. [18]. In a systematic review study, this was accomplished. The ALT level was significantly higher in the severe cases of preeclampsia than in the mild cases.

A study using ROC curve analysis revealed a high correlation between elevated ALT levels and mild preeclampsia ($p < 0.001$) as well as severe preeclampsia ($p = 0.032$). However, an ALT level of 50 IU/L demonstrated a specificity of 97% and a sensitivity of just 3.3% in terms of predicting severe preeclampsia [18]. Serum transaminase levels increased to >10 U/L and ALT levels reached 271±297 U/L in preeclampsia, according to Malvino et al. [20]. Rath et al. [21] also noted elevated ALT and AST values in patients of severe preeclampsia. According to the updated reference ranges, only 37% of the individuals in the pre-eclampsia group with higher liver function tests were abnormal. Pre-eclampsia patients exhibited significantly higher prevalence of elevated liver function tests (54%) with the amended ranges than the pregnancy-induced hypertension group (14%; $P < 0.01$). Pre-eclamptic patients with abnormal liver function tests had comparable levels of hypertension, but they also had greater levels of proteinuria ($P < 0.05$), lower platelet counts ($P < 0.001$), and more maternal problems ($P < 0.01$) when compared to individuals with normal liver function tests [22]. 1056 (53%) of the 2008 women in a follow-up study had at least one abnormal liver function test result [15]. Compared to women with normal findings, those with any abnormal liver function test had a greater chance of unfavorable maternal outcomes. Women in the top quartile were shown to have a higher likelihood of unfavorable outcomes when test results were stratified into quartiles. Adequate levels of AST, ALT, and LDH were linked to unfavorable consequences for mothers. But within certain periods, alterations in liver function tests were not predictive [23].

Conclusion

This research found that high ALT levels had a very good diagnostic accuracy in predicting a poor maternal outcome in pre-eclampsia. Thus, we advise measuring ALT levels in all pre-eclamptic women in order to implement appropriate care plans for high-risk individuals and lower the mother's morbidity and death.

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