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Assessment Of Fructosamine Versus Hba1c For Glycaemic Monitoring In Pregnancy-Associated Hyperglycaemia: A Cross-Sectional Study

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ABSTRACT
Background: *Fructosamine reflects short-term glycaemic control and may serve as a useful alternative to HbA1c in pregnancy, where rapid glycaemic fluctuations occur. This study evaluates fructosamine's utility in monitoring hyperglycaemia during pregnancy and its correlation with maternal and fetal outcomes.*
Objectives: *To assess the correlation between fructosamine and HbA1c, fasting blood sugar (FBS), postprandial blood sugar (PPBS), and to evaluate its association with feto-maternal outcomes.*
Methods: *In this prospective study (May 2023 – Nov 2024), pregnant women in their second trimester were screened using the glucose challenge test (GCT). Based on GCT results, participants were grouped into hyperglycaemic cases and normoglycemic controls. All underwent evaluation of fructosamine, HbA1c, FBS, and PPBS. Correlations between markers and clinical outcomes were analysed.*
Results: *Fructosamine levels were significantly higher in hyperglycaemic cases compared to controls and showed strong positive correlation with HbA1c, FBS, and PPBS. Elevated fructosamine levels were also associated with increased risk of adverse maternal and neonatal outcomes.*
Conclusion: *Fructosamine is a reliable marker of short-term glycaemic control in pregnancy and correlates well with conventional markers. Its association with adverse outcomes supports its role as an alternative to HbA1c, particularly where HbA1c may be limited. Routine use of fructosamine could improve monitoring and management of gestational hyperglycaemia.*
Keywords: *Fructosamine, Hyperglycaemia, Pregnancy, Gestational Diabetes, Glycaemic Monitoring, HbA1c, Maternal Outcomes, Biomarker*

INTRODUCTION

Hyperglycaemia in pregnancy, including gestational diabetes mellitus (GDM) and pre-existing diabetes, poses significant risks to both maternal and fetal health. Effective glycaemic monitoring is essential to minimize complications such as preeclampsia, macrosomia, and neonatal hypoglycaemia. Traditionally, glycosylated haemoglobin (HbA1c) has been used to assess long-term glycaemic control, reflecting average glucose levels over 8–12 weeks [1]. However, its reliability in pregnancy is limited due to altered red blood cell turnover and physiological changes in glucose metabolism during gestation [2].
Given these limitations, there is growing interest in alternative biomarkers that reflect short-term glycaemic fluctuations. Fructosamine, formed by non-enzymatic glycation of serum proteins—primarily albumin—offers a shorter window of glycaemic assessment (2–3 weeks) [3,4]. This makes it particularly suitable for pregnancy, where rapid hormonal shifts and insulin resistance can lead to dynamic changes in blood glucose levels [5].

Unlike HbA1c, fructosamine is unaffected by conditions that alter red blood cell lifespan, such as iron deficiency anaemia and haemoglobinopathies, which are common in pregnancy and can confound HbA1c interpretation [6,7]. Its responsiveness to recent glycaemic changes may support timely therapeutic adjustments, improving maternal and fetal outcomes [8].
Emerging evidence suggests a strong correlation between fructosamine and HbA1c in pregnant women, with comparable efficacy in tracking glycaemic trends [9]. Additionally, elevated fructosamine levels have been linked to adverse pregnancy outcomes, underscoring its potential as both a monitoring tool and a prognostic marker [10].
Despite its advantages, widespread clinical use of fructosamine remains limited. Challenges include lack of standardized reference ranges, variability in assay techniques, and limited clinician familiarity. Addressing these issues through further research and clinical guideline development is critical for its broader adoption.
In this context, the present study aims to evaluate the utility of fructosamine as an alternative biomarker to HbA1c for glycaemic monitoring in pregnancy. Specifically, it investigates the correlation between fructosamine and established glycaemic markers (HbA1c, FBS, and PPBS), and examines its association with maternal and neonatal outcomes in pregnancies complicated by hyperglycaemia.

AIM OF THE STUDY

To assess the clinical utility of fructosamine in hyperglycaemia in pregnancy

OBJECTIVES OF THE STUDY

1. To correlate values of Fructosamine with HbA1c, FBS and PPBS.
2. To correlate Fructosamine levels with fetomaternal outcome.

