Section: Miscellaneous

Original Research Article

EFFICACY AND SAFETY OF DAPAGLIFLOZIN AS AN ADJUVANT THERAPY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND DYSLIPIDEMIA – A PROSPECTIVE RANDOMISED OPEN LABEL STUDY

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is commonly associated with dyslipidaemia, increasing cardiovascular risk. This study evaluated the efficacy and safety of dapagliflozin as an adjunct to metformin and statin therapy compared with standard therapy in patients with T2DM and dyslipidaemia. **Materials and Methods:** This prospective, open-label, randomized controlled study included 90 patients with T2DM and dyslipidaemia, randomized equally into Group A (metformin, dapagliflozin, atorvastatin 10 mg) and Group B (metformin, glimepiride, atorvastatin 20 mg). Participants were followed for 24 weeks. Glycaemic parameters, lipid profile, body weight, body mass index (BMI), and adverse drug reactions were assessed. **Results:** At 24 weeks, Group A demonstrated lower fasting blood glucose (112.89 ± 5.10 vs. 118.02 ± 4.00 mg/dL; p<0.001), postprandial blood glucose (175.22 ± 6.74 vs. 179.87 ± 8.29 mg/dL; p=0.005), and HbA1c (6.86 ± 0.14% vs. 6.91 ± 0.09%; p=0.040) than Group B. Body weight decreased from 70.11 ± 8.07 to 68.31 ± 7.83 kg in Group A but increased from 72.33 ± 6.91 to 74.13 ± 7.00 kg in Group B. Total cholesterol and LDL cholesterol were lower in Group B, whereas triglycerides decreased and HDL cholesterol increased in both groups. Most Group A participants reported no adverse drug reactions (73.3%). **Conclusion:** Dapagliflozin improved glycaemic control, reduced body weight, and demonstrated a favourable safety profile. Dapagliflozin was generally well tolerated, with urinary tract infection being the most common adverse event and no serious adverse drug reactions observed.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) has become one of the major public health challenges worldwide. Recent global estimates show that T2DM affected 506.0 million individuals in 2021, with 23.9 million new cases, 1.6 million deaths, and 75.3 million disability-adjusted life years lost.[1] The global prevalence of diabetes has nearly doubled, increasing from about 7% in 1990 to approximately 14% in 2022.[2]

Along with poor glycaemic control, many patients with T2DM also develop dyslipidemia, which is characterized by abnormal cholesterol and triglyceride levels. This coexistence is common and substantially increases the risk of cardiovascular disease. A nationwide study from Bangladesh reported dyslipidemia in 96.83% of drug-naïve patients with T2DM, with elevated LDL cholesterol in 63.54% and elevated triglycerides in 71.40% of patients.[3] Similarly, a study from Northwest China found a dyslipidemia prevalence of 87.7%, while only 68.0% of patients received treatment and just 43.1% achieved LDL-C control.[4] High rates of dyslipidemia have also been reported among patients with T2DM in Saudi Arabia and Nepal.[5,6] A study from South India found deranged lipid profiles in 164 of 237 (69%) participants, while an Ethiopian study reported an overall dyslipidemia prevalence of 61.3%, with poor glycaemic control significantly associated with abnormal lipid levels.[7,8] These findings highlight the close relationship between poor glycaemic control and dyslipidemia, both of which contribute to an increased risk of cardiovascular complications.

Despite current treatment strategies, many patients receiving metformin together with a statin continue to have inadequate control of both blood glucose and lipid levels, particularly as the disease progresses.

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Dapagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor, has demonstrated effective glucose-lowering properties when added to metformin, with studies reporting HbA1c reductions of around 0.70%, along with improvements in fasting blood glucose (FBG), body weight, and other metabolic parameters.[9] It has also shown favourable effects on lipid parameters compared with other second-line antidiabetic agents.[10] Evidence evaluating the combined effect of dapagliflozin on both glycaemic control and dyslipidemia, particularly in patients receiving concomitant metformin and statin therapy in a real-world Indian setting, remains limited. Therefore, the present study was undertaken to evaluate whether the addition of dapagliflozin to metformin and statin therapy could improve glycaemic control and lipid profile while maintaining an acceptable safety profile in patients with T2DM and dyslipidemia.

Aims and objectives of the study

Aim of the Study

To assess the efficacy and safety of dapagliflozin as an adjuvant therapy to metformin monotherapy with statin on glycaemic control and reducing lipid levels compared with standard therapy in patients with T2DM and dyslipidemia.

