

A Comparison Between Premixed Insulin and Basal-Bolus Insulin Regimens in the Management of Type 2 Diabetes Mellitus

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ABSTRACT

Background: Type 2 diabetes mellitus that results from progressive degeneration of beta cells of pancreas often terminates into insulin dependence for achieving glycemic control. This study was planned to have a look into the difference in glycemic control achieved by premixed 30/70 insulin and basal-bolus insulin in type 2 diabetes mellitus.

Methods: This study was conducted in two diabetes centers in Dhaka from July 2018 to June 2019. During 12-weeks of data collection period, total 100 patients were included according to selection criteria and then divided into two equal groups. In group I (n=50), patients were treated with premixed 30/70 insulin twice daily and in group II (n=50) patients were treated with basal insulin once daily and bolus insulin three times daily for consecutive 12 weeks. Then data was collected and analyzed.

Results: After 12-weeks of treatment mean HbA1c (mean \pm SD) was reduced significantly in both insulin group from 10.41 \pm 1.80% to 7.63 \pm 1.37% ($p < 0.001$) and from 10.40 \pm 2.17% to 7.76 \pm 1.41% ($p < 0.001$) in PM (group I) and in BB (group II) respectively. But the mean HbA1c level (7.63 \pm 1.37% vs 7.76 \pm 1.41%) compared between two groups shows no significant difference. 56% patients in group I and 48% patients in group II achieved their HbA1c target $< 7\%$. FBG level was significantly reduced from 12.49 \pm 5.64mmol/l to 6.64 \pm 1.00mmol/l ($p < 0.002$) in group I and from 12.50 \pm 4.28mmol/l to 6.98 \pm 1.52mmol/l ($p < 0.001$) in group II. But the mean FBG level (6.64 \pm 1.00mmol/l vs 6.98 \pm 1.52mmol/l) compared between two study groups shows no significant difference. 2 hours ABF blood glucose level was also significantly reduced from 16.86 \pm 6.93 mmol/l to 9.35 \pm 1.47 mmol/l ($p = 0.003$) in group I and from 17.85 \pm 5.36 mmol/l to 10.05 \pm 2.18 mmol/l ($p < 0.001$) in group II after 12-weeks.

Conclusion: From this study it can be concluded that both insulin regimens are effective in glycemic control and none is superior to the other in this regard; and, premixed insulin is as safe as basal-bolus insulin.

Keywords: Type 2 diabetes mellitus, Premixed 30/70 insulin, Basal-bolus insulin.

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INTRODUCTION

Diabetes Mellitus, an endocrine disorder, of which the prevalence is rising globally. According to IDF 2025 an estimated 589 million adults aged 20-79 years are currently living with diabetes that represent 10.5% of world's population of this age and by 2045, the number may rise to 852.5 million. Around 3.4 million deaths occur worldwide in a year due to diabetes and its complications. In Bangladesh about 13.9 million people are diabetic with a prevalence of 14.2% in

adult population (20-79 years). Bangladesh is in the 8th position in the world by the total number of people with diabetes and by the year 2050 it is projected to move to the 7th position with 23.1 million type 2 DM patients¹. According to World Health Organization diabetes will be the 7th leading cause of death by the year 2030. Diabetes is a major cost burden on health care facilities in all countries. In 2017 the total healthcare expenditure attributed to diabetes was estimated USD 727 billion².

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The aim of optimum glycemic control in type 2 diabetes mellitus is not only to achieve good glycemic control but also to reduce the risk of long term macrovascular and microvascular complications³. Along with lifestyle modification, insulin therapy can come up with optimum glycemic control and also can improve many of the metabolic complications in type 2 diabetes mellitus⁴. Dietary and life style modifications are the first approach to maintain optimum glycemic control (HbA1c <7.0%, FBS 4.4 to 7.2 mmol/l, 2hr after breakfast <10 mmol/l); beside that many oral and injectable antidiabetic drugs are also used based on effectiveness, cost, risk of hypoglycemia, weight gain and patients' preferences⁵.