METHODOLOGY

Study Design

This prospective observational cohort study aimed to evaluate the utility of fructosamine as an alternative biomarker for monitoring glycaemic control in pregnant women with hyperglycaemia. Participants were recruited during their second trimester and stratified into two groups based on their glucose challenge test (GCT) results: normal GCT (controls) and abnormal GCT (cases). Both groups underwent FBS, PPBS, HbA1c, and fructosamine testing, while the case group also underwent an oral glucose tolerance test (OGTT). Participants were followed until delivery to monitor glycaemic trends and maternal-fetal outcomes.

Study Setting

The study was conducted in the Department of Obstetrics and Gynaecology at Adichunchanagiri Institute of medical sciences and Research Centre, Adichunchanagiri University, Karnataka, India-a tertiary care facility with advanced diagnostic capabilities and access to a broad antenatal population.

Study Duration

The study spanned 18 months, from May 2023 to November 2024, enabling complete follow-up from the 24th week of gestation through delivery.

Study Participants

Inclusion Criteria:

- Pregnant women aged 19–40 years
- Singleton, live intrauterine pregnancies
- Booked at 24 weeks gestation
- Willingness to provide informed consent
- Stratified into hyperglycaemic (abnormal GCT) and normoglycemic (normal GCT) groups

Exclusion Criteria:

- Anaemia or blood dyscrasias
- Type 1 or 2 diabetes mellitus
- Significant comorbidities (e.g., hypertension, thyroid dysfunction, liver disease, cardiovascular disease)
- Multiple gestation or intrauterine fetal demise

Study Sampling
A convenient sampling method was employed, recruiting eligible participants during routine antenatal visits at 24 weeks gestation.

Sample Size
Based on a presumed GDM prevalence of 8%, a 95% confidence level, and 5% margin of error, the calculated sample size was 100. Participants were divided into two equal groups: 50 cases (abnormal GCT) and 50 controls (normal GCT).

Study Groups

- **Control Group (n=50):** Normal GCT results
- **Case Group (n=50):** Abnormal GCT results confirmed via OGTT
  Both groups were monitored for glycaemic control using FBS, PPBS, HbA1c, and fructosamine, with outcomes tracked through delivery.

Study Parameters
Biochemical markers assessed included FBS, PPBS, HbA1c, and fructosamine. OGTT was additionally performed in the case group to confirm GDM diagnosis. These markers were evaluated for their effectiveness in monitoring short- and long-term glycaemic control during pregnancy.

Study Procedure
Following informed consent, GCT was performed at 24 weeks gestation. Participants were assigned to groups based on GCT results. Blood samples were collected for FBS, PPBS, HbA1c, and fructosamine. Case group participants also underwent OGTT. Glycaemic monitoring and fetomaternal outcomes were tracked through routine follow-up until delivery.

Data Collection
Demographic and clinical data were collected at enrolment. Blood samples were processed using standardized laboratory methods—fructosamine by colorimetric assay and HbA1c by HPLC. Clinical and biochemical data were recorded and entered into a structured database for analysis.

Data Analysis
Data were analysed using SPSS v20. Descriptive statistics summarized demographic and clinical characteristics. Independent t-tests compared continuous variables (FBS, PPBS, HbA1c, fructosamine), while Chi-square or Fisher's exact tests assessed categorical data. Pearson correlation assessed relationships between glycaemic markers. ROC analysis was used to evaluate the diagnostic accuracy of fructosamine versus HbA1c in predicting poor glycaemic control and adverse outcomes. A p-value <0.05 was considered statistically significant.

RESULTS

4.1 Demographic Profile of the Respondent

1. Age-wise Distribution of Cases and Controls

The age distribution of cases and controls was analysed using the Pearson chi-square test ($\chi^2 = 6.198$, $p = 0.102$). Although there are variations in the number of participants across different age groups, the p-value indicates that the difference is not statistically significant ($p > 0.05$). This suggests that age distribution between cases and controls is comparable, and age is not a significant confounding factor in the study.