Objectives

Primary Objectives

1. To assess the effect of dapagliflozin on glycaemic control (fasting blood glucose, postprandial blood glucose, and HbA1c) compared to standard therapy.
2. To evaluate the impact of dapagliflozin on lipid profile parameters, including total cholesterol (TC), triglycerides (TG), low-density lipoprotein (LDL), and high-density lipoprotein (HDL).
3. To determine the effect of dapagliflozin on body weight in the study population.

Secondary Objective

1. To assess the safety profile of dapagliflozin by monitoring adverse drug reactions.

MATERIALS AND METHODS

This prospective, open-label, randomized controlled interventional study was conducted at the Institute of Diabetology, Government Stanley Medical College and Hospital, Chennai, between June 2024 and May 2025. The study duration was 24 weeks, during which all enrolled participants were followed up at regular monthly intervals. The study was approved by the Institutional Ethics Committee of Government Stanley Medical College and Hospital, and written informed consent was obtained from all participants.

Sample Size Calculation

The sample size was calculated based on the reference study by Kabir et al. [11] using the formula:

$n = 2(Z\alpha + Z\beta)^2SD^2/(M_1 - M_2)^2$

where $Z\alpha = 1.96$ (95% confidence interval), $Z\beta = 0.84$ (80% power), pooled standard deviation (SD) = 9.84, and the expected mean difference was 2.0. The calculated minimum sample size was 38.57 participants. After accounting for a 10% non-response rate, the required sample size was 42.3 participants per group, which was rounded to 45 participants per group. Thus, a total of 90 participants were included in the study.

Inclusion Criteria

Patients aged 40–65 years with T2DM of more than 6 months duration, receiving metformin monotherapy, with HbA1c between 7.5% and 8.5%, uncontrolled dyslipidaemia (LDL cholesterol 100–130 mg/dL and triglycerides 150–200 mg/dL) despite statin therapy for more than 6 months, controlled hypertension on stable antihypertensive treatment, and willingness to participate by providing written informed consent were included in the study.

Exclusion Criteria

Patients receiving insulin therapy, those with type 1 diabetes mellitus, previous exposure to dapagliflozin, recurrent urinary tract infections (UTIs), benign prostatic hyperplasia, pregnancy or lactation, chronic kidney disease, chronic liver disease, current use of other hypoglycaemic or lipid-lowering medications, positive urine ketones, or known hypersensitivity to the study medications were excluded.

Methods

Eligible patients attending the Diabetology Outpatient Department were screened according to the predefined inclusion and exclusion criteria. After obtaining informed written consent, demographic details, medical history, duration of diabetes, comorbidities, lifestyle habits, and medication history were recorded using a predesigned case record form. All participants underwent detailed general physical examination and baseline clinical assessment.

Baseline investigations included complete blood count, renal function tests, liver function tests, thyroid profile, FBG, postprandial blood glucose, glycated haemoglobin (HbA1c), fasting lipid profile, electrocardiography, blood pressure measurement, height, body weight, and body mass index (BMI).

Participants were randomized into two groups of 45 patients each using computer-generated random numbers. Group A received metformin 500 mg twice daily, dapagliflozin 10 mg once daily, and atorvastatin 10 mg once daily at bedtime along with lifestyle modification. Group B received metformin 500 mg twice daily, glimepiride 1 mg once daily, and atorvastatin 20 mg once daily at bedtime together with lifestyle modification as standard therapy. FBG and postprandial blood glucose were assessed at baseline and during follow-up, while HbA1c, lipid profile, body weight, and BMI were evaluated at baseline, 12 weeks, and 24 weeks.

Lifestyle modification advice was provided to both groups and included a low-carbohydrate diet, regular physical activity of at least 150 minutes per week, smoking cessation, and abstinence from alcohol consumption.

Participants were reviewed monthly for six months to assess treatment compliance and monitor adverse

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events. FBG and postprandial blood glucose were assessed throughout the study, while HbA1c, fasting lipid profile, liver function tests, renal function tests, body weight, and BMI were evaluated at baseline, 12 weeks, and 24 weeks. Patients were instructed to return empty blister packs during follow-up visits to assess medication adherence. Adverse drug reactions and other untoward events were documented at each visit, and appropriate medical management was provided whenever necessary. Rescue therapy was instituted in patients whose glycaemic or lipid parameters remained inadequately controlled during the study period.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequencies and percentages. Baseline and between-group comparisons were performed using the independent sample *t*-test for continuous variables and the Chi-square or Fisher's exact test for categorical variables, as appropriate. Changes in glycaemic parameters, lipid profile, body weight, and BMI over time were analysed using repeated-measures ANOVA. A two-tailed *p*-value <0.05 was considered statistically significant.

