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Original Research Article

Comparison of Glycemic Control between Regular Aspart Insulin and Regular Human Insulin in Gestational Diabetes Mellitus

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Abstract

Background: Insulin therapy is required in gestational diabetes mellitus (GDM) when glycaemic targets are not achieved through lifestyle modification and rapid acting insulin analogues such as regular aspart insulin have been developed to provide more physiological postprandial and fasting glucose control than regular human insulin. This study aimed to compare glycemic control, including fasting, postprandial and glycated haemoglobin parameters, between regular aspart insulin and regular human insulin in women with gestational diabetes mellitus. ***Methods:*** This randomized controlled trial was conducted in the outpatient department of Obstetrics and Gynaecology, BIRDEM General Hospital, Dhaka, from October 2023 to January 2025, among 102 pregnant women with GDM diagnosed after 24 weeks of gestation. Participants were randomly allocated to regular aspart insulin (Group I, n=54) or regular human insulin (Group II, n=48); 49 and 46 women respectively completed follow up at 28, 32 and 36 weeks of gestation and after delivery. Fasting blood sugar, postprandial glucose two hours after breakfast, lunch and dinner and HbA1c were compared using SPSS version 26, with $p<0.05$ considered significant. ***Results:*** Mean age of participants was 29.2 ± 4.6 years and 63.16% were obese before pregnancy. Fasting glucose was significantly lower in Group I at every assessment point ($p<0.0001$). Postprandial glucose values were also significantly higher in Group II at 28 weeks ($p<0.05$ for all three postprandial readings), but these differences attenuated by 32 and 36 weeks and after delivery. HbA1c was comparable between groups at 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). ***Conclusion:*** Regular aspart insulin provided superior fasting glycaemic control throughout pregnancy and more favourable early postprandial control than regular human insulin, while overall glycated haemoglobin remained comparable, supporting its use as an effective glycaemic management option in gestational diabetes mellitus.

Keywords: Gestational diabetes mellitus, regular aspart insulin, regular human insulin, postprandial glucose, glycated haemoglobin.

INTRODUCTION

Gestational diabetes mellitus (GDM) arises from a combination of pancreatic beta cell dysfunction and progressive insulin resistance mediated by placental hormones and its clinical management is fundamentally a problem of glycaemic control [1]. Human placental lactogen, structurally related to growth hormone, alters insulin receptor signalling in peripheral tissues, reducing glucose uptake through changes in receptor phosphorylation and downstream insulin signalling pathways [2]. As maternal glucose crosses the placenta, the fetal pancreas responds with increased insulin secretion, which, given its anabolic properties, drives excessive fetal tissue growth [3]. Because these mechanisms operate continuously across gestation,

achieving consistent glycaemic control, encompassing fasting, postprandial and integrated long term glucose exposure, is central to reducing the downstream risks associated with GDM.

Current guidelines from the American Diabetes Association and the American College of Obstetricians and Gynecologists recommend maintaining fasting plasma glucose below 95 mg/dL, one-hour postprandial glucose below 140 mg/dL, two-hour postprandial glucose below 120 mg/dL and glycated haemoglobin between 6% and 6.5%, ideally around 6% if this can be achieved without significant hypoglycaemia [4]. Medical nutrition therapy and physical activity remain the first line intervention and allow the majority of women with GDM, up to 80 to 90%, to reach these glycaemic targets [5]. When lifestyle intervention alone proves insufficient, most guidelines, including those of the Canadian Diabetes Association and the National Institute for Health and Care Excellence, recommend initiating pharmacological therapy if glycaemic targets are not met after one to two weeks of lifestyle modification [6].

Regular human insulin has traditionally been the mainstay of pharmacological treatment for GDM, but its pharmacokinetic profile constrains its practical use. With an onset of thirty to sixty minutes, a peak effect at two to four hours and a duration extending up to six to eight hours, regular human insulin must be injected well ahead of meals to adequately blunt postprandial glucose rise and mistimed administration increases the risk of both postprandial hyperglycaemia and delayed hypoglycaemia [7]. Insulin aspart, a rapid acting human insulin analogue, was engineered to overcome these constraints through more rapid subcutaneous absorption, producing an earlier onset, an earlier peak and a shorter overall duration of action [8]. Detailed pharmacokinetic and pharmacodynamic studies have confirmed that aspart formulations achieve earlier appearance in the circulation and a greater early glucose lowering effect than conventional insulin aspart or regular human insulin across a range of doses [9]. A systematic review and meta-analysis of rapid acting insulin analogues in type 1 diabetes and GDM similarly concluded that these agents provide more physiological postprandial glucose control than regular human insulin, translating into modestly improved glycaemic outcomes in special populations including pregnancy [10].