When indicated, starting an insulin regimen often depends on some factors like efficacy, safety as well as convenience and simplicity of available formulations⁶. Basal-bolus (BB) consists of multiple injections (basal insulin once or twice plus bolus insulin before meal) mimicking body's normal insulin release. While premixed (PM) insulin combines rapid acting and intermediate acting insulin offering fewer daily injection and less chance of hypoglycemia⁷.

Several studies have compared the efficacy of these two insulin regimen. Some studies demonstrate similar efficacy on glycemic control with both regimens and some studies shows some discrepancy^{8,9,10}. In comparison between basal-bolus and premixed insulin Home et al. has shown that HbA1c, FBS and 2hrs ABF were significantly reduced in both study groups with significant weight gain occurred in both groups¹¹. Some studies have also showed difference in the hypoglycemic event between BB and PM insulin¹². And, this study may give an idea about premixed insulin and basal-bolus insulin in the management of type 2 diabetes mellitus and thereby may help the physicians to select a suitable regimen in appropriate situation.

MATERIALS & METHODS

This cross sectional quasi-experimental study was carried out at the Endocrinology Outpatient Department of Dhaka Medical College Hospital, Dhaka and the Outpatient Department of Ibrahim General Hospital (National Healthcare Network), Mirpur, Dhaka. The study was carried out over a period of one year (July 2018 to June 2019). Ethical clearance was taken from ethical review committee of both Dhaka Medical College Hospital and Ibrahim General Hospital authority. These two hospitals in Dhaka were selected

for convenience of communication and data collection. Patients were selected from above mentioned hospitals according to the inclusion and exclusion criteria. Informed written consent was taken from the patients after complete explanation of purpose and procedure of the study.

Inclusion criteria:

1. Diagnosed cases of type 2 diabetes mellitus.
2. Patients prescribed with premixed 30/70 insulin or glargine based basal-bolus regimen for first time.
3. Patients willing to continue their insulin throughout the study period (12-weeks).
4. Patients of both gender and aged (30-70) years.

Exclusion criteria:

1. Patients receiving medications like steroids, thiazide and beta blockers which interfere with blood glucose level.
2. Pregnant and lactating women.
3. Patients with serious concomitant disease, chronic kidney and liver disease.

About 135 patients were interviewed and their baseline height, weight, BMI, and initial FBG, blood glucose 2hrs ABF and HbA1c were recorded from laboratory report during first visit. Then the patients were counselled for a follow up visit in the same diabetes center after 12-weeks with their relevant investigation reports. Again, in follow-up visit information of FBG, 2hrs ABF, HbA1c, height, weight and any history of hypoglycemia in last 3 months were recorded in the data collection form. During follow-up visit about 35 patients were dropped out as some patients did not come in follow up and some did not do any investigations which were advised. Finally, total 100 patients were included in the study group. Among them 50 patients were included in group I who were in premixed 30/70 insulin and 50 patients in group II who were in glargine based basal-bolus insulin. Qualitative data were expressed as frequency distribution and percentage, then compared by chi square test. Quantitative data were expressed as mean \pm SD. 'p' value ≤ 0.05 was considered as statically significant at 95% confidence interval. The data were analyzed by using statistical software SPSS (version 25.0).

RESULTS

In this study most of the patients (38.0%) were between 50-59 years' age group in both the treatment groups, and the mean age of the patients were (48.24 \pm 9.75) years in group I and (49.80 \pm 9.17) years in group II.

Out of 100 cases male patients were predominant in both group, 58.0% in group I and 54.0% in group II. Most of the respondents were housewife (36.0%) in both treatment groups and other occupations were as follows 21.0% service, 16.0% business, 14.0% retired, 4.0% farmer, 4.0% labor and 5.0% others. The monthly family income of most of the respondents (42.0%) were in between 10,000- ≤ 30,00 taka and 9.0% respondents had lowest ≤10,000-taka monthly income. Regarding education 27.0% completed their education up to HSC, 21.0% primary, 18.0% SSC, 17.0% graduate, 3.0% post-graduate and also 14.0% were illiterate.