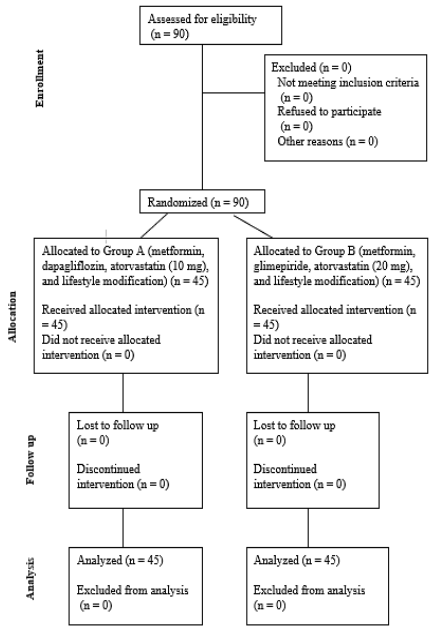

Figure 1: Consort flow diagram

RESULTS

The most common age group was 45–54 years in both groups. Males constituted 53.3% of Group A and 48.9% of Group B. The mean duration of diabetes was 2.09 ± 0.95 years in Group A and 2.18 ± 0.96 years in Group B. Hypertension was present in 62.2% and 55.6% of participants in Groups A and B. Smoking was reported by 24.4% of Group A and 33.3% of Group B, while alcohol use was reported by 31.1% and 24.4%. The mean baseline weight was 70.11 ± 8.07 kg in Group A and 72.33 ± 6.91 kg in Group B, with corresponding BMI values of 26.71 ± 4.00 kg/m² and 26.89 ± 3.65 kg/m². Baseline FBG, postprandial blood glucose, HbA1c, total cholesterol, triglycerides, LDL cholesterol, and HDL cholesterol were comparable between the two groups. [Table 1]

Table 1: Baseline Characteristics of the Study Participants

Characteristic	Category	Group A	Group B	p-value
Age (years)	40–44	7 (15.6%)	8 (17.8%)	-
	45–49	10 (22.2%)	9 (20.0%)	-
	50–54	10 (22.2%)	12 (26.7%)	-
	55–59	8 (17.8%)	7 (15.6%)	-
	60–65	10 (22.2%)	9 (20.0%)	-
Gender	Male	24 (53.3%)	22 (48.9%)	-
	Female	21 (46.7%)	23 (51.1%)	-
Duration of diabetes (years)	Mean ± SD	2.09 ± 0.95	2.18 ± 0.96	-
Hypertension	Yes	28 (62.2%)	25 (55.6%)	-
	No	17 (37.8%)	20 (44.4%)	-
Smoking	Yes	11 (24.4%)	15 (33.3%)	-
	No	34 (75.6%)	30 (66.7%)	-
Alcohol use	Yes	14 (31.1%)	11 (24.4%)	-
	No	31 (68.9%)	34 (75.6%)	-
Anthropometric parameters	Height (cm)	162.64 ± 9.50	164.56 ± 8.20	-
	Weight (kg)	70.11 ± 8.07	72.33 ± 6.91	0.164
	BMI (kg/m²)	26.71 ± 4.00	26.89 ± 3.65	0.816

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Biochemical parameters	FBS (mg/dL)	146.84 ± 8.00	148.73 ± 10.00	0.326
	Postprandial blood glucose (mg/dL)	246.58 ± 7.10	246.71 ± 6.73	0.928
	HbA1c (%)	7.95 ± 0.18	7.92 ± 0.17	0.563
	TC (mg/dL)	189.84 ± 6.41	190.75 ± 7.49	0.539
	Triglycerides (mg/dL)	171.67 ± 9.74	173.20 ± 11.50	0.499
	LDL cholesterol (mg/dL)	115.44 ± 5.97	115.91 ± 7.19	0.739
	HDL cholesterol (mg/dL)	40.07 ± 3.29	40.20 ± 3.35	0.85