	Group		Total
AGE	Cases	Control	
19 to 25	16	28	44
26 to 30	19	13	32
31 to 35	13	7	20
36 to 40	2	2	4
Total	50	50	100
Pearson chi-square = 6.198, p-value = 0.102			

Table: Age-wise Distribution of Cases and Controls

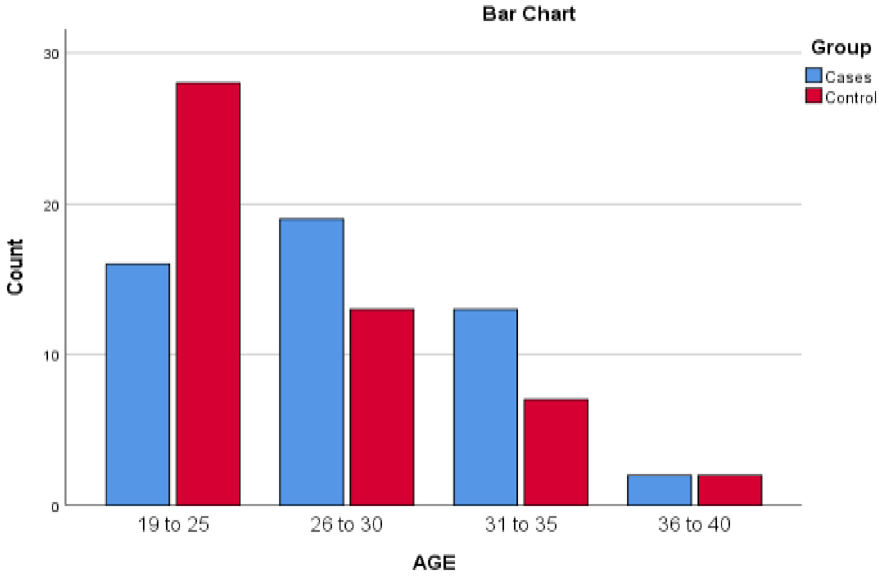

Figure: **Age-wise Distribution of Cases and Controls**

2. Gravida-wise Distribution of Cases and Controls

The distribution of cases and controls based on gravida status was analysed using the Pearson chi-square test ($\chi^2 = 1.449$, $p = 0.229$). Although there is a difference in the number of primigravida and multigravida participants between the groups, the p-value indicates that this difference is not statistically significant ($p > 0.05$). This suggests that gravida status is not a significant factor distinguishing cases from controls in this study.

Table: Gravida-wise Distribution of Cases and Controls

	Group		Total
GRAVIDA	Cases	Control	
multi	30	24	54
primi	20	26	46
Total	50	50	100
Pearson chi-square = 1.449, p-value = 0.229			

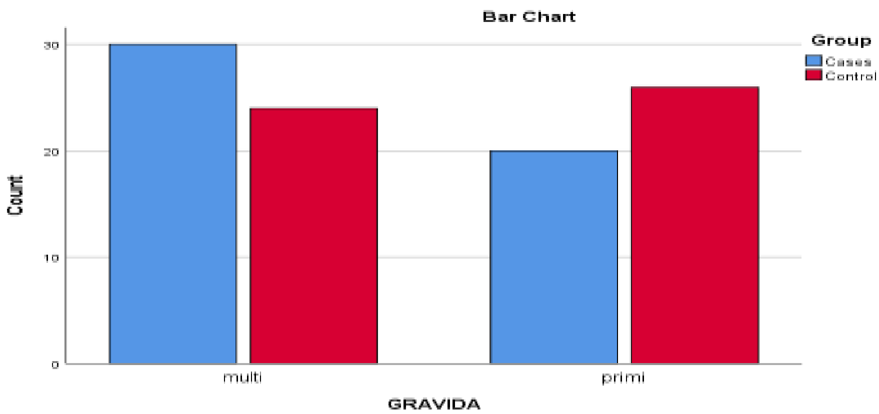

Figure: Gravida-wise Distribution of Cases and Controls

3. Distribution of Period of Gestation (POG) During Sample Collection Among Cases and Controls

The distribution of cases and controls based on the period of gestation (POG) at the time of sample collection was analysed using the Pearson chi-square test ($\chi^2 = 0.000$, $p = 1.000$). The identical distribution of participants in both groups across the 24–26 weeks and 27–28 weeks categories, along with a p-value of 1.000, indicates no statistically significant difference. This confirms that the timing of sample collection was uniform between cases and controls, minimizing potential bias related to gestational age.

