

TREATMENT PATTERNS AND GLYCEMIC OUTCOMES OF REAL-WORLD SGLT2-INHIBITORS BASED THERAPIES IN TYPE 2 DIABETES: A MULTICENTRIC STUDY FROM INDIA

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ABSTRACT

Objectives: This study aimed to describe the real-life use of sodium-glucose cotransporter-2 (SGLT2) inhibitor-based therapies as well as assess their effect on glycated hemoglobin (HbA1c) levels in individuals with type 2 diabetes mellitus (T2DM).

Methods: A prospective observational study was carried out from 6 diabetes centers (five in Pune, Maharashtra, and one in Trichy, Tamil Nadu). A total of 500 adults whose diabetes was being treated with an SGLT2 inhibitor alone or in combination with other antidiabetic drugs were enrolled. Treatment details, baseline characteristics, and HbA1c values at enrollment and at 26 weeks were recorded. Changes in HbA1c were reported using descriptive statistics and appropriate comparative statistical tests in the computer package, Version 26 of the software package, the Statistical Package for Social Sciences.

Results: The mean HbA1c at baseline was $8.93 \pm 1.8\%$ which was reduced to $7.36 \pm 1.4\%$ at 26 weeks of therapy (mean reduction: 1.57%, $p < 0.0001$). Combination of such agents as Remogliflozin+Vildagliptin+Metformin+Sitagliptin (mean HbA1c reduction: $-25.9 \pm 21.6\%$) and Dapagliflozin + Sitagliptin + Metformin ($-26.5 \pm 8.4\%$) resulted in marked improvements. Overall, almost 72% of the therapeutic regimens resulted in a decrease in HbA1c of more than 0.5%.

Conclusion: In routine clinical practice, SGLT2 inhibitor-based treatments particularly when combined with dipeptidyl peptidase-4 inhibitors and metformin were associated with meaningful and consistent reduced HbA1c among Indian patients with T2DM.

Keywords: Type 2 diabetes mellitus, Sodium-glucose cotransporter-2 inhibitors, Remogliflozin, Dapagliflozin, Glycated hemoglobin reduction, Real-world study.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic and progressive disease of metabolic dysfunction that is identified by consistent hyperglycemia that is caused by either insulin resistance, impaired insulin secretion, or both. It continues to increase on a global scale and is a particularly serious health challenge in India. According to these latest estimates, 72.9 of Indians were suffering with diabetes in 2017 and this number will rise to 134.3 million in the year 2045 [1]. The Indian Council of Medical Research (ICMR) Guidelines for the Management of T2DM have emphasized that the burden of insulin resistance and dysfunction of beta cells are responsible for the natural process of the disease [2]. The "Asian Indian phenotype" of increased visceral adiposity, insulin resistance, and an earlier age of onset of metabolic abnormalities predisposing an Indian adult to T2DM at an earlier age and at a lower degree of obesity (body mass index) as compared to Western populations [3,4].

The pathophysiology of T2DM was elaborated in the DeFronzo's landmark Banting lecture in 2009 as "Ominous Octet" model which describes eight organ systems that are perturbed in glucose dysregulation including decreased insulin secretion from pancreatic beta cells; increased glucagon from alpha cells; increased hepatic glucose production; decreased peripheral glucose uptake; increased lipolysis; incretin defects; increased renal glucose reabsorption; and abnormalities of central nervous system insulin signaling [5]. It shows that targeting one pathway individually is likely to achieve less than optimal glycemic durability and emphasizes the importance of early and rational combination therapy.

The sodium-glucose cotransporter-2 (SGLT2) inhibitors decrease glucose in the blood by an insulin-independent process by increasing the excretion of glucose into urine. Beyond glycemic control, they have proven to have cardiovascular and renal benefits in major outcome trials such as EMPA-REG OUTCOME, CANVAS, and DECLARE-TIMI 58 [6-8]. Despite their increasing use, the real-world evidence of the performance of SGLT2 inhibitor use in combination with other oral or injectable therapies in Indian clinical settings is still limited.

The present study was aimed at addressing this evidence gap. Specifically, it aimed to: (i) evaluate absolute and percentage changes in glycated hemoglobin (HbA1c) over 26 weeks in three different treatment regimens based on SGLT2 inhibitors (monotherapy, dual-therapy, and triple-therapy); (ii) compare glycemic responses in the three sets of treatments; and (iii) draw inferences from the results in light of the Ominous Octet model [5] and current ICMR/Research Society for the Study of Diabetes in India (RSSDI) recommendations [1,9]. By analyzing regimens and HbA1c efficacy in various clinical practice settings from multiple real-world centers, this study gives us insight on the effectiveness of regimens based on SGLT2 inhibitors in a routine clinical practice in India.