Direct comparative data specifically quantifying the full glycaemic profile, fasting, sequential postprandial and glycated haemoglobin, of regular aspart insulin against regular human insulin within a single cohort of women with GDM remain relatively limited, with much of the existing literature drawn from retrospective series or from studies in the broader diabetes population rather than GDM specifically [11]. This gap is particularly relevant in Bangladesh, where GDM affects an estimated 13% of pregnancies [12] and where insulin selection in routine antenatal care is frequently guided by cost and availability rather than by locally generated comparative glycaemic evidence.

This study was therefore undertaken to comprehensively compare glycaemic control, incorporating fasting glucose, sequential postprandial glucose and glycated haemoglobin across gestation and after delivery, between regular aspart insulin and regular human insulin among pregnant women with GDM, in order to characterize the full pattern of glycaemic response associated with each insulin type.

MATERIALS AND METHODS

This was a randomized controlled trial carried out in the outpatient department of Obstetrics and Gynaecology, BIRDEM General Hospital, Dhaka, Bangladesh, between October 2023 and January 2025. The study population consisted of pregnant women with gestational diabetes mellitus attending antenatal care at this center. A total of 102 eligible women, aged 18 to 35 years and diagnosed with GDM after 24 weeks of gestation, were enrolled and randomly allocated by lottery method to receive either regular aspart insulin (Group I, n=54) or regular human insulin (Group II, n=48). Follow up was conducted at 28, 32 and 36 weeks of gestation and after delivery; five participants from Group I and two from Group II were lost to follow up, leaving 49 women in Group I and 46 women in Group II for the final glycaemic analysis.

Selection Criteria

Inclusion Criteria:

- Pregnant women aged 18 to 35 years diagnosed with gestational diabetes mellitus
- Diagnosis established after 24 weeks of gestation
- Women requiring insulin therapy following inadequate glycaemic control with lifestyle measures

Exclusion Criteria:

- Women with overt (pre-existing) diabetes mellitus, type 1 or type 2
- Women 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
- Women who did not provide informed consent

Data Collection Procedure

Data were collected prospectively using a pretested, semi-structured questionnaire administered to all participants at enrolment and at each scheduled follow up visit. Baseline sociodemographic information, obstetric history and anthropometric measurements,

including height and weight for calculation of pre-pregnancy body mass index, were recorded at enrolment through direct interview and clinical examination. At 28, 32 and 36 weeks of gestation and after delivery, venous blood samples were collected by trained laboratory personnel to measure fasting blood sugar and postprandial glucose two hours after breakfast, lunch and dinner, using standard laboratory assay methods and glycated haemoglobin was additionally measured at 28 and 36 weeks. Each participant was assigned an individual, dedicated data collection sheet to ensure that serial values could be tracked accurately across the follow up period and all measurements were performed under uniform laboratory conditions to minimize inter-observer and inter-assay variability, thereby ensuring the reliability and internal consistency of the glycaemic data used for comparison between the two insulin groups.

Ethical Consideration

Ethical clearance was obtained from the Institutional Review Board of BIRDEM General Hospital before the study began. Written informed consent was obtained from every participant after the purpose, procedures and potential risks and benefits of the study had been explained in a language they understood. Participant confidentiality was preserved throughout using unique identification numbers rather than personal identifiers and all participants were free to withdraw from the study at any time without any impact on their subsequent clinical management.

Statistical Analysis

All data were analyzed using Statistical Package for Social Sciences (SPSS), version 26. Continuous variables, including fasting and postprandial glucose values and HbA1c, were expressed as mean ± standard deviation and compared between groups using the unpaired t test, while categorical variables were expressed as frequency and percentage; a p value of less than 0.05 was considered statistically significant throughout the analysis.

