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Original Research Article

Glycemic control, maternal and neonatal outcomes in gestational diabetes mellitus treated with regular aspart insulin in comparison with regular human insulin

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is associated with adverse maternal and neonatal outcomes, making optimal glycemic control essential during pregnancy. Rapid-acting insulin analogues may provide better postprandial glucose control than regular human insulin. This study aimed to compare glycemic control and maternal and neonatal outcomes among women with GDM treated with regular aspart insulin versus regular human insulin.

Methods: This randomized controlled trial was conducted at the outpatient Department of Obstetrics and Gynaecology, BIRDEM General Hospital, Dhaka, from October 2023 to January 2025. A total of 102 women diagnosed with GDM after 24 weeks' gestation were randomly assigned to receive regular aspart insulin (Group I, n=54) or regular human insulin (Group II, n=48). Follow-up was performed at 28-, 32- and 36-weeks' gestation and after delivery. Ninety-five participants completed follow-up (49 and 46, respectively). Fasting blood sugar (FBS), HbA1c, birth weight and maternal and neonatal outcomes were compared. Statistical significance was set at $p < 0.05$.

Results: Group I achieved significantly lower FBS than Group II at 28, 32 and 36 weeks' gestation and postpartum (all $p < 0.0001$). HbA1c and birth weight were comparable between groups. Maternal complications did not differ significantly. Neonatal hypoglycaemia occurred less frequently in Group I than Group II (6.1% vs 19.6%, $p = 0.048$).

Conclusion: Regular aspart insulin provided superior fasting glycemic control and reduced neonatal hypoglycaemia compared with regular human insulin, without increasing maternal complications, supporting its use as an effective treatment option for GDM.

Keywords: Gestational diabetes mellitus, Insulin aspart, Regular human insulin, Fasting blood glucose, Neonatal hypoglycaemia

INTRODUCTION

GDM is among the most frequent medical complications of pregnancy and its prevalence is rising in step with increasing maternal obesity, affecting up to 18% of

pregnancies in some populations.¹ The international association of diabetes and pregnancy study groups criteria, endorsed by the world health organization, the international federation of gynecology and obstetrics and the American diabetes association, define GDM using

fasting, one hour and two-hour plasma glucose thresholds following a 75 gram oral glucose challenge.² Suboptimal glycemic control in GDM substantially increases the risk of adverse outcomes for both mother and offspring and is strongly associated with subsequent maternal type 2 diabetes as well as childhood obesity and early metabolic syndrome in the offspring.³

The pathophysiology of GDM centers on progressive insulin resistance driven by placental hormones, superimposed on limited pancreatic beta cell reserve. As gestation advances, placental hormones such as human placental lactogen increasingly impair insulin action so that more glucose is directed toward the growing fetus, when maternal beta cells cannot adequately compensate, hyperglycaemia results. Persistent maternal hyperglycaemia crosses the placenta and stimulates fetal hyperinsulinaemia, predisposing to excessive fetal growth and, after delivery, to neonatal hypoglycaemia once the maternal glucose supply is abruptly withdrawn.⁴

When lifestyle modification and medical nutrition therapy are insufficient to achieve glycemic targets, pharmacological treatment becomes necessary and insulin remains the preferred first line agent because it does not cross the placenta and allows precise, titratable control of glucose.⁵ Insulin therapy in GDM has consistently been shown to reduce both maternal and fetal morbidity compared with inadequately treated hyperglycaemia.⁶ Traditionally, regular human insulin has been used to control mealtime glucose excursions in pregnancy, but its pharmacokinetic profile, an onset of thirty to sixty minutes, a peak at two to four hours and a duration extending to six to eight hours, requires injection well before meals and carries a recognized risk of both postprandial hyperglycaemia and delayed hypoglycaemia when meal timing is imprecise.⁷

Insulin aspart, a rapid acting human insulin analogue, was developed to overcome these limitations. Structural modification of the insulin molecule accelerates monomer dissociation and subcutaneous absorption, producing an earlier onset, an earlier peak and a shorter overall duration of action than regular human insulin.⁸ Formulation strategies that promote faster monomer formation after injection further enhance this early absorption advantage.⁹

