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Original Research Article

Efficacy and safety of empagliflozin (SGLT2 inhibitor) in Bangladeshi patients with type 2 diabetes mellitus

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder requiring effective glycemic control to prevent complications.
Methods: This 8-month, randomized, open-label, interventional, single centered trial enrolled 86 Bangladeshi patients with poorly controlled T2DM (HbA1c ≥7.5%) on various antidiabetic regimens. Participants received Empagliflozin 10mg/25mg in addition to their ongoing therapy. Follow-ups at 6 weeks and 6 months evaluated glycemic control, lipid profile, renal parameters and adverse effects. Based on clinical response, the dosage was increased to 25 mg in selected cases. Statistical analyses included paired t-tests and Wilcoxon Signed Rank tests for normally and non-normally distributed variables.
Results: Hypertension was prevalent in 73.3% of cases, while chronic kidney disease (CKD), ischemic heart disease and dyslipidemia were observed in 12.8%, 14% and 37.2% of cases, respectively. Significant reductions in fasting blood sugar, postprandial blood sugar, systolic blood pressure ($p<0.001$ for all) and HbA1c ($p<0.001$) were observed at both 6-week and 6-month follow-ups. BMI reduction was significant at 6 months ($p=0.03$), while serum potassium increased significantly at both time points ($p=0.02$, $p=0.01$). Serum creatinine showed a significant decline at 6 months, while changes in LDL, triglycerides, HDL and total cholesterol were not statistically significant. Adverse effects were minimal, with 3.5% experiencing genital mycotic infections and 1.2% experiencing hypoglycemia.
Conclusions: Empagliflozin effectively improved glycemic control and systolic blood pressure reduction with minimal adverse effects in Bangladeshi T2DM patients while increasing serum potassium level.

Keywords: Empagliflozin, Glycemic control, SGLT2 inhibitor, T2DM

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a major public health concern globally, with increasing prevalence in Bangladesh.[1] Effective glycemic control is critical in reducing complications such as cardiovascular disease, nephropathy and neuropathy. SGLT2 inhibitors, including Empagliflozin, have emerged as promising therapeutic agents by reducing glucose reabsorption in the kidneys and promoting glycosuria.[2] Type 2 diabetes is more widespread and a leading cause of mortality and discomfort worldwide. Despite the money invested on research, professional treatment and public health actions, the rate of rise is still rising. Some areas, including Western Europe and Pacific islands, are unfairly burdened.[3] However, region-specific data regarding

efficacy and safety in Bangladeshi patients remain limited. This study evaluates the impact of Empagliflozin on glycemic control, metabolic parameters and safety outcomes in this population.

Recent studies have highlighted the additional cardiovascular and renal benefits of SGLT2 inhibitors beyond glycemic control. Empagliflozin has demonstrated a significant reduction in heart failure hospitalizations and cardiovascular mortality among patients with established atherosclerotic disease.[4] Moreover, it has shown renoprotective effects by delaying the progression of kidney disease and reducing albuminuria.[5]

These outcomes make Empagliflozin an attractive option for patients in resource-limited settings like Bangladesh, where both cardiovascular and renal complications of diabetes are common.[6] Understanding its local efficacy and safety profile is essential for optimizing diabetes management strategies and guiding clinicians in evidence-based prescribing.

METHODS

This study was conducted in Holy family red-crescent hospital, Dhaka, Bangladesh, between the months of March and October 2024. This research was carried out as an interventional experiment that was randomized, open-label and lasted for a total of eight months. Participants who met the eligibility criteria were adults who had been diagnosed with type 2 diabetes and had a HbA1c level that was equal to or more than 7.5%. Regardless of whether the patients had previously been treated with oral medications, insulin or both, they were eligible for enrolment in the study as long as they did not have any contraindications for SGLT2 inhibitors. A total 86 data was collected for this study.

The inclusion criteria included Diagnosis of Type 2 Diabetes Mellitus, HbA1c equal or greater than 7.5% at enrollment, In between 18-65 years, eGFR criteria: >30 ml/min/1.73 m^2 whereas exclusion criteria were Patients with history of severe hypoglycemic events within 6 months prior to enrolment, Had severe volume depletion events within 6 months prior to enrolment, History of diabetic ketoacidosis, Patients with recurrent urinary tract infections, Acute coronary syndrome (non-STEMI, STEMI unstable angina pectoris), stroke or transient ischemic attack within 4 weeks of informed consent, Known decompensated liver disease, Severe renal impairment <30 ml/min/1.73 m^2, Patients who are pregnant or lactating.

