Galectin-7 For Early Risk Prediction Of Preeclampsia In Normotensive Primigravida ; A Prospective Cohort Study

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ABSTRACT

Background

Preeclampsia is a multisystem hypertensive disorder of pregnancy that contributes substantially to maternal and perinatal morbidity worldwide. Galectin 7, a β-Galactoside-binding lectin implicated in apoptosis, epithelial integrity, and immune regulation, has recently been proposed as a potential biomarker for placental dysfunction. The study aims to evaluate serum galectin 7 levels in the first and second trimester of pregnancy with conventional clinical parameters for preeclampsia.

Methods

A prospective study among 279 primigravida women attending the OBG outpatient at Sri Ramachandra Institute of Higher Education and Research, Chennai. The participants were followed from early pregnancy until delivery; 112 developed PE were classified as cases and 167 normotensive as controls. Galectin 7 were estimated using ELISA for both Trimesters. Additional data collected included the BP, Urine protein, Uric acid, Magnesium, Baby weight/gender and Mode of delivery and were analyzed using appropriate statistical tests.

Result

Galectin-7 levels were significantly elevated in cases vs. controls (1st trimester: 7.197 ± 7.543 vs 2.806 ± 2.574 ng/mL; $p < 0.001$; 2nd trimester: 24.578 ± 8.506 vs 4.687 ± 2.771 ng/mL; $p < 0.001$). Similarly, 2nd trimester systolic/diastolic BP were higher in cases ($p < 0.001$). PE group had more operative deliveries, lower neonatal birth weight, and similar gender distribution. Proteinuria appeared only later, underscoring Galectin-7 as an early predictive biomarker.

Conclusion
Galectin 7 outperforms late onset markers like BP/Proteinuria for early PE prediction, supporting its integration into screening protocols to mitigate morbidity.
Keywords: Preeclampsia, Normotensive Primigravida, Galectin-7, Early prediction, Biomarkers, Reproductive health (SDG 3).
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INTRODUCTION: Preeclampsia is a complex multisystem disorder of pregnancy that affects about 3-8% of pregnancies worldwide and it is also a leading cause of maternal and perinatal morbidity. It is characterized by new -onset hypertension and proteinuria after 20th weeks of gestation and is largely driven by abnormal placentation and subsequent placental ischemia. The widely explained "two stage theory" describes preeclampsia's pathophysiology as beginning with impaired trophoblast invasion and inadequate remodeling of spiral arteries, resulting in uteroplacental perfusion (stage1) which then triggers systemic endothelial dysfunction and clinical manifestation (stage 2). Despite advances in understanding, early prediction and prevention remain challenging due to the late-onset of traditional clinical signs,such as elevated blood pressure and proteinuria (1). Women with the history of preeclampsia face heightened risks for chronic conditions, including chronic hypertension, cardiovascular disease, stroke, metabolic syndrome, cognitive decline and end-stage renal disease. Preeclampsia also endangers Foetal and neonatal health with offspring experiencing elevated risk for both short and long-term complications. Acutely, these infants often face preterm birth and intrauterine growth restrictions, while long-term they show increased susceptibility to neurodevelopmental disorders, diabetes mellitus, coronary heart disease and hypertension . Traditional diagnosis of preeclampsia relies primarily on clinical and laboratory assessments after twenty weeks of gestations , focusing on hypertension and evidence of organ dysfunction (2).

The core diagnostic criteria for prediction of preeclampsia are :

Blood Pressure Measurement

- New-onset hypertension occurring after 20 weeks of gestation, defined as:
- Systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg on two occasions at least 4 hours apart in a previously normotensive woman

Proteinuria Assessment

• Proteinuria is defined as any one of the following:

- ≥300 mg protein in a 24-hour urine collection, or .
- Protein-to-creatinine ratio (PCR) ≥0.3 mg/mg (equivalent to approximately 30 mg/mmol), or
- Urine dipstick reading of ≥2+ (when quantitative methods are unavailable)

Alternatively, Preeclampsia may be diagnosed in the absence of proteinuria if new-onset hypertension is accompanied by one or more of the following:

- Thrombocytopenia (platelet count <100,000/uL)
- Renal insufficiency (serum creatinine ≥1.1 mg/dL or doubling of baseline creatinine)
- Impaired liver function
- Pulmonary edema
- New-onset headache or visual disturbances
- Uteroplacental dysfunction (e.g., fetal growth restriction) [3].