At baseline, FBG was 146.84 ± 8.00 mg/dL in Group A and 148.73 ± 10.00 mg/dL in Group B. At 12 weeks, the values were 120.02 ± 4.60 mg/dL and 125.69 ± 4.30 mg/dL and further decreased to 112.89 ± 5.10 mg/dL and 118.02 ± 4.00 mg/dL at 24 weeks. Postprandial blood glucose decreased from 246.58 ± 7.10 mg/dL and 246.71 ± 6.73 mg/dL at baseline to 175.22 ± 6.74 mg/dL and 179.87 ± 8.29 mg/dL at 24 weeks in Groups A and B. Mean HbA1c decreased from 7.95 ± 0.18% to 6.86 ± 0.14% in Group A and from 7.92 ± 0.17% to 6.91 ± 0.09% in Group B over 24 weeks. Repeated-measures ANOVA confirmed significant changes over time for all glycaemic parameters (all $p < 0.001$). Significant time × group interactions were observed for postprandial blood glucose ($p = 0.017$) and HbA1c ($p = 0.037$), whereas FBG showed no significant interaction ($p = 0.100$). [Table 2]

Table 2: Comparison of Glycaemic Parameters Between the Study Groups

Parameter	Group	Baseline	12 Weeks	24 Weeks
FBG (mg/dL)	Group A	146.84 ± 8.00	120.02 ± 4.60	112.89 ± 5.10
	Group B	148.73 ± 10.00	125.69 ± 4.30	118.02 ± 4.00
	Between-group *p*-value	0.326	<0.001	<0.001
Postprandial blood glucose (mg/dL)	Group A	246.58 ± 7.10	179.24 ± 6.20	175.22 ± 6.74
	Group B	246.71 ± 6.73	185.22 ± 6.33	179.87 ± 8.29
	Between-group *p*-value	0.928	<0.001	0.005
HbA1c (%)	Group A	7.95 ± 0.18	6.98 ± 0.17	6.86 ± 0.14
	Group B	7.92 ± 0.17	7.02 ± 0.14	6.91 ± 0.09
	Between-group *p*-value	0.563	0.294	0.04

The baseline total cholesterol was 189.84 ± 6.41 mg/dL in Group A and 190.75 ± 7.49 mg/dL in Group B. At 24 weeks, the corresponding values were 194.13 ± 0.14 mg/dL and 168.35 ± 7.97 mg/dL. Baseline triglyceride levels were 171.67 ± 9.74 mg/dL and 173.20 ± 11.50 mg/dL, which changed to 148.47 ± 10.97 mg/dL and 144.78 ± 11.26 mg/dL at 24 weeks in Groups A and B. LDL cholesterol changed from 115.44 ± 5.97 mg/dL and 115.91 ± 7.19 mg/dL at baseline to 120.24 ± 5.28 mg/dL and 94.00 ± 7.32 mg/dL at 24 weeks. HDL cholesterol increased from 40.07 ± 3.29 mg/dL and 40.20 ± 3.35 mg/dL at baseline to 44.20 ± 2.91 mg/dL and 45.40 ± 2.26 mg/dL. Repeated-measures ANOVA demonstrated a significant effect of time for all lipid profile parameters (all $p < 0.001$). Significant time × group interactions were observed for total cholesterol, triglycerides, LDL cholesterol (all $p < 0.001$), and HDL cholesterol ($p = 0.002$). [Table 3]

Table 3: Comparison of Lipid Profile Parameters Between the Study Groups

Parameter	Group	Baseline	12 Weeks	24 Weeks
Total cholesterol (mg/dL)	Group A	189.84 ± 6.41	191.00 ± 6.30	194.13 ± 0.14
	Group B	190.75 ± 7.49	169.60 ± 8.15	168.35 ± 7.97
	Between-group *p*-value	0.539	<0.001	<0.001
Triglycerides (mg/dL)	Group A	171.67 ± 9.74	150.27 ± 11.29	148.47 ± 10.97
	Group B	173.20 ± 11.50	146.58 ± 12.13	144.78 ± 11.26
	Between-group *p*-value	0.499	0.139	0.119
LDL cholesterol (mg/dL)	Group A	115.44 ± 5.97	118.20 ± 5.54	120.24 ± 5.28
	Group B	115.91 ± 7.19	95.90 ± 7.23	94.00 ± 7.32
	Between-group *p*-value	0.739	<0.001	<0.001
HDL cholesterol (mg/dL)	Group A	40.07 ± 3.29	42.78 ± 3.14	44.20 ± 2.91
	Group B	40.20 ± 3.35	44.36 ± 2.16	45.40 ± 2.26
	Between-group *p*-value	0.85	0.007	0.032