METHODS

This multicentric, prospective observational study was conducted at five specialized diabetic care centers in Pune, Maharashtra and one in Trichy, Tamil Nadu in India. Consecutive eligible patients attending these centers during the study period were enrolled. A total of 500 patients 18 years or older with a confirmed diagnosis of T2DM

on a SGLT2 inhibitor as monotherapy or in combination with other oral or injectable agents were recruited into this study. Patients were excluded if they had severe renal impairment (estimated glomerular filtration rate <30 mL/min/1.73 m²), advanced heart failure (New York Heart Association class III-IV), type 1 diabetes mellitus, pregnancy or lactation, or incomplete baseline or follow-up data. Ethics committee approval (EC reference number 202304/02, letter dated April 08, 2023) was obtained from the Institutional Ethics Committee of Vishwaraj Hospital, Pune.

The patient demographic information, clinical history, current antidiabetic medications, and laboratory parameters were noted at baseline and 26 weeks following treatment. For the purpose of the data analysis, the treatments were categorized according to the major antidiabetic regimen consisting of an SGLT2 inhibitor and any secondary additional antidiabetic therapies. Each treatment was classified in two parts, (1) the main antidiabetic treatment including an SGLT2 inhibitor and (2) the concomitant background treatment, as for example, metformin, dipeptidyl peptidase-4 (DPP-4) inhibitors, sulfonylureas, thiazide diabetics, or insulin. Unique combinations of these medications were identified, to facilitate the comparison of glycemic outcomes of different treatment patterns. All of the entries were reviewed to make sure that each individual participant was only included once. Duplicate or incomplete records were deleted by manual review process. HbA1c values at baseline and at 26 weeks were cross checked for accuracy before being included in the final analysis dataset.

The absolute change in HbA1c was determined by calculating the change in HbA1c from baseline to week 26. The percentage reduction was calculated with respect to each patient's baseline HbA1c concentration. Patients were further grouped on the basis of their primary SGLT2-based regimen and stratified with respect to whether or not any secondary add-on therapies were prescribed to them. Descriptive statistics were used to summarize demographic and clinical variables. Python (pandas, numpy) was used for data cleaning and computation of HbA1c changes, while the Statistical Package for the Social Sciences version 26 was used for inferential analyses. Mean HbA1c reductions across treatment groups were compared using one-way analysis of variance (ANOVA). Independent samples t-tests were used for two-group comparisons. Subgroup analyses with small sample sizes were descriptive. A two-sided $p < 0.05$ was considered statistically significant.

RESULTS

There were a total of 500 patients included for the analysis. The mean age of study population was 54.2±12 years and males were 55%. The average time of duration of diabetes was 7.1±3.6 years. The most common of these comorbidities was hypertension, which appeared in 52.8% of the population, followed by cerebrovascular disease (stroke or cerebrovascular accident) in patients (22.8%). Information on body mass index and renal function parameters such as estimated glomerular filtration rate was not uniformly available across participating centers and, therefore, could not be included in the analysis. Patients were classified according to their baseline SGLT2 inhibitors-based therapy. Of the entire cohort, 23.8% were on SGLT2 inhibitor monotherapy, and 33.8% of patients were on dual therapy (SGLT2 inhibitor plus

metformin or SGLT2 inhibitor plus DPP-4 inhibitor). Triple oral therapy (SGLT2 inhibitor+DPP-4 inhibitor+Metformin) was 16.2% of patients. An additional 26.2% were given an intensified triple regimen with extra DPP-4 inhibitor component. Concomitant insulin use was found in all groups (n=47; 9.4%) due to the use of insulin in patients with a higher glycemic burden.

The distribution of patients among therapy groups, classified according to the use of insulin, is shown in Table 1.