Early prediction of preeclampsia transforms reactive management into proactive care, significantly improving maternal and fetal outcomes (4). High risk women identified through the first trimester screening can initiate low dose Aspirin (150MG daily from 12 to 16 weeks), reducing preterm preeclampsia by 82% as demonstrated in the ASPRE trial, while enhancing antenatal surveillance with frequent blood pressure monitoring uterine artery Doppler and growth scans prevent progression to eclampsia and HELLP syndrome (5). Lifestyle interventions include calcium supplementations in deficient populations and optimize delivery timing further mitigate risk, with screening programs achieving 75 to 90% detection rates for preterm preeclampsia at 10% false positives. These strategies reduce iatrogenic prematurity from 40% to 20% and enable timely foetal optimisation, ultimately lowering severe maternal morbidity by 20 to 50%, as reported in UK and Australian cohorts (4).

Biomarkers play a crucial role in the early prediction of preeclampsia by identifying biochemical and physiological changes that occur in the placenta and maternal system well before clinical symptoms like hypertension and proteinuria develop. These markers detectable in the first trimester (10th to 14th weeks), provide insight into abnormal placental development, endothelial dysfunction and angiogenic imbalance, which are fundamental pathophysiological processes in preeclampsia (6). Commonly studied biomarkers include placental growth factor (PIGF) soluble fms

like tyrosine kinase-1 (sFlt-1), Pregnancy associated plasma protein A (PAPP-A) and more recently, emerging proteins such as placental protein-13 and galectin- 7. When combined with material risk factors and uterine artery Doppler ultrasound measurements, biomarkers panel can achieve detection rates of 75 to 90% for Pre term preeclampsia with a 10% false positive rate, markedly improving early risk stratification compared to traditional clinical indicators (6,7,8). The early identification of women at high risk enables the timely initiation of preventive therapies. Traditional diagnostics, relying mainly on blood pressure measurements and proteinuria assessments, often detect the disease only after significant pathological changes have already occurred, resulting in lower sensitivity during early gestation and missed opportunities for prevention. In contrast, biomarkers provide a window into early pathophysiological changes, shifting clinical care from reactive management to proactive preventive strategies, which have been linked to decreased maternal mobility by 20-50% in implemented screening programs. Moreover, advances and point of care testing technology promised to extend access to biomarker based screening to low source settings, potentially reducing global disparities in preeclampsia outcomes. Thus, biomarkers stand as an indispensable tool in revolutionising early production and management of preeclampsia to improve both maternal and fetal health (5,8,9).

Galectin 7 offers significant advantages for early preeclampsia prediction due to its specific expression in placental trophoblast cells (syncytiotrophoblast and in extravillous trophoblast), enabling detection of placental dysfunction during the critical implantation phase. As a mechanistic driver rather than a bystander, it may actively contribute to pathogenesis by dysregulation the renin-angiotensin-aldosterone system, upregulating anti angiogenic sFlt1 and impairing spiral artery remodeling processes central to preeclampsia that manifest weeks before clinical symptoms. This positions galectin 7 as a prospective serum biomarker detectable in the first trimester (10 to 20 weeks) with prior studies showing elevation preceding hypertension, unlike late emerging traditional markers. Key benefits include high discriminatory potential of preterm preeclampsia straightforward ELISA measurements suitable for routine screening and therapeutic implication, neutralizing galectin- 7 could improve placental and prevent disease progression, as suggested by mouse models where its administration induced preeclampsia features. Its placental specificity provides direct insight into stage 1 pathophysiology (poor trophoblast invasion), complementing multi-marker, panels (PIGF, PP13) to boost detection rates while remaining cost effective for low resource settings. Overall galectin-7 may act like a bridge in early prediction with targeted intervention opportunities.(10,11,12).

Aim

1. To measure Galectin 7 levels during the 1st and 2nd trimester serum samples from Normotensive primigravida and compare the levels with those who developed preeclampsia (n=112) and remaining normotensive controls (n=167).
2. To evaluate the traditional preeclampsia biomarkers such as urine protein , blood pressure along with other parameters such as Magnesium and uric acid levels across both trimesters between the case and controls along with the mode of delivery , baby weight and Gender of the baby.
3. To assess the predictive performance of galectin 7 as an early biomarker for preeclampsia compared to traditional parameters using statistical analysis.
4. To perform a ROC analysis and obtain the cutt off value .

MATERIALS AND METHOD

Study Design and Participants : A prospective cohort study that enrolls 279 Normotensive primigravida patients who attended the Department of OBG (OP) at Sri Ramachandra Institute of Higher Education and Research. The patients' serum samples were collected during their 1st trimester (12th to 16th weeks) and 2nd trimester (16th to 20th weeks) were collected based on the inclusion and exclusion criteria and the patients were followed up till the time of delivery.