Table -1: Demographic profile of Study participants

Demographic variables	Group-I (n=50)	Group-II (n=50)
Mean age (year)	48.24±9.75	49.80±9.17
Gender (male/female)	58/42	54/46
Family history positive (%)	76%	82%
Duration of DM <5 years	56%	62%

In this study the mean HbA1c level reduced significantly in both insulin groups after 12-weeks, from 10.41±1.80% to 7.63±1.37% (p=0.001) and from 10.40±2.17% to 7.76±1.41% (p=0.001) in PM (group I) and in BB (group II) respectively (table-2).

But the mean HbA1c level (7.63±1.37% vs 7.76±1.41%) compared between two groups after 12-weeks was no significant difference (table-3). 56% patients in group I and 48% patients in group II achieved their HbA1c target <7% according to American Diabetes Association, 2025, after 12-weeks of treatment.

FBG level was significantly reduced from 12.49±5.64 mmol/l to 6.64±1.00 mmol/l (p value 0.002) in group I and from 12.50±4.28 mmol/l to 6.98±1.52 mmol/l (p=0.001) in group II (table-4). But the mean FBG level (6.64±1.00mmol/l vs 6.98±1.52mmol/l) compared between two study groups shows no significant difference. 60.0% patients in group I and 52.0% patients in group II achieved glycemic target FBG 4.4-7.2 mmol/l.

2 hrs ABF blood glucose level was also significantly reduced from 16.86±6.93 mmol/l to 9.35±1.47 mmol/l (p=0.003) in group I and from 17.85±5.36 mmol/l to

10.05±2.18 mmol/l (p = 0.001) in group II after 12-weeks of treatment (table-5). Glycemic target of 2hrs ABF <10 mmol/l was achieved by 64.0% in group I and 58.0% in group II but rest of the patients failed to achieve glycemic target.

Table -2: Mean HbA1c level in two study groups during the study period (12-weeks).

HbA1c	Group I (n=50)	Group II (n=50)
	Mean±SD (%)	Mean±SD (%)
Before treatment	10.41±1.80	10.40±2.17
After 12 wks treatment	7.63±1.37	7.76±1.41
P Value	0.001	0.001

Table -3: Mean HbA1c compared between two study groups after 12 weeks of treatment.

Study groups	After 12 weeks of treatment	
	Mean±SD (%)	P value
Group I	7.63±1.37%	0.643
Group II	7.76±1.41%	

Table 4: Mean fasting blood glucose level in two study groups during the study period (12-weeks).

Fasting blood glucose (mmol/L)	Group I (n=50)	Group II (n=50)
	Mean±SD (mmol/l)	Mean±SD (mmol/l)
Before Treatment	12.49±5.64	12.50±4.28
After 12 wks treatment	6.64±1.00	6.98±1.52
P Value	0.002	0.001

Table -5: The mean blood glucose level of 2hrs ABF in two study groups during the study period (12-weeks).

2hrs after breakfast (mmol/l)	Group I (n=50)	Group II (n=50)
	Mean±SD (mmol/l)	Mean±SD (mmol/l)
Before Treatment	16.86±6.93	17.85±5.36
After 12 wks treatment	9.35±1.47	10.05±2.18
P Value	0.003	0.001

About 28% patients in group I and 20% patients in group II (figure-1) gave history of hypoglycemia during the study period.