	Group		Total
POG during sample collection	Cases	Control	
24 - 26 Weeks	44	44	88
27 - 28 Weeks	6	6	12
Total	50	50	100
Pearson chi-square = 0.000, p-value = 1.000			

Table: Distribution of Period of Gestation (POG) During Sample Collection Among Cases and Controls

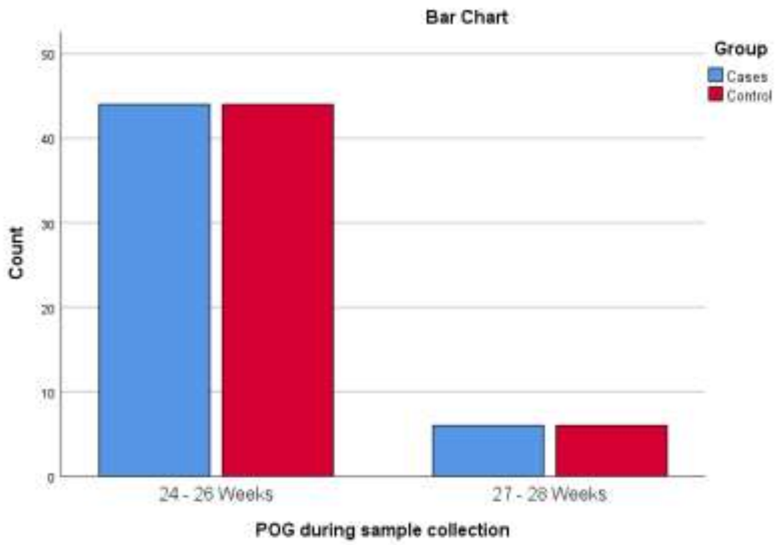

Figure: Distribution of Period of Gestation (POG) During Sample Collection Among Cases and Controls

4. Comparison of Fructosamine Levels Between Cases and Controls

The mean fructosamine level was significantly higher in cases (241.98 ± 31.143 µmol/L) compared to controls (172.57 ± 49.052 µmol/L). The difference was statistically significant ($p < 0.001$), indicating that fructosamine levels are notably elevated in hyperglycaemic pregnant individuals. This suggests that fructosamine may serve as a reliable biomarker for distinguishing hyperglycaemic cases from normoglycemic controls.

Table: Comparison of Fructosamine Levels Between Cases and Controls

	Group	N	Mean	Std. Deviation	P value
FRUCTOSAMINE	Cases	50	241.98	31.143	0.000
	Control	50	172.57	49.052	

5. **Mode of Delivery Among Cases and Controls**

The mode of delivery showed a statistically significant difference between cases and controls ($\chi^2 = 48.280$, $p < 0.001$). A higher proportion of cases underwent lower segment caesarean section (LSCS) (36 cases vs. 15 controls), whereas assisted vaginal deliveries (forceps/vacuum) and normal vaginal deliveries were more frequent among controls. Additionally, full-term normal delivery (FTND) was observed in only 7 cases compared to 1 control, while FTND with right mediolateral episiotomy (FTND+RMLE) was more common in controls (7 controls vs. 0 cases). The significant p-value (<0.001) indicates that hyperglycaemia in pregnancy is associated with an increased likelihood of caesarean section and reduced chances of spontaneous vaginal delivery.

Table: Mode of Delivery Among Cases and Controls

	Group		Total
PROCEDURE	Cases	Control	
ftnd	7	1	8
ftnd+rmle	0	7	7
lscs	36	15	51
nvd	2	0	2
ptvd	4	1	5
vavd	1	2	3
Total	50	26	76
Pearson chi-square = 48.280, p-value = 0.000			