SAMPLE SIZE CALCULATION : :

The study of Subha Sivagami et al 2020 [14] reported the incidence of 38%. Based on the incidence with the Relative Precision of 15% and Confidence level of 95%. The sample size required to be followed up would be a minimum of 279 where women who develop Preeclampsia would be considered as cases and the rest of the samples would be taken as control.

Formula : $n = (Z^2 1\text{-}\alpha/2)(1\text{-}p)p / \xi^2 p$

Inclusion Criteria: Pregnant women aged 18-40 years group with less than 12th weeks of Gestation period.

Exclusion Criteria: : Subjects with metabolic syndrome, Gestational diabetes mellitus, cardiovascular disease, thyroid disease, hematologic disease, and polycystic ovary syndrome prior to pregnancy, as well as infection, multiple pregnancy will also be excluded from the study. Subjects if they conceived the fetus using assisted reproductive

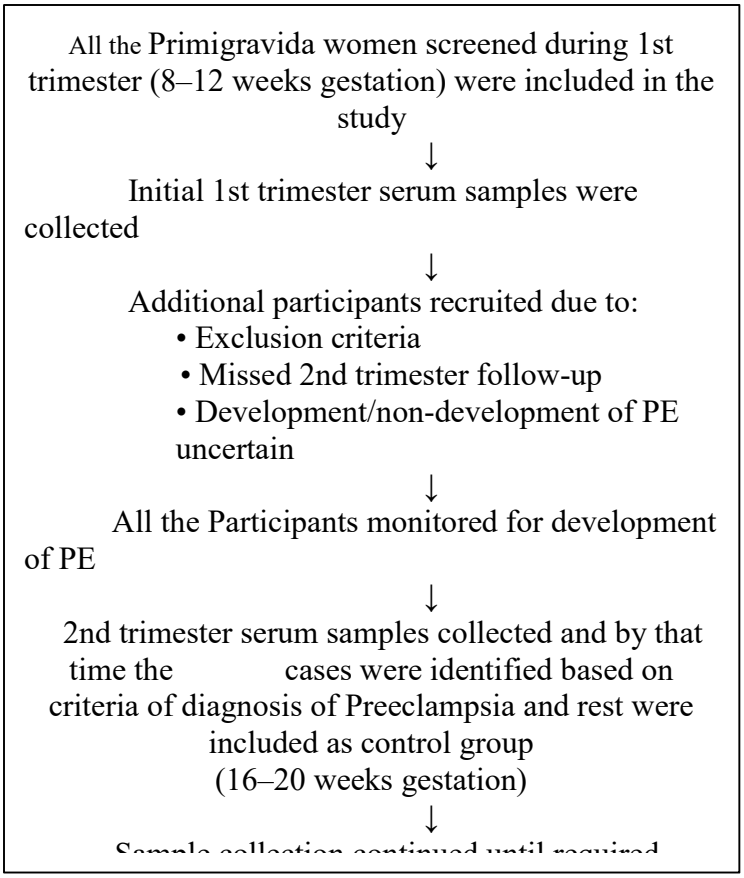
technology, such as in-vitro fertilization and intrauterine insemination; reported disease like cancer, tuberculosis, and HIV infection also will not be included in the study group.

Sample collection: Blood samples were collected from the Normotensive primigravida during their 1st trimester and 2nd trimester visits , the samples were centrifuged at 3000 rpm for 10 minutes and the separated serum was stored at −20°C until analysis.

Participants Recruitment and Follow up:

All primigravida women attending antenatal screening during the first trimester (8-12 weeks of gestation) were recruited for the study. Initial serum samples were collected during the first trimester. Additional participants were recruited throughout the study period to compensate for exclusions, missed second-trimester follow-up visits, and cases in which the development or non-development of preeclampsia could not be determined. All participants were monitored prospectively for the development of preeclampsia (PE). During the second trimester (16-20 weeks of gestation), serum samples were collected, and participants who met the diagnostic criteria for preeclampsia were classified as cases, while the remaining participants were included in the normotensive control group. Recruitment and sample collection continued until the required number of preeclampsia cases was achieved Subsequently, both cases and controls were followed prospectively until delivery. The final study population comprised 279 participants including women who developed preeclampsia and normotensive controls.

Study Participants Recruitment Flow Chart :



Analysis Method

Serum Galectin-7 was analyzed using the Sandwich ELISA Technique. Traditional parameters included the regular Blood pressure monitoring , Urine protein quantification by dipstick and confirmation using protein/creatinine ratio. Serum uric acid was estimated using the enzymatic uricase method. Serum magnesium was measured using the colorimetric calmagite method.

All tests were performed using a semi-automated biochemistry analyzer following standard laboratory protocols.