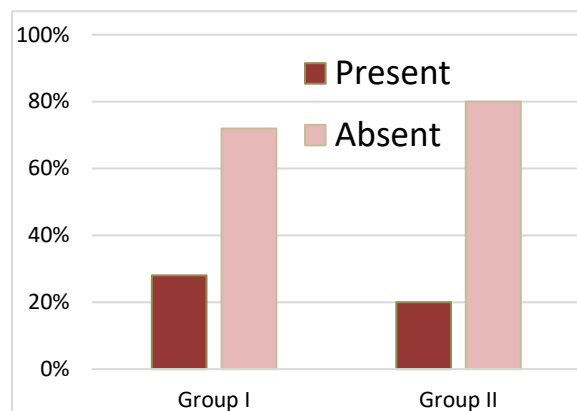


Figure-1: Hypoglycemic episodes among the respondents.

In this study it is observed that mean body weight was significantly increased from 59.82 ± 12.33 kg to 60.40 ± 13.38 kg in group I and from 59.00 ± 12.36 kg to 60.33 ± 12.97 kg in group II after 12-weeks of treatment but in comparison between two groups there was no significant (p value 0.741) difference. Mean BMI (24.10 ± 4.17 kg/m² vs 24.43 ± 4.59 kg/m²) compared between two groups after 12-weeks also shown no significant difference. 64.0% patients with premixed insulin and 68.0% patients with basal-bolus insulin gained body weight after 12-weeks. Body weight remain unchanged in 20.0% patients in group I and 16.0% patients in group II and weight lost has occurred in 16.0% cases in both groups (figure-2).

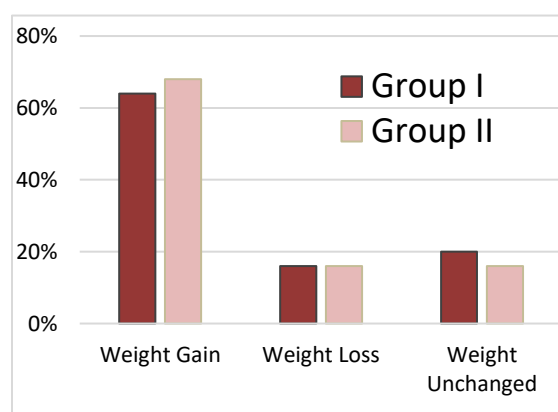


Figure 2: Percentage of patients gained weight after 12 weeks of treatment.

Patient adherence was comparatively better with premixed insulin in group I than with basal-bolus insulin in group II. 82% patients take insulin regularly in group I but in group II, 70% patients demonstrate consistent compliance. Fear of number of injections and the hypoglycemic event were main cause for this non adherence.

DISCUSSION

This hospital based observational study has been carried out to compare the effect of premixed 30/70 insulin and glargine based basal-bolus insulin regimen on glycemic index (FBS, 2hrs ABF and HbA1c) of type 2 diabetes patients. In this study, demographic profile showed that insulin was prescribed more to male patients (58.0% in group I and 54.0% in group II) in comparison to female patients which may indicate that males were predominantly coming for consultation than female. This finding is similar with previous study conducted by Bhuyan & Fardus, 2019¹³, where males were more (53.6%) than female (46.4%) but Fottrell, et al., 2018 shown number of females were more than male in their study¹⁴. The predominant age group of this study was 50-59 years (36% in group I and 40% in group II), which is similar with previous studies. In the study conducted by Samdani, et al., 2017, showed major age group was 50-59 years (37.5%)¹⁵.

In this study most of the respondents were house wife, total 36.0% of whole population (32.0% in group I and 40.0% in group II). In the study conducted by Siddique, et al., 2017, also showed predominant occupation was housewife (55.6%) and second most was the service (17.3%)¹⁶. The highest number of respondents, total 42.0% of whole population (40.0% in group I and 44.0% in group II) were in the monthly income group of 10,001- \leq 30,000 taka and Samdani, et al., 2017, also showed similar result¹⁵. Most of the patients in this study were completed their higher secondary education (27.0%). Islam, et al., 2016, also showed similar result in their study¹⁷. In this study patients of both groups have positive family history of diabetes mellitus, 76.0% and 82.0% in group I and group II respectively. Haque, et al., 2017, in their study also shown most of the patients had positive family history of diabetes¹⁸. In this study respondents were distributed by the duration of type 2 diabetes (<5years and \geq 5years). The duration of type 2 diabetes in most of the patients was <5 years, 56.0% in group I and 62.0% in group II. Islam, et al., 2015, in their study shows similar findings¹⁹.