Comparative work outside pregnancy has consistently demonstrated that rapid acting aspart preparations achieve lower postprandial glucose excursions with reduced glycaemic variability and fewer hypoglycaemic episodes than regular human insulin and a retrospective analysis in women with GDM similarly reported significantly lower postprandial glucose after regular aspart insulin than after regular human insulin.¹⁰ Newer insulin analogues have also been reported to offer clinical advantages over conventional formulations across a range of diabetes populations, including a lower risk of hypoglycaemia.¹¹ Despite this accumulating evidence, the overall estimated prevalence of GDM in Bangladesh is already substantial,

at approximately 13%, yet locally generated comparative evidence on regular aspart insulin against regular human insulin, integrating glycaemic trends with maternal and neonatal clinical outcomes within randomized controlled trials, remains limited.¹² Existing comparative studies have more often reported isolated glycaemic indices or delivery related parameters in isolation, rather than a combined assessment of fasting glycaemic control alongside downstream maternal and neonatal complications.¹³

This study was therefore undertaken to assess glycemic control, principally fasting glycaemia, together with maternal and neonatal outcomes among pregnant women with GDM treated with regular aspart insulin in comparison with regular human insulin, with the aim of generating context specific evidence to inform insulin selection in routine obstetric care.

METHODS

This was a randomized controlled trial conducted in the outpatient department of Obstetrics and Gynaecology, BIRDEM General Hospital, Dhaka, Bangladesh, from October 2023 to January 2025. The study population comprised pregnant women with gestational diabetes mellitus attending the outpatient department for antenatal care during the study period. A total of 102 eligible women were enrolled and randomly allocated in an approximately 1:1 fashion by lottery method into two groups: Group I received regular aspart insulin (n=54) and Group II received regular human insulin (n=48). Follow up assessments were scheduled at 28, 32 and 36 weeks of gestation and after delivery. Five participants in Group I and two in Group II were lost to follow up, leaving 49 women in Group I and 46 women in Group II for final analysis.

Inclusion criteria

Women with gestational diabetes mellitus aged 18 to 35 years, diagnosis of GDM made after 24 weeks of gestation and women requiring insulin therapy for glycaemic control.

Exclusion criteria

Women with overt diabetes mellitus (pre-existing type 1 or type 2 diabetes), GDM patients managed with neutral protamine Hagedorn insulin, mixed type insulin, or oral hypoglycaemic agents, women with severe medical or surgical comorbidities, known allergy to regular aspart insulin or regular human insulin and women who declined informed consent.

Data collection procedure

A pretested semi-structured questionnaire was used to record sociodemographic characteristics, obstetric history and anthropometric measurements, including height and weight for calculation of pre-pregnancy body mass index, at enrolment. Venous blood samples were collected at 28,

32 and 36 weeks of gestation and after delivery to measure fasting blood sugar and postprandial glucose two hours after breakfast, lunch and dinner, together with glycated haemoglobin at 28 and 36 weeks. Maternal outcomes, including gestational age and mode of delivery, preterm birth, pre-eclampsia and polyhydramnios and neonatal outcomes, including birth weight, respiratory distress syndrome, jaundice, hypoglycaemia and neonatal intensive care unit admission, were recorded prospectively by the treating clinical team on an individual, structured data sheet for each participant, ensuring consistency and completeness of data capture across both groups.

Ethical consideration

Ethical clearance was obtained from the Institutional Review Board of BIRDEM General Hospital prior to commencement of the study. Written informed consent was obtained from all participants after the purpose, procedures and potential risks and benefits of the study had been explained in a language they understood. Confidentiality was maintained throughout by assigning each participant a unique identification number and participants retained the right to withdraw from the study at any stage without any effect on their ongoing clinical care.

Statistical analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS), version 26. Descriptive statistics were expressed as frequency and percentage for categorical variables and as mean±standard deviation for continuous variables; the unpaired t test was used to compare continuous variables such as fasting blood sugar, HbA1c and birth weight between the two groups, while the chi square test or Fisher's exact test, as appropriate, was used to compare categorical maternal and neonatal outcomes and a p value of less than 0.05 was considered statistically significant throughout.