The mean body weight in Group A decreased from 70.11 ± 8.07 kg at baseline to 68.31 ± 7.83 kg at 24 weeks, whereas Group B increased from 72.33 ± 6.91 kg to 74.13 ± 7.00 kg during the same period. Similarly, BMI in Group A decreased from 26.70 ± 4.00 kg/m² to 26.02 ± 3.87 kg/m², while Group B increased from 26.89 ± 3.65 kg/m² to 27.57 ± 3.73 kg/m² over 24 weeks. Repeated-measures ANOVA demonstrated a significant effect of time on body weight and BMI (both $p < 0.001$). Significant time × group interactions were observed for both body weight and BMI (both $p < 0.001$). [Table 4]

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Table 4: Comparison of Body Weight and BMI Between the Study Groups

Parameter	Group	Baseline	12 Weeks	24 Weeks
Body weight (kg)	Group A	70.11 ± 8.07	69.04 ± 7.98	68.31 ± 7.83
	Group B	72.33 ± 6.91	73.14 ± 6.93	74.13 ± 7.00
	Between-group *p*-value	0.164	0.011	<0.001
BMI (kg/m²)	Group A	26.70 ± 4.00	26.30 ± 3.90	26.02 ± 3.87
	Group B	26.89 ± 3.65	27.20 ± 3.69	27.57 ± 3.73
	Between-group *p*-value	0.816	0.27	0.057

Among participants in Group A, 33 (73.3%) reported no adverse drug reactions, while UTI was observed in 10 (22.2%) participants and gastrointestinal side effects in 2 (4.4%) participants. All participants in Group B experienced weight gain (45, 100.0%). [Table 5]

Table 5: Comparison of Adverse Drug Reactions Between the Study Groups

Adverse Drug Reaction	Group A	Group B
None	33 (73.3%)	0
UTI	10 (22.2%)	0
Gastrointestinal side effects	2 (4.4%)	0
Weight gain	0 (0.0%)	45 (100.0%)

DISCUSSION

T2DM is a chronic metabolic disorder that often coexists with dyslipidaemia, increasing the risk of cardiovascular complications. This study was conducted to evaluate the efficacy and safety of dapagliflozin as an adjunct to standard therapy in improving glycaemic control, lipid profile, body weight, and safety outcomes. The findings demonstrated improved glycaemic control and body weight reduction in Group A, while lipid profile changes varied between the groups. Dapagliflozin was generally well tolerated, with only mild adverse drug reactions observed.

In our study, the two groups were comparable with respect to their demographic, clinical, anthropometric, and biochemical characteristics at baseline. The distribution of age, sex, duration of diabetes, hypertension, smoking and alcohol use, as well as baseline body weight, BMI, glycaemic indices, and lipid profile parameters was similar between the groups. Similarly, Sharma et al. reported comparable baseline characteristics between the vildagliptin and remogliflozin groups. The mean age was 50.57 ± 10.01 and 49.10 ± 9.36 years, baseline HbA1c was 8.31 ± 0.92% and 8.30 ± 1.05%, and body weight was 65.27 ± 10.49 kg and 71.40 ± 14.03 kg, with no significant between-group differences prior to treatment.[12]

Similarly, Wangnoo et al. reported a comparable baseline clinical profile in Indian patients with type 2 diabetes mellitus, with a median age of 53 years, 61.2% male participants, a mean diabetes duration of 7.1 ± 5.7 years, body weight of 74.2 ± 12.6 kg, BMI of 28.0 ± 4.4 kg/m², and HbA1c of 8.6 ± 0.8%. Hypertension (29.1%) was the most common comorbidity, followed by dyslipidaemia (18.4%).[13] These findings indicates that the study groups were comparable before treatment initiation, thereby strengthening the validity of the comparisons between the interventions.