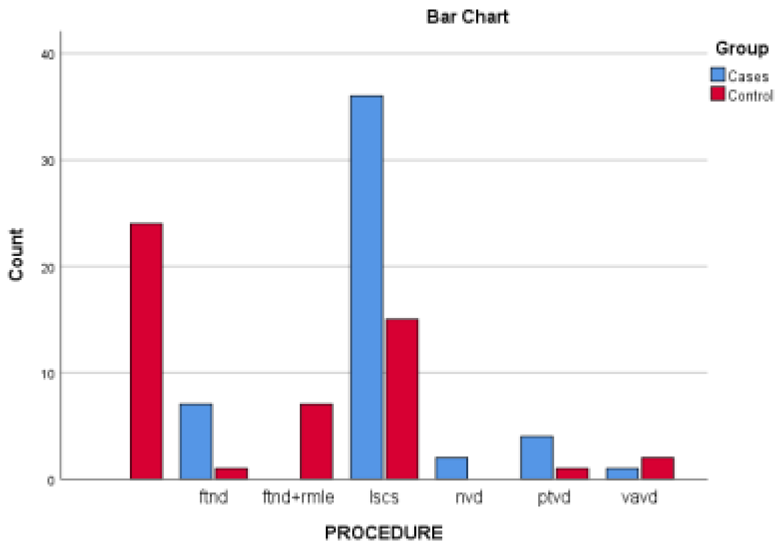

Figure: Mode of Delivery Among Cases and Controls

6. **Comparison of Baby Weight Between Cases and Controls**

The mean birth weight of babies born to cases (2.9772 ± 0.57166 kg) was significantly lower than that of controls (3.1569 ± 0.34089 kg), with a p-value of 0.037. This indicates a statistically significant difference ($p < 0.05$), suggesting that hyperglycaemia in pregnancy may be associated with slightly lower birth weights. While the difference is modest, it highlights the potential impact of maternal glycaemic status on fetal growth and birth outcomes.

Table: Comparison of Baby Weight Between Cases and Controls

	Group	N	Mean	Std. Deviation	P value
baby Weight	Cases	50	2.9772	0.57166	0.037
	Control	26	3.1569	0.34089	

7. **Correlation of Fructosamine with Glycaemic Parameters**

The correlation analysis between fructosamine and various glycaemic parameters revealed significant positive associations. Fructosamine showed the strongest correlation with OGCT ($r = 0.670$, $p < 0.001$), followed by HbA1c ($r = 0.530$, $p < 0.001$), PPBS ($r = 0.510$, $p < 0.001$), and FBS ($r = 0.412$, $p < 0.001$). The statistically significant p-values indicate that fructosamine is strongly associated with glycaemic indices, supporting its potential utility as a biomarker for monitoring hyperglycaemia in pregnancy.

Table: Correlation of Fructosamine with Glycaemic Parameters

		FRUCTOSAMINE
OGCT	Correlation	0.670**
	P value	0.000
HBA1C	Correlation	0.530**
	P value	0.000
FBS	Correlation	0.412**
	P value	0.000
PPBS	Correlation	0.510**
	P value	0.000

8. NICU Admission Among Newborns of Cases

Out of 50 newborns in the case group, 7 (14%) required NICU admission, while 43 (86%) did not. This indicates that a proportion of newborns born to mothers with hyperglycaemia in pregnancy required specialized neonatal care, potentially due to complications associated with maternal glycemic status. Further analysis may be needed to assess the reasons for NICU admissions and their correlation with maternal glucose levels.