At the time of enrolment, each participant was supplied with an additional dose of Empagliflozin 10 mg in addition to the medication regimen that they were already following. Glycemic parameters, renal function and lipid profiles were assessed during follow-up evaluations that were carried out at six weeks and six months after the initial baseline examination. The dosage of some patients was increased to 25 mg based on the clinical response experienced by those patients. For the purpose of conducting statistical studies, paired sample t-tests were utilized for variables that were normally distributed, whereas Wilcoxon Signed Rank tests were utilized for variables that were not normally distributed. Statistical analysis was done using statistical package for social science version 27.

RESULTS

A total of 86 patients participated, with a majority (64%) aged 45–64 years. The mean age was 54.26±9.58 years and females comprised 62.8% of the cohort. Hypertension was the most common comorbidity (73.3%), followed by dyslipidemia (37.2%), ischemic heart disease (14%) and CKD (12.8%).

Total 86 patients participated in this study. Most of participants were aged 45–64 years (64.0%), with mean age of 54.26 years +-9.58. Females comprised a larger proportion (62.8%) than males. Hypertension was highly prevalent, affecting 73.3% of participants. Chronic kidney disease (CKD) was relatively uncommon (12.8%), ischemic heart disease and dyslipidemia were present in 14% and 37.2% of participants.

Significant reductions in fasting blood sugar, postprandial blood sugar and HbA1c were observed at both follow-ups ($p<0.001$ for all measures). BMI showed a significant reduction at 6 months ($p=0.03$). Serum potassium increased significantly at both 6 weeks ($p=0.02$) and 6 months ($p=0.01$), while serum sodium showed a marginal decrease ($p=0.05$) at 6 months. Changes in LDL, triglycerides, HDL and total cholesterol were not statistically significant ($p>0.05$).

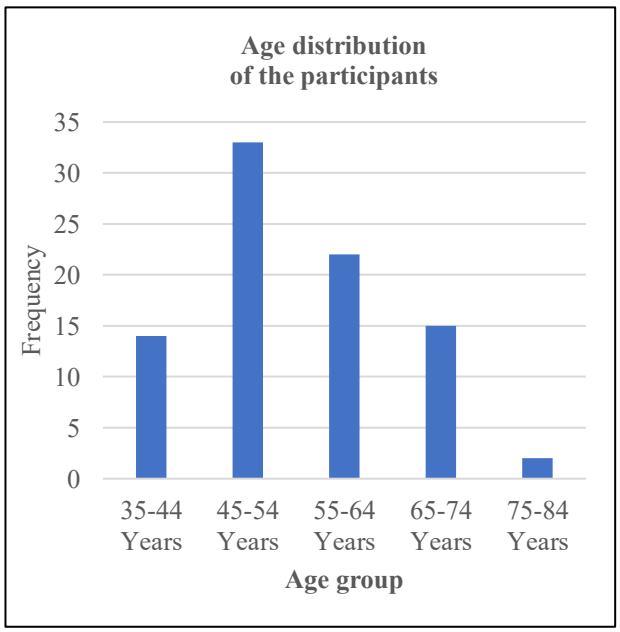

Figure 1: Different age distribution of the study participants.

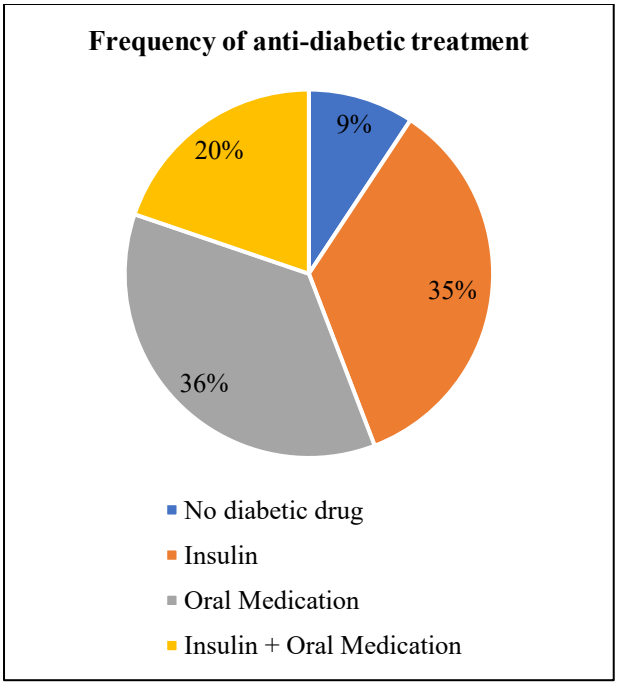

Figure 2: Frequency of anti-diabetic treatment of the patients.

Table 2 displays the mean change between enrolment, 6 weeks and 6 months through paired sample t test. BMI decreased significantly only by 6 months (p=0.03) and serum potassium increased significantly at both time points (p=0.02 and p=0.01). HDL and Total cholesterol did not decline in significant level. The results of the Wilcoxon Signed Rank test for non-normally distributed variables. Notably, fasting blood sugar, postprandial blood sugar, HbA1C and systolic blood pressure significantly decreased from enrolment to both Week 6 and 6 months (p<0.001 for all).