RESULTS

This study enrolled 102 pregnant women with GDM, of whom 49 in Group I (regular aspart insulin) and 46 in Group II (regular human insulin) completed follow up and were included in the final glycaemic analysis. Participants were predominantly in their late twenties to early thirties and the majority were obese before pregnancy. Across all points of assessment, fasting glucose was significantly lower with regular aspart insulin, postprandial glucose differences were most pronounced early in the follow up period and HbA1c remained comparable between the two treatment groups throughout gestation.

Table 1: Age Distribution of the Study Population

Age (years)	Frequency (n)	Percentage (%)
≤20 years	4	4.2
21–25 years	15	15.8
26–30 years	32	33.7
≥30 years	44	46.3
Mean ± SD	29.2 ± 4.6	

Table 1 shows the frequency distribution of the study population by age. 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.

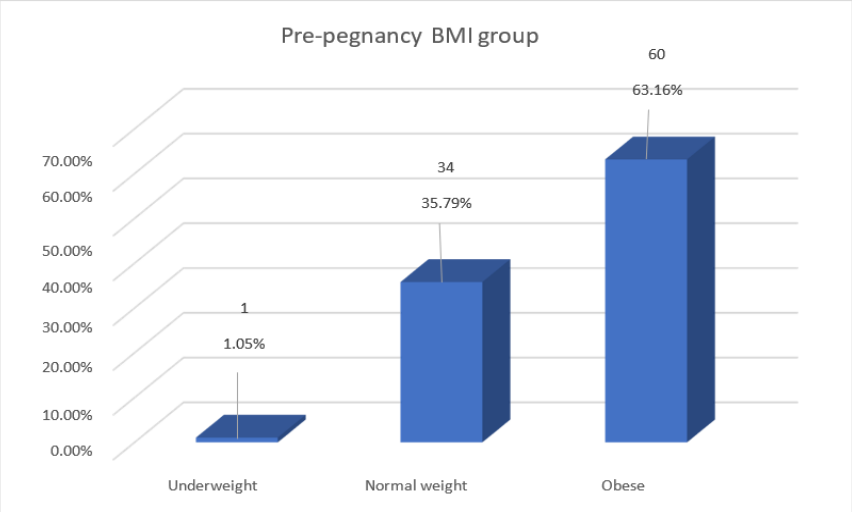

Figure 1: Distribution of the respondents according to their pre-pregnancy BMI

Figure 1 shows the pre-pregnancy body mass index distribution of the respondents. Of the respondents, 1.05% (1 respondent) were underweight, 35.79% (34 respondents) had a normal pre-pregnancy weight and 63.16% (60 respondents) were classified as obese, indicating that the majority of participants fell into the obese category before pregnancy.

Table 2: Complete Comparison of Glycemic Parameters Between Regular Aspart Insulin and Regular Human Insulin

Parameter	Group I (n=49) Mean ± SD	Group II (n=46) Mean ± SD	p value
28th week — FBS	5.9 ± 0.5	7.6 ± 1.7	<0.0001
28th week — 2h post-breakfast (ABF)	8.9 ± 1.1	9.5 ± 1.3	0.021
28th week — 2h post-lunch (AL)	9.5 ± 1.0	10.1 ± 1.3	0.009
28th week — 2h post-dinner (AD)	9.1 ± 1.0	9.7 ± 1.5	0.014
28th week — HbA1c (%)	6.1 ± 1.0	6.4 ± 1.4	0.327
32nd week — FBS	5.4 ± 0.5	6.6 ± 1.9	<0.0001
32nd week — ABF	7.4 ± 1.4	7.9 ± 2.0	0.156
32nd week — AL	7.6 ± 1.6	8.1 ± 2.0	0.189
32nd week — AD	7.4 ± 1.7	7.5 ± 2.0	0.882
36th week — FBS	5.2 ± 0.5	6.3 ± 1.7	<0.0001
36th week — ABF	6.9 ± 1.4	7.2 ± 1.7	0.436
36th week — AL	7.2 ± 1.5	7.5 ± 1.6	0.324
36th week — AD	7.1 ± 1.7	6.7 ± 1.9	0.612
36th week — HbA1c (%)	5.8 ± 1.0	5.9 ± 1.4	0.697
After delivery — FBS	4.9 ± 0.5	5.9 ± 1.5	<0.0001
After delivery — ABF	6.4 ± 1.3	6.6 ± 1.3	0.655
After delivery — AL	6.5 ± 1.5	6.2 ± 1.3	0.711
After delivery — AD	6.2 ± 1.3	6.1 ± 1.6	0.719

FBS: fasting blood sugar; ABF: 2 hours after breakfast; AL: 2 hours after lunch; AD: 2 hours after dinner; unpaired t test used for all comparisons.