Table: NICU Admission Among Newborns of Cases

Nicu admission	Frequency	Percent
Yes	7	14
No	43	86
Total	50	100.0

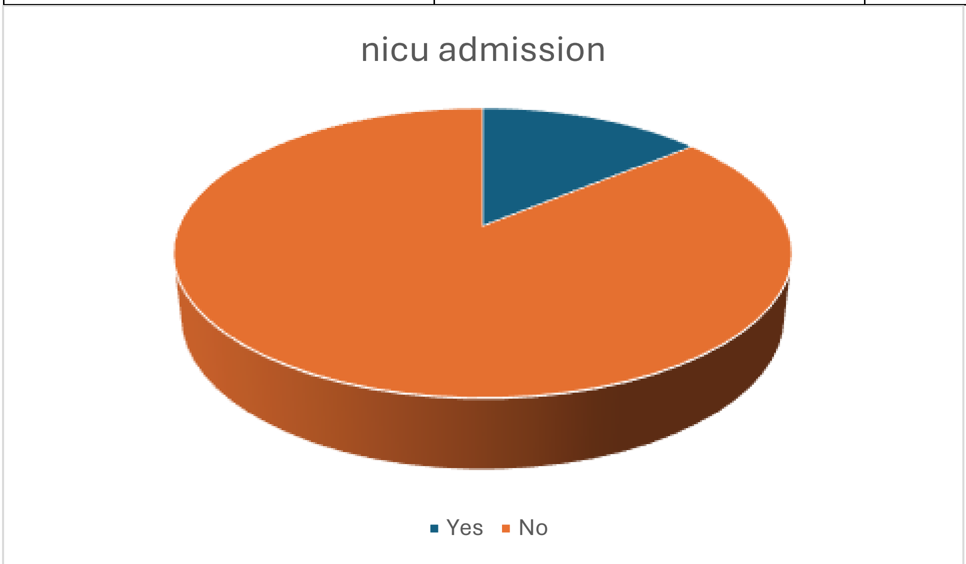

Figure: NICU Admission Among Newborns

9. Neonatal Complications Observed in Cases

Among the newborns of hyperglycaemic mothers, various neonatal complications were observed. Hypocalcaemia was the most common (4%), followed by hypomagnesemia (2%), polycythaemia (2%), renal agenesis (2%), and sacral agenesis (2%). A total of 12% of neonates had reported complications. These findings suggest that maternal hyperglycaemia may contribute to a spectrum of neonatal metabolic and congenital abnormalities, emphasizing the need for close monitoring and early intervention in affected pregnancies.

Table: Neonatal Complications Observed in Cases

neonatal complications	Frequency	Percent
HYPOCALCEMIA	2	4
HYPOMAGNESIEMIA	1	2
POLYCYTHEMIA	1	2
RENAL AGENESIS	1	2
SACRAL AGENESIS	1	2
No	6	12

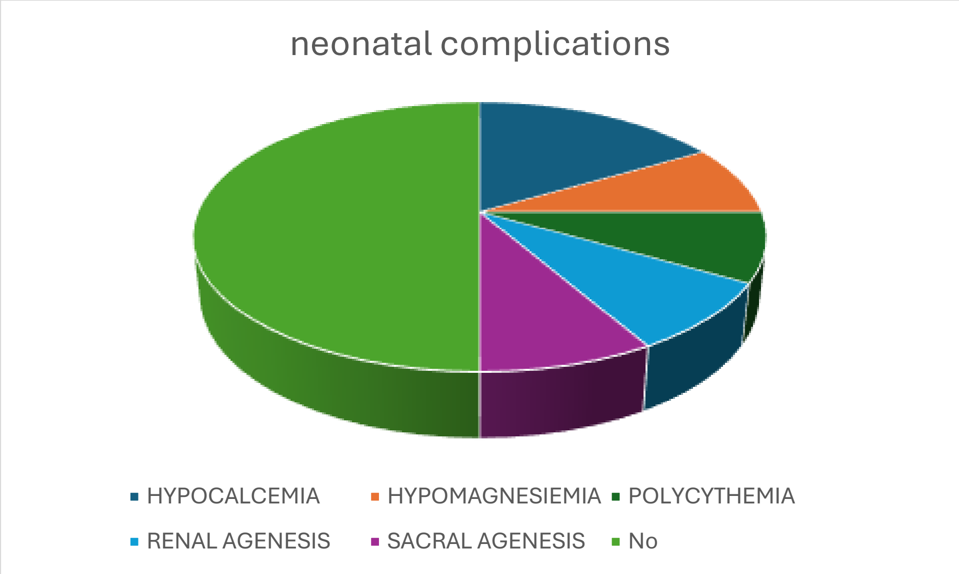

Figure: Neonatal Complications Observed in Cases

10. Maternal Complications Among Cases

Various maternal complications were observed in hyperglycaemic pregnancies. Gestational hypertension was reported in 8% of cases, polyhydramnios in 12%, postpartum haemorrhage (PPH) during labour in 6%, and prolonged labour in 8%. These findings highlight the increased risk of maternal complications associated with hyperglycaemia in pregnancy, emphasizing the need for vigilant antenatal monitoring and timely intervention to improve maternal and fetal outcomes.