Statistical analysis: Data entry was made in Microsoft Excel and statistical analysis was performed

in Statistical Package for Social Sciences (SPSS) Software Version 27.0. Continuous variables were expressed as Mean ± Standard Deviation (M±SD).The Man-Whitney test was used to compare parameters between cases and controls. Chi-square test was used to compare categorical variables. Receiver Operating Characteristics (ROC) Curve Analysis was performed. A p-value of 0.05 was set as the critical value for significance.

RESULTS

In a prospective cohort of 279 normotensive primigravida women, 112 developed preeclampsia while 167 remained normotensive. Serum Galectin-7 were significantly higher in women who later developed preeclampsia compared to controls in both as (shown in the Figure 1)(Table 1) 1st trimester (7.197 ±7.543 vs 2.806 ±2.574 ng/mL; $p < 0.001$) and 2nd trimester (24.578 ± 8.506 vs 4.687 ± 2.771 ng/mL; $p < 0.001$).

Similarly, as shown in Figure 2, Table 1 , Systolic and diastolic blood pressure were elevated in preeclampsia cases when compared with controls with a greater rise observed in the 2nd trimester ($p < 0.001$).Proteinuria was markedly more frequent and severe in the preeclampsia group compared to controls (($p < 0.001$) consistent with diagnostic criteria.

In Figure 3A, Serum uric acid levels were also significantly elevated in cases during the 1st trimester (3.32 ±0.39mg/dL vs 2.81± 0.66mg/dL,p <0.001) and 2nd trimester (4.24± 1.10mg/dL, vs 3.14 ± 0.96mg/dL, p<0.001). Figure 3B, Magnesium levels were significantly lower in Preeclamptic women in 1st trimester (1.80±0.39mg/dL vs 1.54±0.22mg/d) (p< 0.001) and declining further by the 2nd trimester(1.90±0.59mg/dL vs 0.79±0.83mg/dL)(p<0.001). Figure 3C, shows the correlation of uric acid and magnesium levels of both the case and control between 1st and 2nd Trimesters. Figure 3D and Table 2 shows comparison between the modes of delivery between case and normotensive control, and shows a higher proportion of operative deliveries (LSCS, Emergency LSCS) among preeclamptic cases when compared to normotensive controls. The Bar chart showing the neonatal gender distribution between groups shows no marked imbalance between male and female neonates across groups. Similarly the baby weight was collected by following up the the patients which showed that the mean birth weight was lower in the preeclamptic case group (**2.**88 ± 0.39 kg) compared to normotensive controls (2.99 ± 0.40 kg**)** that indicates an adverse effect and impact on fetal growth (Table 1).

These findings indicate that galectin-7 rises significantly earlier and more markedly than traditional biomarkers , suggesting that galectin-7 serum has a superior potential as an early predictive biomarker for Preeclampsia. This highlights the utility of Galectin-7 serum measurements in early pregnancy risk assessment to prompt closer monitoring and timely interventions for women at risk of preeclampsia.

Table 3 and Figure 4 shows the Receiver Operating Characteristics (ROC) Curve Analysis of Galectin-7 in prediction of preeclampsia. For a cut-off value of 1.75 at first trimester, Galectin 7 had sensitivity of 82.1% and specificity of 50.3% (Area Under Curve=0.70) For a cut-off value of 4.25 at second trimester, Galectin 7 had sensitivity of 97.3% and specificity of 44.9% (Area Under Curve=0.97).

BIOMARKER	STD.DEV	MEAN	df	t	P VALUE
GALECTIN 7 (1st Trimester)	Case - 7.543 Control- 2.574	Case - 7.197 Control- 2.806	277	6.950	< 0.001
GALECTIN 7 (2nd Trimester)	Case - 7.197 Control- 2.806	Case - 24.578 Control- 4.687	277	28.099	< 0.001
Systolic Pressure (1st Trimester)	Case - 4.822 Control- 5.973	Case - 114.027 Control-110.090	277	5.818	< 0.001
Diastolic Pressure (1st Trimester)	Case - 4.598 Control- 6.201	Case - 74.411 Control- 70.719	277	5.385	< 0.001
Systolic Pressure (2nd Trimester)	Case - 15.067 Control- 6.412	Case - 128.955 Control- 115.192	277	10.481	< 0.001
Diastolic Pressure (2nd Trimester)	Case - 9.794 Control- 5.446	Case - 82.045 Control- 73.790	277	9.014	< 0.001
Uric Acid (1st Trimester)	Case - 0.392 Control- 0.660	Case - 3.320 Control- 2.812	277	7.321	< 0.001
Uric Acid (2nd Trimester)	Case - 0.964 Control- 1.102	Case - 4.241 Control- 3.143	277	-8.797	< 0.001
Magnesium (1st Trimester)	Case - 0.227 Control- 0.395	Case - 1.547 Control- 1.838	277	-7.039	< 0.001
Magnesium (2nd Trimester)	Case - 0.837 Control- 0.600	Case - 0.794 Control- 1.919	277	4.498	< 0.001
Urine Protein (1st and 2nd trimester)	Case -0.000 Control- 0.000	Case - 71.542 Control- 0.000	-	-	< 0.001
Birth weight	Case - 0.39 control-0.40	Case - 2.88kg control-2.99kg			