RESULTS

This randomized controlled trial enrolled 102 pregnant women with GDM, of whom 49 receiving regular aspart insulin (Group I) and 46 receiving regular human insulin (Group II) completed follow up and were included in the final analysis. Fasting blood glucose was consistently and significantly lower in Group I than Group II throughout gestation and after delivery, whereas HbA1c and birth weight did not differ significantly between the groups. Maternal complications occurred at broadly similar rates in both groups, while neonatal hypoglycaemia was significantly less frequent in Group I.

Table 1 shows the baseline sociodemographic and pre-pregnancy characteristics of the respondents. The mean age of participants was 29.2±4.6 years, with the largest proportion, 46.3%, aged 30 years or above, followed by 33.7% aged 26 to 30 years, 15.8% aged 21 to 25 years and

4.2% aged 20 years or younger. Regarding pre-pregnancy body mass index, the majority of women, 63.16%, were classified as obese, 35.79% had a normal pre-pregnancy weight and only 1.05% were underweight.

Table 2 shows the comparison of key glycemic indicators between the two insulin groups. Fasting blood sugar was significantly lower in Group I than in Group II at every point of assessment, at 28 weeks (5.9±0.5 versus 7.6±1.7 mmol/l), 32 weeks (5.4±0.5 versus 6.6±1.9 mmol/l), 36 weeks (5.2±0.5 versus 6.3±1.7 mmol/l) and after delivery (4.9±0.5 versus 5.9±1.5 mmol/l), with all differences statistically significant ($p<0.0001$). In contrast, HbA1c values were comparable between the groups at both 28 weeks (6.1±1.0 versus 6.4±1.4, $p=0.327$) and 36 weeks (5.8±1.0 versus 5.9±1.4, $p=0.697$), indicating that overall glycaemic exposure across pregnancy was similar despite the consistently lower fasting values observed with regular aspart insulin.

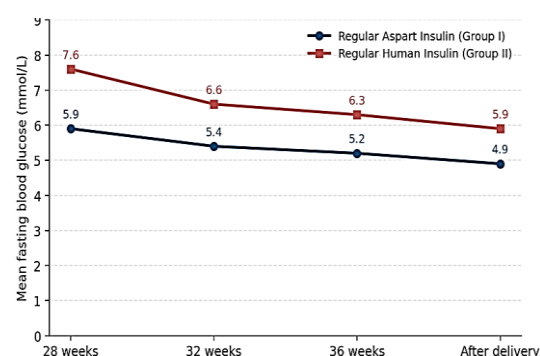


Figure 1: Trend of fasting blood glucose during pregnancy and after delivery according to insulin type.

Figure 1 illustrates the trend of mean fasting blood glucose across the follow up period. Both groups showed a gradual decline in fasting glucose as pregnancy progressed and after delivery; however, the curve for Group I remained consistently below that of Group II at every assessment point, reflecting sustained superior fasting glycaemic control with regular aspart insulin compared with regular human insulin throughout the study period.

Table 3 shows the comparison of newborn birth weight between the two groups. Mean birth weight was slightly higher in Group I (2.9±0.6 kg) than in Group II (2.7±0.6 kg); however, this difference was not statistically significant ($p=0.890$), indicating broadly comparable neonatal growth outcomes between the two insulin regimens. Table 4 shows the comparison of maternal complications between the two groups. Preterm birth occurred in 18.3% of Group I and 28.2% of Group II ($p=0.253$). Pre-eclampsia was observed in 26.5% of Group I and 37.0% of Group II ($p=0.275$). Polyhydramnios was present in 24.5% of Group I and 32.6% of Group II ($p=0.380$) and premature rupture of membranes was reported in 6.1% of Group I and 15.2% of Group II ($p=0.148$). None of these differences reached statistical

significance, indicating that maternal complication rates were broadly comparable between the two insulin regimens. Table 5 shows the comparison of neonatal complications between the two groups. Respiratory distress syndrome was observed in 16.3% of Group I and 30.4% of Group II ($p=0.103$) and neonatal jaundice occurred in 24.5% of Group I and 34.8% of Group II ($p=0.271$). Neonatal hypoglycaemia was significantly less

frequent in Group I than in Group II (6.1% versus 19.6%, $p=0.048$). NICU admission was also numerically lower in Group I than in Group II (8.2% versus 21.8%), although this difference did not reach statistical significance ($p=0.062$). These findings indicate that, while most neonatal complications did not differ significantly, regular aspart insulin was associated with a significantly lower rate of neonatal hypoglycaemia.