Table: Maternal Complications Among Cases

maternal complications	Frequency	Percent
Gest.HTN	4	8.0
POLYHYDRAMNIOS	6	12.0
PPH(DURING LABOUR)	3	6.0
PROLONGED LABOUR(DURING LABOUR)	4	8.0

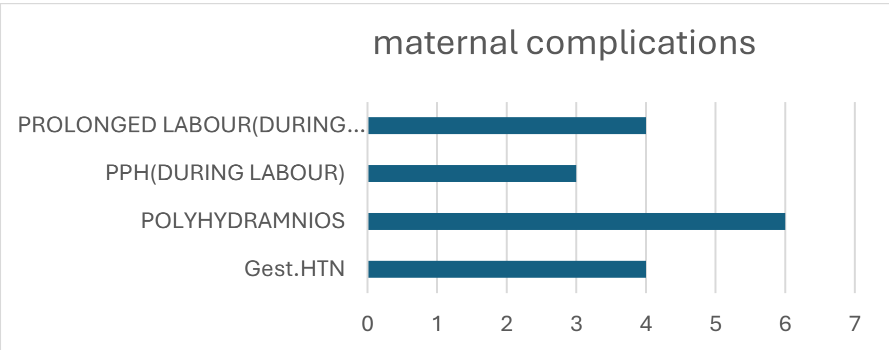

Figure: Maternal Complications Among Cases

DISCUSSION

This study evaluated the clinical utility of **fructosamine** as a biomarker for hyperglycemia in pregnancy. Unlike HbA1c, which reflects long-term glycemic control, fructosamine provides insight into glucose levels over a shorter period (1–3 weeks), making it particularly suitable for the dynamic metabolic changes of pregnancy. This is especially relevant in **gestational diabetes mellitus (GDM)**, where timely glycemic monitoring is essential to reduce maternal and fetal complications.

Fructosamine levels were significantly elevated in hyperglycemic pregnant women compared to controls, aligning with prior research by Meek et al. (2021) and Bernier et al. (2022), which also linked fructosamine to insulin resistance and perinatal outcomes. Its ability to reflect short-term glycemic variations supports its potential role in **adjusting therapeutic interventions in real-time** and improving risk stratification during pregnancy.

A strong positive correlation was found between fructosamine and key glycemic markers, including HbA1c ($r = 0.530$), OGCT ($r = 0.670$), FBS ($r = 0.412$), and PPBS ($r = 0.510$), all statistically significant ($p < 0.001$). These findings echo studies by Toyoshima et al. (2023) and Peer et al. (2021), supporting fructosamine's use alongside HbA1c to provide a **more complete picture of glycemic control**. The combination may be particularly useful in detecting recent glucose fluctuations, which HbA1c alone may miss.

The study also observed significantly higher values for OGCT, HbA1c, FBS, and PPBS in cases versus controls, further confirming hyperglycemia. Previous research by Ajayi & Timothy (2024) and Doumatey et al. (2021) emphasized fructosamine's reliability in populations with conditions like anaemia or hemoglobinopathies that may limit HbA1c's accuracy. This reinforces the **value of a multi-marker approach** in prenatal care.

Adverse **gestational outcomes** such as preterm delivery, increased caesarean section rates, and neonatal complications were more common in hyperglycemic pregnancies. Elevated fructosamine levels were associated with these outcomes, suggesting its potential in **predicting obstetric risks**. These findings are consistent with literature noting that poor glycemic control can lead to placental dysfunction and inflammatory responses contributing to early labour and fetal distress.

Neonatal outcomes, including low birth weight, higher NICU admissions, and metabolic disturbances, were significantly more prevalent among hyperglycemic mothers. Maternal complications such as gestational hypertension and polyhydramnios were also more common, emphasizing the systemic effects of hyperglycemia. Fructosamine's association with these outcomes suggests it could serve as an **early warning marker**, prompting timely interventions to mitigate risk.

Clinically, fructosamine offers a **valuable addition to prenatal screening**, especially in settings where HbA1c may be unreliable. Its shorter half-life makes it useful for frequent monitoring and treatment adjustments. Implementing fructosamine testing in routine practice could enhance individualized glycemic management, reducing the risk of maternal and neonatal complications.

In conclusion, this study supports fructosamine as a **reliable and practical biomarker** for hyperglycemia in pregnancy. Further research with larger, longitudinal cohorts is needed to establish trimester-specific reference ranges and evaluate its full predictive potential in obstetric care.

Strength Of The Study

The study highlights the primary advantage of fructosamine in the management of GDM lies in its ability to provide a more immediate reflection of recent changes in blood glucose levels.