Table 1: Comparison of biomarkers and clinical parameters between control and case of both 1st and 2nd trimesters

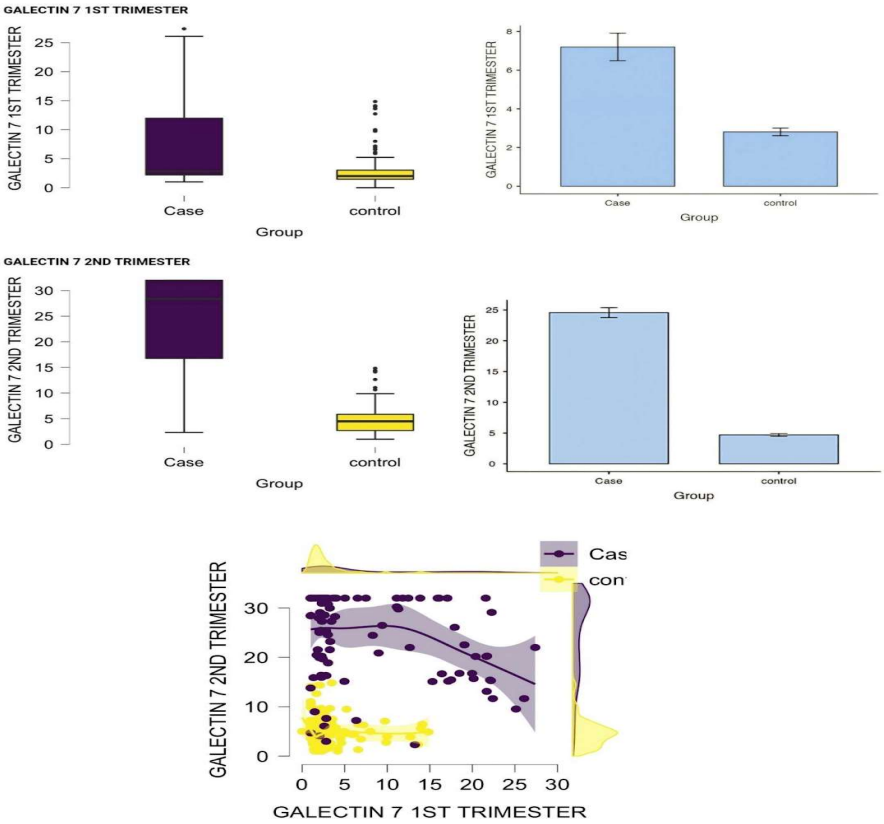


Figure 1: Comparison and Correlation of Galectin-7 (1st and 2nd trimester) between Case and control.