The present study demonstrated a progressive improvement in glycaemic parameters in both groups over the 24-week follow-up period. Group A consistently achieved lower FBG and postprandial blood glucose levels than Group B during follow-up. Although HbA1c values were comparable between the groups at baseline and at 12 weeks, Group A showed lower HbA1c levels by the end of the study, indicating better long-term glycaemic control. Similarly, Wangnoo et al. reported that dapagliflozin-based combination therapy produced a mean HbA1c reduction of 1.2 ± 1.1% and a fasting plasma glucose reduction of 24.4 ± 62.9 mg/dL over 24 weeks (p<0.0001).[13]

Reddy et al. observed that dapagliflozin add-on therapy reduced mean FBG from 184 mg/dL to 135 mg/dL, a 26.63% reduction, over three months (p=0.001).[14] Similarly, Sharma et al. reported an 8.1% reduction in mean HbA1c with remogliflozin compared with a 2.4% reduction with vildagliptin after 90 days of treatment (p < 0.001).[12] These findings suggest that add-on therapy with SGLT2 inhibitors is effective in improving glycaemic control in patients with type 2 diabetes mellitus, resulting in sustained reductions in FBG, postprandial blood glucose, and HbA1c.

Our findings showed changes in lipid profile parameters in both groups during the study period. Total cholesterol and LDL cholesterol were lower in Group B than in Group A at follow-up, while triglyceride levels decreased in both groups without a significant between-group difference. HDL cholesterol increased in both groups, with higher values observed in Group B during follow-up. Similarly, Martha et al. conducted a systematic review and meta-analysis of dose-comparison trials and reported that dapagliflozin was associated with a modest increase in LDL cholesterol of 2.33 mg/dL compared with placebo or active comparators (95% CI: 1.46–3.19; p<0.00001).[15]

In contrast, Kabir et al. conducted a randomized placebo-controlled trial in patients with dyslipidaemia and reported that dapagliflozin significantly reduced LDL cholesterol from 4.6 ± 3.16 mmol/L to 1.9 ± 1.7 mmol/L (p=0.002), along

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with reductions in triglyceride levels and an increase in HDL cholesterol. The lipid profile findings should be interpreted with caution, as Group B received a higher dose of atorvastatin (20 mg vs. 10 mg), which may have contributed to the greater reduction in total cholesterol and LDL cholesterol.[11] These findings indicate that lipid profile changes were influenced by the treatment regimen, although differences in atorvastatin dosage may have contributed to the observed outcomes.

The findings of the present study indicated that body weight decreased progressively in Group A throughout the study period, whereas Group B showed an increase in body weight during follow-up. A similar trend was observed for BMI, with a reduction in Group A and an increase in Group B, although the between-group difference was not statistically significant. Similarly, Huh and Kim followed 200 Korean patients with type 2 diabetes for one year after starting dapagliflozin and found that 61% achieved clinically meaningful weight loss of at least 3% of body weight.[16] Similarly, Wangnoo et al. reported a mean weight reduction of 2.1 ± 4.0 kg with dapagliflozin-based combination therapy over 24 weeks ($p<0.0001$).[13]

Most participants in Group A did not experience any adverse drug reactions during the study period. UTI was the most commonly reported adverse event, followed by gastrointestinal side effects, while weight gain was observed among all participants in Group B. Similarly, Wangnoo et al. reported an overall adverse event rate of 11.2%, with UTI occurring in 2.6% of patients and no serious adverse events recorded over 24 weeks.[13] These findings indicate that dapagliflozin promotes weight reduction while maintaining a favourable safety profile, supporting its use as an effective adjunctive therapy in type 2 diabetes mellitus.

The present study demonstrated that dapagliflozin as an adjunct to standard therapy improved glycaemic control, promoted weight reduction, and was well tolerated. Lipid profile findings should be interpreted cautiously because differences in concomitant atorvastatin dosage may have influenced the observed outcomes.

Limitations

This single-centre, open-label study had a relatively small sample size and a 24-week follow-up, which may limit the generalizability of the findings and introduce potential bias. The use of different atorvastatin doses between the groups may have influenced the lipid profile outcomes.

CONCLUSION

Dapagliflozin as an adjunct to metformin demonstrated superior glycaemic control and significant weight reduction compared with glimepiride-based therapy in patients with type 2 diabetes mellitus and dyslipidaemia. Although total cholesterol and LDL cholesterol increased modestly, triglycerides decreased and HDL cholesterol improved during follow-up. Dapagliflozin was generally well tolerated, with urinary tract infection being the most common adverse event and no serious adverse drug reactions observed. These findings support dapagliflozin as an effective and safe adjunctive treatment.

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