Table 2 presents the complete comparison of glycemic parameters between the two insulin groups across all follow up points. Fasting blood sugar was significantly lower in Group I than Group II at 28, 32 and 36 weeks of gestation and after delivery, with all differences highly significant (p<0.0001). At 28 weeks, postprandial glucose after breakfast, lunch and dinner was also significantly higher in Group II (p=0.021, p=0.009 and p=0.014 respectively), but these postprandial differences were no longer statistically significant at 32 weeks, 36 weeks or after delivery. HbA1c did not differ significantly between the groups at either 28 weeks (p=0.327) or 36 weeks (p=0.697), indicating that, despite early postprandial and consistent fasting advantages with regular aspart insulin, integrated glycaemic exposure over each measurement interval was similar between the two treatment groups.

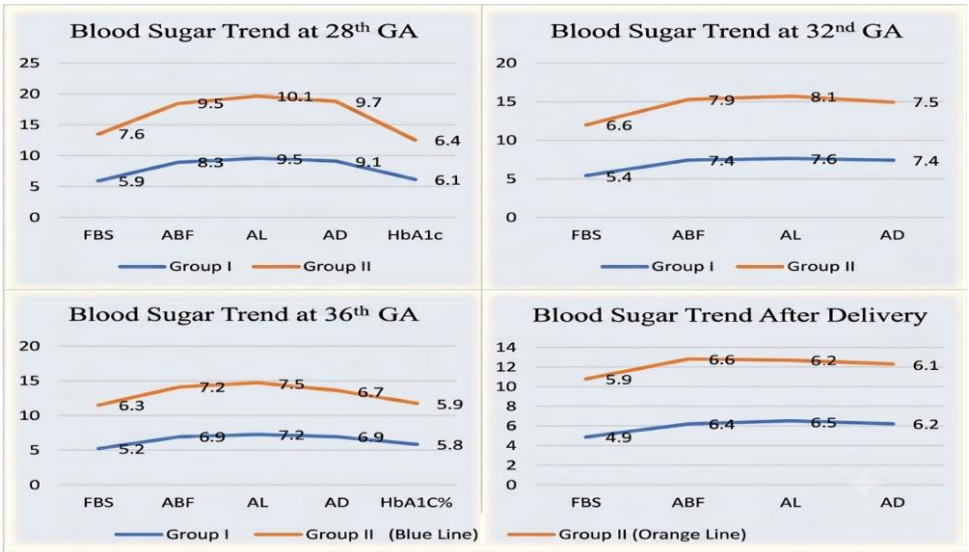

Figure 2: Longitudinal glycemic profile of regular aspart insulin versus regular human insulin during pregnancy and after delivery

Figure 2 illustrates the complete longitudinal glycemic profile of both groups across all four assessment points. At 28 weeks, Group I showed lower values than Group II across fasting and all three postprandial readings, along with a similar HbA1c. By 32 and 36 weeks, the gap between groups narrowed for postprandial readings while the fasting glucose advantage in Group I persisted. After delivery, fasting glucose remained lower in Group I, while postprandial values were similar between groups. Overall, the figure demonstrates that regular aspart insulin produced consistently better fasting glycaemic control throughout the study period, with its postprandial advantage most evident earlier in the third trimester and diminishing as pregnancy progressed.

DISCUSSION

This study provides a comprehensive comparison of the full glycaemic profile associated with regular aspart insulin and regular human insulin in women with gestational diabetes mellitus. Fasting blood glucose was significantly lower with regular aspart insulin at every point of assessment across pregnancy and after delivery, a pattern consistent with its more rapid and predictable pharmacokinetic profile relative to regular human insulin [8]. Detailed pharmacodynamic comparisons of faster acting aspart formulations have shown an earlier onset of glucose lowering effect and greater early exposure than either conventional insulin aspart or regular human insulin, providing a plausible mechanistic explanation for the sustained fasting advantage observed across all four follow up points in this cohort [9].