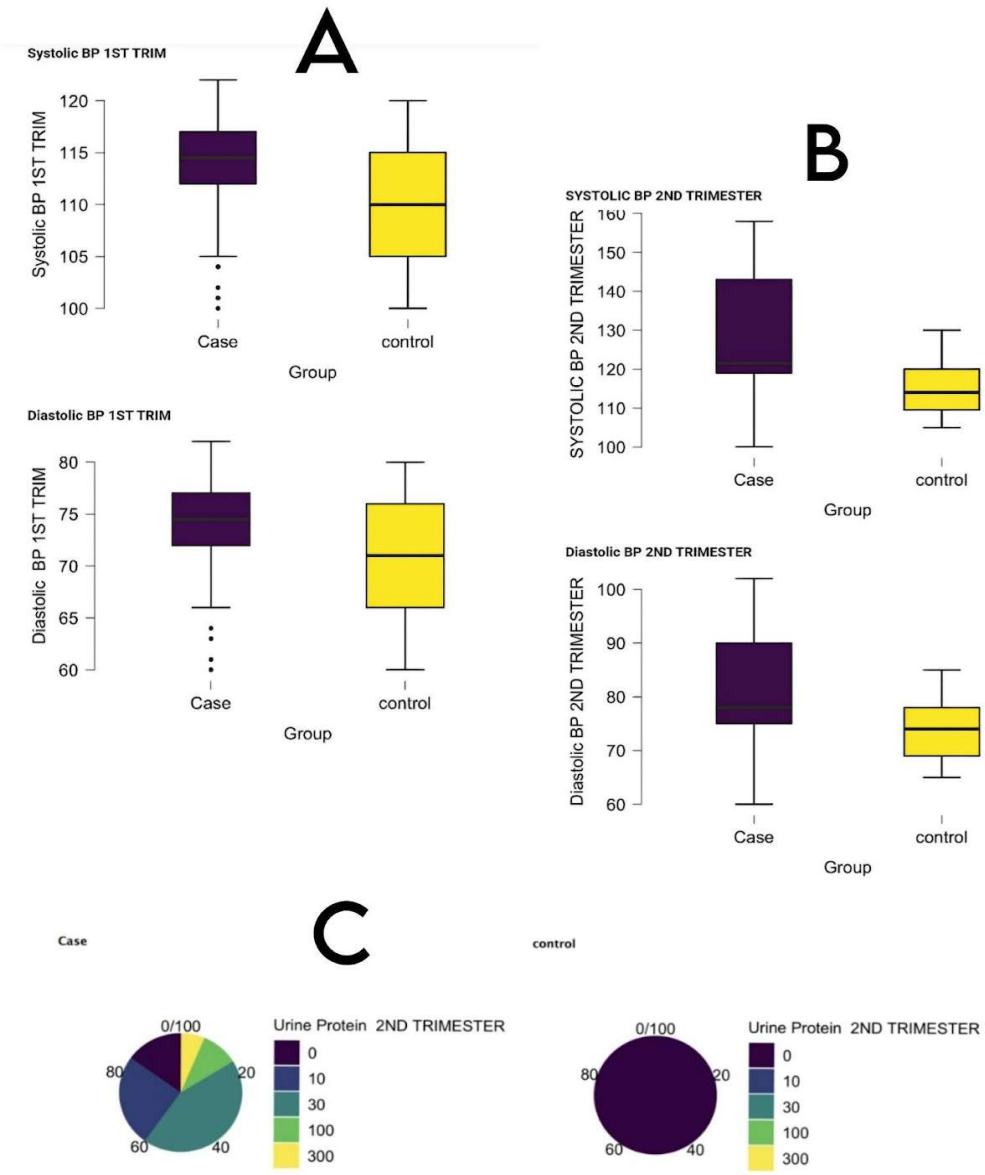


Figure 2 : A) Comparison of Blood pressure (1st trimester) between Case and control. **B)** Comparison of Blood pressure (2nd trimester) between Case and control. **C)** Comparison of Urine protein (1st and 2nd trimester) between Case and control.