Additionally, serum creatinine and diastolic blood pressure showed significant reductions, but only at 6 months. A marginally significant decline in serum sodium was observed at 6 months (p=0.05). In contrast, LDL and triglycerides did not exhibit any significant changes (p>0.05). Serum creatinine decreased significantly at 6 months.

Table 3 displays the Wilcoxon Signed Rank test for the non-normally distributed variables. Fasting blood sugar, postprandial blood sugar, HbA1C, systolic blood pressure significantly decreased (p<0.001 for all) from enrolment to both Week 6 and 6 months. Serum creatinine and diastolic blood pressure showed statistically significant reductions in only 6 months.

Serum sodium showed a marginally significant decline (p=0.05) at 6 months. LDL and triglycerides showed no significant changes (p>0.05). Minimal adverse effects were reported. Genital mycotic infections occurred in 3 patients (3.5%) at 6 weeks and 1 patient (1.2%) experienced a hypoglycemic episode.

Table 1: Demographics and clinical history of the patients.

Variables	Frequency	%
Age group (in years)		
35-44	14	16.3
45-54	33	38.4
55-64	22	25.6
65-74	15	17.4
75-84	2	2.3
Sex		
Male	32	37.2
Female	54	62.8
Hypertension		
Absent	23	26.7
Present	63	73.3
Chronic kidney disease		
Absent	75	87.2
Present	11	12.8
Ischemic heart disease		
No	74	86
Yes	12	14
Dyslipidemia		
No	54	62.8
Yes	32	37.2

Table 2: Paired sample t test for different metabolic parameters.

	Paired difference between time			
	Between enrolment and 6 weeks	P value	Between enrolment and 6 months	P value
BMI	-0.13	0.2	-0.5	0.03
Serum potassium	0.13	0.02	0.14	0.01
Serum total cholesterol	4.49	0.2	9.44	0.1
Serum HDL	0.23	0.6	0.4	0.7

Table 3: Wilcoxon Signed Rank test for different metabolic parameters.

Differences of variables	Paired difference between time			
	Z score between enrolment and 6 weeks	P value	Z score between enrolment and 6 months	P value
Systolic blood pressure	-3.00	0.03	-4.05	0
Diastolic blood pressure	-1.35	0.18	-3.00	0
Fasting blood sugar	-5.20	0	-6.12	0
Postprandial blood sugar	-6.51	0	-7.31	0
HbA1C	-3.45	0	-6.65	0
Serum creatinine	-1.20	0.2	-4.68	0
Serum sodium	-1.10	0.3	-2.45	0.05
Serum LDL	-2.82	0.78	-2.9	0.67
Serum triglyceride	-0.86	0.38	-2.08	0.45

DISCUSSION

The study demonstrated that Empagliflozin significantly improved glycemic control in Bangladeshi patients with T2DM while maintaining an acceptable safety profile. The reductions in fasting and postprandial blood glucose, along with HbA1c, align with previous studies conducted in Bangladesh in a multicentered study in 2024, also in a similar study in Rajshahi Diabetic Association General Hospital, Rajshahi in 2023.[7,8] The slight but significant weight reduction at 6 months suggests potential benefits in obesity management among diabetic patients. Although in many studies SGLT2 inhibitors were less likely to cause hyperkalemia in people with T2DM, also they had little effect on lowering blood potassium, Serum potassium elevation was observed in this study, may be by increasing the amount of potassium excreted by the kidneys.[9,10] The decrease in serum creatinine at 6 months may indicate renal benefits, although long-term studies are necessary to confirm this finding. Lipid profile changes were not statistically significant, suggesting that Empagliflozin may not have a major impact on lipid metabolism within this cohort. Supporting another study in Czech Republic in 2021.[11] A significant lowering of systolic blood pressure was observed in this study which may indicate cardiovascular benefits of empagliflozin.[12] The incidence of genital mycotic infections (3.5%) was within expected ranges reported in global studies, reinforcing the need for patient education regarding hygiene and preventive care. The single hypoglycemic event (1.2%) suggests a low risk of severe hypoglycemia with Empagliflozin, which is beneficial in managing elderly or comorbid patients.

Limitation of the study includes smaller sample size due to the single centered nature of this study.

CONCLUSION

This study provides evidence that Empagliflozin effectively improves glycemic control in Bangladeshi patients with T2DM with minimal adverse effects. The significant reduction in fasting and postprandial blood glucose, HbA1c and BMI suggests its potential as a valuable addition to existing diabetes treatment regimens. Also decreased systolic blood pressure indicates cardiac benefits. While serum potassium elevation and mild infections were observed, overall safety was favorable. Larger-scale, long-term studies are warranted to further evaluate its benefits and risks in the Bangladeshi population.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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