At 28 weeks, postprandial glucose after breakfast, lunch and dinner was also significantly higher in the regular human insulin group, but this postprandial difference progressively narrowed at 32 and 36 weeks and was no longer evident after delivery. Pettitt *et al.,* in an early comparison of insulin aspart, regular insulin and no exogenous insulin in women with GDM, found that insulin aspart produced a significantly reduced postprandial glucose area under the curve compared with no insulin, an effect not replicated with regular insulin, indicating a more physiological postprandial response with the rapid acting analogue [13]. The attenuation of postprandial differences observed later in the present study may reflect progressive dose titration in both groups as insulin resistance increased through the third trimester, narrowing the practical advantage of a faster acting formulation once both regimens were more aggressively adjusted to meet glycaemic targets. Jovanovic and Pettitt similarly noted that insulin choice in pregnancy is often adapted dynamically according to the pattern of hyperglycaemia present, with rapid acting analogues offering their clearest benefit for postprandial control while basal-bolus adjustments become more influential once both fasting and postprandial glucose are elevated together [14].

Despite the consistent fasting and early postprandial advantages associated with regular aspart insulin, HbA1c did not differ significantly between the two groups at either 28 or 36 weeks. This finding is in keeping with a post hoc analysis by Mathiesen *et al.,* of a large pregnancy registry, which found no significant difference in composite pregnancy outcomes between insulin aspart and other bolus insulins, although insulin aspart was associated with modestly lower HbA1c by the end of the third trimester in that cohort [15]. The absence of a significant HbA1c difference in the present study likely reflects the fact that HbA1c integrates glycaemia across an extended period, including postprandial glucose values that became statistically similar between groups from 32 weeks onward, thereby diluting the isolated fasting advantage observed with regular aspart insulin. The CopenFast trial, which compared faster acting insulin aspart with conventional insulin aspart throughout pregnancy and post-delivery in women with type 1 or type 2 diabetes, was similarly designed around this principle, using continuous glucose monitoring metrics such as time in range in addition to HbA1c to more sensitively capture glycaemic differences that HbA1c alone may not fully reflect [16,17].

Taken together, these results suggest that the clinical advantage of regular aspart insulin over regular human insulin in gestational diabetes mellitus is most pronounced for fasting glucose throughout pregnancy and for early third trimester postprandial control, consistent with reports that newer insulin analogues provide more predictable and physiological glycaemic profiles than conventional human insulin formulations across diabetes populations [18]. This pattern aligns with international treatment targets that specifically emphasize fasting and postprandial thresholds rather than HbA1c alone as the primary metrics for glycaemic surveillance in gestational diabetes mellitus [19]. The comprehensive, multi-timepoint comparison undertaken in the present study extends earlier work that examined isolated glycaemic parameters or delivery related outcomes in insulin aspart versus regular insulin comparisons [20], by demonstrating how the relative advantage of regular aspart insulin evolves across gestation rather than remaining static. Given that a substantial majority of the present cohort were obese before pregnancy, a factor independently linked to greater glycaemic and metabolic risk in women with gestational diabetes [21], the consistent fasting glucose benefit observed with regular aspart insulin may be of particular relevance in populations with a high background prevalence of pre-pregnancy obesity, such as the present Bangladeshi cohort. Continuous or more frequent glucose monitoring approaches, as increasingly used in contemporary gestational diabetes research, may further help to clarify the clinical significance of the postprandial and fasting differences identified in this study [22].

Limitations and Recommendations

This study was limited by its single center design and relatively modest sample size, which may have reduced the ability to detect smaller postprandial differences at later gestational time points. Larger, multicenter studies incorporating continuous glucose monitoring are recommended to more precisely characterize the comparative glycaemic profile of regular aspart insulin and regular human insulin in gestational diabetes mellitus.

CONCLUSION

This study demonstrates that regular aspart insulin provides significantly better fasting glycaemic control than regular human insulin throughout pregnancy and after delivery in women with gestational diabetes mellitus, together with a more favourable postprandial profile earlier in the third trimester. Overall glycated haemoglobin remained comparable between the two treatment groups at all assessment points. These findings indicate that regular aspart insulin offers a more physiological and consistent pattern of glycaemic control across pregnancy than regular human insulin, supporting its consideration as an effective option for glycaemic management in gestational diabetes mellitus.

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Conflicts of Interest: There are no conflicts of interest.

Ethical Approval: The study was approved by the Institutional Ethics Committee.

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