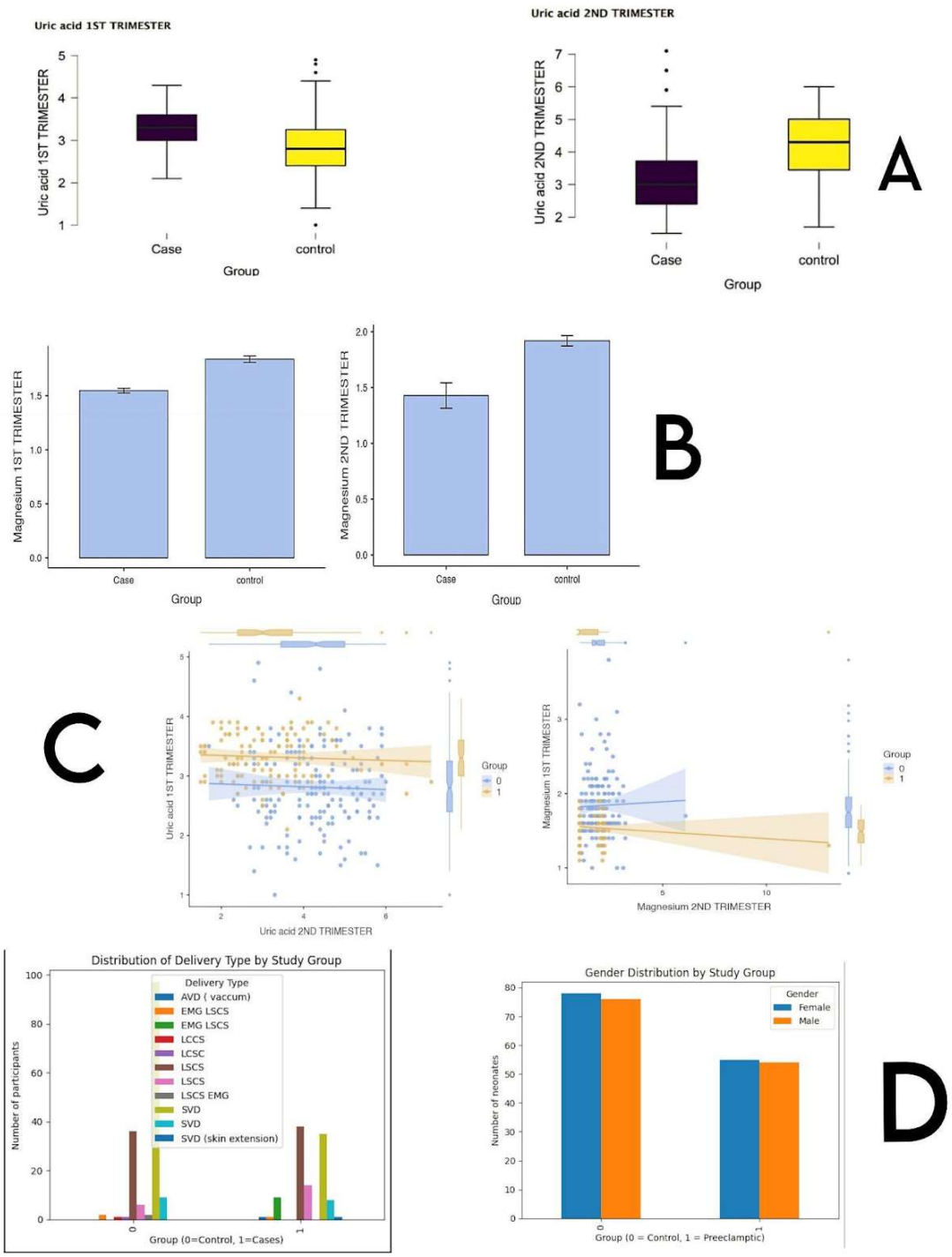


Figure 3 : A) Comparison of Serum uric acid (1st and 2nd trimester) between Case and control. **B)** Comparison of Magnesium (1st and 2nd trimester) between Case and control. **C)** Correlation of Serum uric acid and Magnesium of 1st and 2nd trimester between case and control. **D)** Distribution of mode of delivery and Gender of the baby between case and control.

Table 2 : Comparison of Post pregnancy Variables between cases and control

		Controls	Cases	p-value
Mode of delivery	**SVD n (%)**	116 (69.5)	45 (40.2)	**<0.001***
	LSCS n (%)	51 (30.5)	67 (59.8)	
Birth weight of the child	**M+SD**	2.95 (2.74-3.24)	2.99 (2.76-3.14)	0.38
Gender of the child	**Male n (%)**	82 (49.1)	60 (53.6)	0.27
	Female n (%)	85 (50.9)	52 (46.4)	