Table 1: Baseline sociodemographic and pre-pregnancy characteristics of the study participants (n=95).

Characteristic	Frequency (N)	%
Age group (in years)	≤20	4.2
	21–25	15.8
	26–30	33.7
	≥30	46.3
	Mean age±SD (in years)	29.2±4.6
Pre-pregnancy BMI	Underweight	1.05
	Normal weight	35.79
	Obese	63.16

Table 2: Comparison of key glycemic indicators between regular aspart insulin and regular human insulin during pregnancy.

Variable	Aspart (Mean±SD)	Human (Mean±SD)	P value
FBS at 28 weeks (mmol/l)	5.9±0.5	7.6±1.7	<0.0001
FBS at 32 weeks (mmol/l)	5.4±0.5	6.6±1.9	<0.0001
FBS at 36 weeks (mmol/l)	5.2±0.5	6.3±1.7	<0.0001
FBS after delivery (mmol/l)	4.9±0.5	5.9±1.5	<0.0001
HbA1c at 28 weeks (%)	6.1±1.0	6.4±1.4	0.327
HbA1c at 36 weeks (%)	5.8±1.0	5.9±1.4	0.697

Table 3: Comparison of birth weight of newborn between the two groups.

Parameter	Group I (n=49)	Group II (n=46)	P value
Birth weight (kg), mean±SD	2.9±0.6	2.7±0.6	0.89

Table 4: Comparison of maternal complications between the two groups.

Maternal complication	Group I (n=49) N (%)	Group II (n=46) N (%)	P value
Preterm birth	9 (18.3)	13 (28.2)	0.253
Pre-eclampsia	13 (26.5)	17 (37.0)	0.275
Polyhydramnios	12 (24.5)	15 (32.6)	0.38
Premature rupture of membranes	3 (6.1)	7 (15.2)	0.148

Table 5: Comparison of neonatal complications between the two groups.

Neonatal complication	Group I (n=49) N (%)	Group II (n=46) N (%)	P value
Respiratory distress syndrome	8 (16.3)	14 (30.4)	0.103
Neonatal jaundice	12 (24.5)	16 (34.8)	0.271
Neonatal hypoglycaemia	3 (6.1)	9 (19.6)	0.048
NICU admission	4 (8.2)	10 (21.8)	0.062

DISCUSSION

This study demonstrated that women treated with regular aspart insulin achieved significantly better fasting

glycaemic control than those treated with regular human insulin throughout pregnancy and after delivery. At 28, 32 and 36 weeks of gestation, mean fasting blood sugar was consistently lower in Group I than in Group II and this

advantage persisted after delivery, with all differences reaching high statistical significance. Misra and Mathieu, in their review of newer insulin analogues, reported that rapid acting formulations such as aspart provide more predictable and often superior basal glycaemic control compared with conventional human insulin preparations, a pattern that closely mirrors the present findings.¹¹ The pharmacokinetic properties of regular aspart insulin, characterized by more rapid subcutaneous absorption and an earlier peak effect than regular human insulin, plausibly explain this consistent fasting glucose advantage, since more predictable absorption reduces the likelihood of residual circulating insulin mismatched to fasting glucose demand.⁸ Despite this clear separation in fasting glucose values, HbA1c did not differ significantly between the two groups at either 28 or 36 weeks.

Because HbA1c reflects average glycaemia over the preceding eight to twelve weeks, including postprandial excursions that were not the primary focus of the present comparison, this finding suggests that overall glycaemic exposure across the full day was broadly comparable between the groups even though fasting control differed. This dissociation between fasting glucose and integrated glycaemic exposure has been described previously, with rapid acting analogues chiefly benefiting postprandial and fasting parameters without necessarily producing large differences in HbA1c over a comparable treatment duration.¹¹

Birth weight was marginally higher in Group I than Group II, but this difference was not statistically significant, indicating that both insulin regimens produced broadly similar fetal growth outcomes without evidence of increased macrosomia risk in either group. This is consistent with the findings of Pooransari et al who compared insulin aspart with regular insulin in women with GDM and likewise reported comparable neonatal growth parameters between treatment groups, alongside more favourable delivery related outcomes with insulin aspart, including a lower rate of caesarean section.¹³ Together with the present results, this supports the interpretation that the principal clinical advantage of regular aspart insulin in GDM lies in glycaemic stability rather than in altering fetal growth trajectory per se.