In this study, there was significant reduction of HbA1c from $10.41 \pm 1.80\%$ to $7.63 \pm 1.37\%$ in group I and from $10.40 \pm 2.17\%$ to $7.76 \pm 1.41\%$ in group II respectively. Mitra, et al., 2024, an observational study has shown similar result of significant lower HbA1c from $8.38\% \pm 1.08\%$ to $7.61\% \pm 0.61\%$ with a percentage of 9.18% with PM insulin and from $7.90\% \pm 0.78\%$ to $7.34\% \pm 0.63\%$ with a percentage change of 7.08% with BB insulin²⁰. Peng, et al., 2022 also show similar result with percentage change 13.30% with PM insulin and 10.75% with BB insulin²¹. Anyanwagu, et al., 2017, in 24-weeks, randomized study has shown there was significant reduction of HbA1c by 0.28% and 1.4% in basal-bolus and premixed 30/70 arm respectively⁸. In the aspect of FBG, significant reduction of fasting blood glucose in both groups from 12.49 ± 5.64 mmol/l to 6.64 ± 1.00 mmol/l in group I and from 12.50 ± 4.28 mmol/l to 6.98 ± 1.52 mmol/l in group II. Mitra, et al., 2024 also shown similar result with PM insulin from 182.06 ± 49.30 mg/dl to 131.6 ± 19.41 mg/dl and with BB insulin from 191.43 ± 44.46 mg/dl to 141.26 ± 15.17 mg/dl after 12-weeks¹⁹. In the study conducted by Shi, Li & Hou, 2017, has shown significant control of FBG with BB insulin than PM insulin¹². In the study there is also significant reduction of blood glucose 2 hrs ABF from 17.85 ± 5.36 mmol/l to 10.05 ± 2.18 mmol/l in group I with premixed 30/70 insulin and from 16.86 ± 6.93 mmol/l to 9.35 ± 1.47 mmol/l in group II with basal-bolus regimen. Mitra, et al., 2024 also shown better glycemic control with premixed 30/70 than basal-bolus regimen²⁰. In this study 28.0% patients in group I and 20.0% patients in group II gave history of hypoglycemia during the period of 12-weeks but none of the patients required hospital admission. Bellido, et al, 2015, in their study has shown more patient in premixed group (19.1%) had hypoglycemia than basal-bolus group (14.8%)²². Jin, et al, 2016 shown in their study that more patients experienced hypoglycemic events with basal-bolus regimen than premixed regimen¹⁰. In this study 64.0% patients with premixed insulin and 68.0% patients with basal-bolus insulin gained body weight after 12-weeks. Body weight remain unchanged in 20.0% patients in group I and 16.0% patients in group II and weight lost has occurred in 16.0% cases in both groups. A retrospective study by Bia, et al, 2023, shown similar outcome⁷. Patient adherence was comparatively better with premixed insulin in group -I than with basal-bolus insulin in group-II. 82% patients take insulin regularly in group -I but in group-II, 70% patients demonstrate consistent compliance. Fear of number of injections and the hypoglycemic event were main cause for this non adherence. Islam, et al, 2025 shows similar result³.

Conclusion

On the basis of this study findings it can be concluded that, both premixed 30/70 and glargine based basal-bolus regimen has effective glycemic control in type 2 diabetes patients but in comparison between two groups there is no significant difference. Both insulin regimens cause some change on body weight and BMI, and also have some hypoglycemic events. So, physicians can use both insulin regimens as per patients need. This result may provide some preliminary information for further investigation.

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Conflict of interest

None.

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