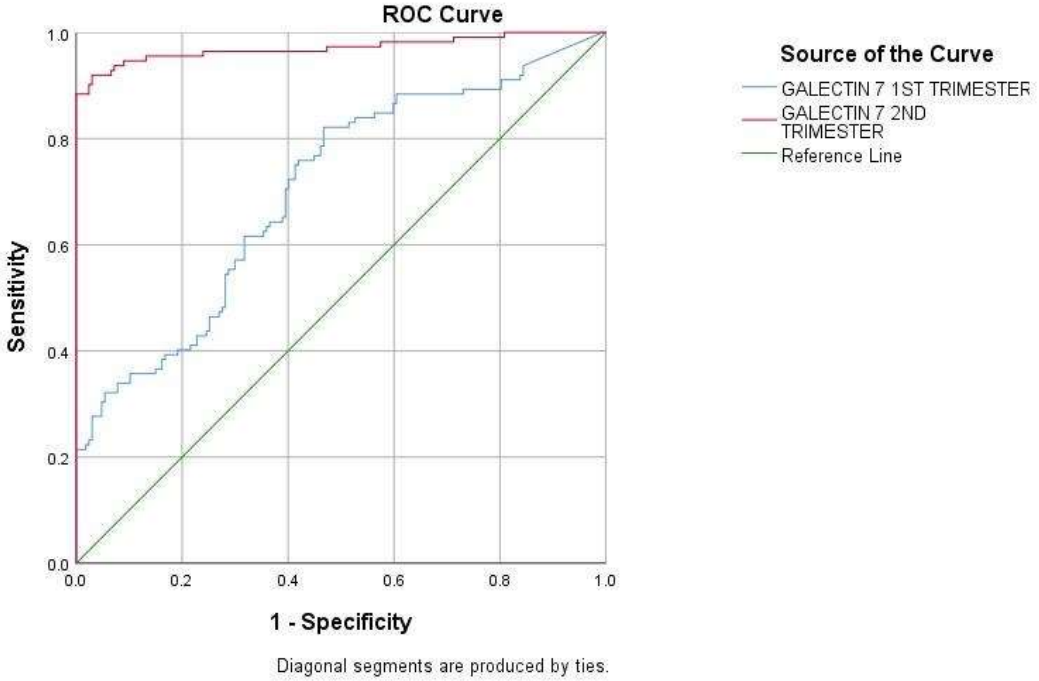


Figure 4: ROC Curve Analysis of Galectin 7

		AUC	Sensitivity	Specificity	PPV
GALECTIN 7	**1st trimester**	0.70	82.1%	50.3%	52.5%
	2nd trimester	0.97	97.3%	44.9%	54.2%

Table 3 : ROC Analysis of Galectin 7

DISCUSSION : This prospective cohort study demonstrates that serum galectin-7 levels are markedly elevated in the first and second trimester samples from primigravida who developed preeclampsia showing superior early discriminatory capacity compared to traditional biomarkers including blood pressure, protein, uric acid and magnesium. These findings align with prior research establishing galectin 7 as a trophoblast specific marker of impaired Placentation, where it's this dysregulation during spiral artery remodelling upregulates sFlt-1 and activates renin-angiotensin system- pathogenic mechanism confirmed in murine models (10). Traditional markers confirmed expected later- stage changes reflective of maternal endothelial dysfunction, but lacked first trimester, predictive utility, highlighting galectin 7's unique advantage in detecting preclinical placental insufficiency (4,13). Our cohort study provides robust validation exceeding smaller prior studies with prospective design and serial sampling minimising bias.

STRENGTHS AND LIMITATIONS

This study has several notable strengths. It is a prospective cohort study conducted among normotensive primigravida women, with follow-up throughout pregnancy, enabling the early identification of factors associated with the subsequent development of preeclampsia. The study incorporates a comprehensive assessment of biochemical parameters (serum uric acid and magnesium), novel biomarker evaluation (Galectin-7), clinical parameters (blood pressure and urine protein), and pregnancy outcomes (Birth weight, neonatal gender, and mode of delivery), thereby enhancing the predictive assessment of preeclampsia. Furthermore, serum samples were collected during both the first and second trimesters facilitating the evaluation of early gestational changes and improving the potential for early risk stratification.

However, certain limitations should be acknowledged. The study was a single-center, hospital-based investigation conducted at a tertiary care institution, which may limit the generalizability of the findings to broader populations. Although significant associations between serum uric acid, magnesium. Galectin-7 levels, and the development of preeclampsia were observed, potential confounding factors such as maternal body mass index (BMI), nutritional status, dietary habits, and socioeconomic status were not adjusted for using multivariable analysis. Additionally, the predictive performance of Galectin-7 requires validation in larger and more diverse populations. Therefore, large-scale multicenter prospective studies incorporating adjustment for potential confounders are warranted to further validate the utility of Galectin-7, along with routine biochemical parameters, as an early predictive biomarker for preeclampsia.

CONCLUSION: This study conducted at Sri Ramachandra Institute of Higher Education and Research demonstrates that serum Galectin 7 levels are markedly elevated in 1st and 2nd trimesters samples from Normaotensive primigravida who subsequently develop Preeclampsia , with significantly greater discriminatory power compared to traditional biomarker including Blood pressure , urine protein, uric acid and magnesium levels along with Delivery details such as Mode of delivery, baby weight and Gender. The early rise in Galectin-7 (7.197 ± 7.543 vs 2.806 ± 2.574 ng/mL; $p < 0.001$) in the 1st trimester precedes clinical manifestation and outperforms conventional parameters that show changes primarily in later gestation. These findings show that galectin-7 as a superior early predictive biomarker for preeclampsia risk stratification , enabling timely antenatal surveillance and intervention to mitigate maternal -fetal complications. Further research involving larger, diverse groups of women is needed to confirm these results and explore how galectin 7 could work alongside other tests to best predict and manage preeclampsia.

Author's contribution: Saroash Zulfishaan R - Conceptualization. Data Collection, Data Analysis Manuscript Drafting and Data Interpretation..

Dr.Leena Chand conceptualized the review, provided supervision and revised the manuscript. Dr. Anusha R and Dr. Preet Agarwal - Literature review, Manuscript editing and approved the final version.

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Informed consent: The Informed consent was obtained from all the participants in the study.

Data sharing statement : All data generated or analysed during this study are included in this published article.

Declaration of Artificial intelligence : The authors declare that no AI Tool was used in the manuscript writing. The authors take full responsibility for the integrity and accuracy of the content presented.

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