The study establishes a strong link between fructosamine and other parameters like OGCT,HbA1C, FBS and PPBS and adverse maternal and neonatal outcomes such as hypertension ,hypothyroid ,PPH, prolonged labour and increased NICU admissions due to preterm ,hypoglycaemia ect.

Limitations

Despite its significant findings, this study has certain limitations that must be acknowledged:

1. Sample Size Constraints – A larger, more diverse cohort would improve the generalizability of the findings.
2. Lack of Longitudinal Data – The study design did not track fructosamine levels across multiple time points during pregnancy, limiting the ability to assess its temporal trends.

3. Potential Confounders – Factors such as dietary variations, medication use, and comorbid conditions were not extensively analysed and may have influenced the results.
4. Limited Availability of Comparative Studies – Although past research has explored fructosamine in various clinical settings, studies specifically focused on pregnancy remain limited, necessitating further validation.
5. Lack of Cost-Effectiveness Analysis – The economic feasibility of incorporating fructosamine testing into routine prenatal care was not assessed and should be explored in future research.

Future Aspects of the Study

This study highlights fructosamine as a promising biomarker for glycaemic monitoring in pregnancy, particularly where HbA1c may be unreliable. Future research should focus on longitudinal studies tracking fructosamine levels across all trimesters to understand its dynamic trends and establish trimester-specific reference ranges. Large, multicentric trials are needed to standardize cut-off values and validate its predictive value for adverse maternal and neonatal outcomes.

Comparative studies with continuous glucose monitoring (CGM) and other emerging markers like glycated albumin or 1,5-anhydroglucitol (1,5-AG) can further clarify its role in routine care. Cost-effectiveness analyses are essential to assess its feasibility in resource-limited settings. Additionally, integrating fructosamine into risk prediction models or clinical guidelines could enhance early detection and treatment of gestational hyperglycaemia.

Exploring its utility in women with pre-existing diabetes and evaluating patient-centred outcomes such as satisfaction and adherence may also broaden its clinical relevance. Future work should also consider the use of machine learning to incorporate fructosamine into predictive algorithms for improved maternal and fetal outcomes. With further validation, fructosamine has the potential to become an integral part of individualized, timely, and effective antenatal care.

CONCLUSION

This study highlights the potential of fructosamine as a clinically valuable biomarker for monitoring hyperglycaemia in pregnancy. The findings demonstrate that fructosamine levels are significantly elevated in hyperglycemic pregnant women and strongly correlate with conventional glycemic markers such as OGCT, HbA1c, FBS, and PPBS. Furthermore, fructosamine's association with adverse maternal and neonatal outcomes, including preterm delivery, increased caesarean section rates, and neonatal complications, underscores its relevance in obstetric care. Its ability to reflect short-term glycemic changes provides an advantage over HbA1c, allowing for more responsive monitoring of blood glucose fluctuations in pregnancy. These findings suggest that fructosamine could serve as an adjunct or alternative biomarker to traditional glycemic assessments, particularly in cases where HbA1c may be unreliable due to anaemia or altered red blood cell turnover.

Incorporating fructosamine testing into routine pregnancy screening may enhance the early identification of hyperglycemic pregnancies, enabling timely interventions to improve maternal and fetal outcomes. Establishing standardized reference ranges specific to pregnancy and defining its role in existing gestational diabetes management guidelines would be crucial steps toward its clinical implementation. Future research should focus on large-scale studies to validate fructosamine's predictive value for pregnancy complications and determine its efficacy in guiding treatment modifications. Additionally, the development of cost-effective and accessible fructosamine testing methods could facilitate its broader adoption in prenatal care.

Despite the study's promising findings, certain limitations must be acknowledged, including sample size constraints, the need for longitudinal monitoring, and potential confounding factors that were not fully accounted for. Addressing these limitations in future research will further strengthen the evidence supporting fructosamine's clinical utility. Overall, this study contributes to the growing body of research advocating for alternative biomarkers in glycemic monitoring and provides a foundation for integrating fructosamine into routine obstetric practice. With further validation, fructosamine holds promise as an important tool for optimizing glucose management in pregnancy, reducing the risks associated with hyperglycemia, and ultimately improving maternal and neonatal health outcomes.

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