Maternal complications, including preterm birth, pre-eclampsia, polyhydramnios and premature rupture of membranes, did not differ significantly between the two groups in the present study, although each complication was numerically more frequent in the regular human insulin group. Pre-eclampsia in particular occurred in over a third of women in Group II compared with just over a quarter in Group I.

Pre-pregnancy obesity and suboptimal glycaemic control are both established risk factors for hypertensive disorders of pregnancy Wang et al reported that a higher pre-pregnancy body mass index and glycated haemoglobin were independently associated with greater metabolic risk

in women with gestational diabetes, while Abraham et al and Romani et al similarly described obesity as a consistent risk factor for pre-eclampsia through mechanisms of chronic low grade inflammation and endothelial dysfunction.^{14,15} Lewandowska et al further demonstrated that pre-pregnancy obesity carried a stronger association with pre-eclampsia and gestational hypertension than several other commonly assessed risk factors.¹⁶

Since almost two thirds of participants in the present cohort were obese before pregnancy, background obesity prevalence may have contributed to the numerically higher, although not statistically significant, rate of hypertensive and fluid related complications observed in the regular human insulin group, an interpretation supported by Macura et al who observed that less consistent glycaemic control in pregnancies complicated by diabetes was associated with a higher burden of maternal complications, including pre-eclampsia and polyhydramnios.¹⁷

Neonatal outcomes revealed the most clinically important difference between the two groups: neonatal hypoglycaemia occurred significantly less often among infants of mothers treated with regular aspart insulin than among those treated with regular human insulin. This finding is biologically coherent, since more stable maternal fasting glycaemia in late pregnancy reduces the degree of fetal hyperinsulinaemia that predisposes to postnatal hypoglycaemia once the maternal glucose supply is withdrawn at delivery, a mechanism previously highlighted by Rosenfeld et al and Thornton et al in their review of neonatal hypoglycaemia.¹⁸

Similarly, in a randomized trial comparing faster acting insulin aspart with regular insulin aspart in pregnant women with diabetes, Nørgaard et al reported improved neonatal metabolic outcomes associated with tighter maternal glycaemic control.¹⁹ Earlier work by Pettitt et al likewise found that insulin aspart achieved superior postprandial glucose control compared with regular human insulin in women with GDM, providing a plausible mechanistic basis for the reduced neonatal hypoglycaemia rate observed in the present study.²⁰

Although NICU admission and respiratory distress syndrome were also numerically more common in the regular human insulin group, these differences did not reach statistical significance, likely reflecting the limited sample size and the multifactorial nature of these outcomes.

Overall, the present findings support the interpretation that regular aspart insulin confers a measurable advantage in fasting glycaemic control and in reducing neonatal hypoglycaemia risk, while achieving broadly comparable maternal safety and fetal growth outcomes relative to regular human insulin in the management of gestational diabetes mellitus.

Limitations

This study was limited by its relatively modest sample size, drawn from a single tertiary center, which may have reduced power to detect differences in less common maternal and neonatal complications and by follow up restricted to the immediate postpartum period.

CONCLUSION

This study shows that regular aspart insulin achieves significantly better fasting glycaemic control than regular human insulin throughout pregnancy and after delivery in women with gestational diabetes mellitus, while overall glycaemic exposure reflected by HbA1c remains comparable between the two regimens. Maternal complications did not differ significantly between groups and neonatal outcomes were generally similar except for a significantly lower rate of neonatal hypoglycaemia among infants of mothers treated with regular aspart insulin.

These findings support regular aspart insulin as a favourable option for glycaemic management in gestational diabetes mellitus, offering improved fasting control and reduced neonatal hypoglycaemia risk without compromising maternal safety.

Recommendations

Larger multicentre studies with extended follow up into infancy are recommended to confirm these findings and clarify the longer-term metabolic implications of insulin choice in gestational diabetes mellitus.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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