A detailed breakdown of regimens that are based on SGLT2 inhibitors is provided in Table 2. The most common dual therapy regimens included dapagliflozin and sitagliptin (n=39) and dapagliflozin and vildagliptin (n=36) followed by remogliflozin and metformin (n=19) and remogliflozin and vildagliptin (n=25). Dapagliflozin 10 mg was the most prescribed (n=107) in the monotherapy group. The mostly prescribed triple therapy was remogliflozin-based combinations, particularly Remogliflozin+Vildagliptin+Metformin (n=77); an intensified version of the same triple regimen with an additional DPP-4 inhibitor was over 131 subjects. Insulin add-on therapy was seen in all categories with a predominant use of insulin add-on therapy in monotherapy (n=10), dual therapy (n=18 collectively), and triple therapy (n=14) which suggest use of insulin add-on therapy in patients with increased glycemic burden or unsatisfactory response to oral therapy alone.

HbA1c changes from baseline to Week 26 showed a stepwise benefit with treatment intensity of the SGLT2 inhibitor-based therapy as follows (Table 3). Patients taking monotherapy demonstrated reduction to a mean of 1.10% (11.75% relative) compared to 1.58% relative reduction observed in patients on dual therapy. A further incremental benefit was seen with triple therapy (SGLT2+DPP-4 inhibitor+metformin) which led to a mean reduction of 1.85% (18.68% relative). The greatest improvement among Triple+Extra DPP-4 group with mean HbA1c reduction of 2.06% (20.36% relative). The stepwise increase in HbA1c reduction with treatment intensity was statistically significant across therapy groups (one-way ANOVA, $p < 0.001$). Mean HbA1c reductions are reported with 95% confidence intervals to indicate the precision of treatment effect estimates.

Fig. 1 describes mean percentage reduction in HbA1c across SGLT2 inhibitor-based therapy groups at week 26. Bars represent mean percentage reduction in HbA1c from baseline to Week 26 across therapy groups. Error bars indicate standard deviation. The superimposed dashed trend line represents mean Week-26 HbA1c values and illustrates that patients with higher baseline glycemic burden achieved greater absolute and relative HbA1c reductions with increasing treatment intensity.

A subset of patients was receiving additional oral antidiabetic agents in addition to their SGLT2 inhibitor-based regimens primarily from the monotherapy and dual therapy groups (Table 4). Glimepiride was prescribed in 18.8% and gliclazide was prescribed in 6.2% and voglibose was prescribed in 4.0% of the subjects. These agents were not used in the Triple+Extra DPP-4 group. HbA1c reductions in patients treated with glimepiride or voglibose were comparable to the overall

Table 1: Baseline and therapy distribution

Therapy group	Drug class combination	n without insulin	n with insulin	Total n	Percentage of total
Monotherapy	SGLT2 inhibitor	104	15	119	23.8
Dual therapy (SGLT2+Metformin)	SGLT2 inhibitor+Biguanide	21	6	27	5.4
Dual therapy (SGLT2+DPP-4)	SGLT2 inhibitor+DPP-4 inhibitor	130	12	142	28.4
Triple therapy	SGLT2 inhibitor+DPP-4 inhibitor+Biguanide	68	13	81	16.2
Triple+Extra DPP4	SGLT2 inhibitor+DPP-4 inhibitor+Biguanide (+extra DPP-4)	130	1	131	26.2
Total	—	453	47	500	100

Triple+Extra DPP-4 denotes an intensified oral regimen comprising an SGLT2 inhibitor, metformin, and a DPP-4 inhibitor, with the addition of a second DPP-4 inhibitor. SGLT2: Sodium-glucose cotransporter-2, DPP-4: Dipeptidyl peptidase-4

Table 2: Distribution of therapy regimens

Therapy group (Class)	Drug regimen	Class	n	Insulin add-on (n)
Monotherapy (SGLT2 inhibitor)	Dapagliflozin (10 mg)	SGLT2 inhibitor	107	10
*Other monotherapy ¹	-	SGLT2 inhibitor	12	2
Dual therapy (SGLT2 inhibitor+Biguanide)	Dapagliflozin (10 mg)+Metformin (500 mg)	SGLT2 inhibitor+Biguanide	8	2
	Remogliflozin (100 mg)+Metformin (500 mg)		19	4
Dual therapy (SGLT2 inhibitor+DPP-4 inhibitor)	Dapagliflozin (10 mg)+Sitagliptin (100 mg)	SGLT2 inhibitor+DPP-4 inhibitor	39	4
	Dapagliflozin (10 mg)+Vildagliptin (100 mg)		36	3
	Dapagliflozin (5 mg)+Vildagliptin (100 mg)		23	2
	Empagliflozin (25 mg)+Linagliptin (5 mg)		13	1
*Other dual therapy ²	Remogliflozin (100 mg)+Vildagliptin (50 mg)	SGLT2 inhibitor+DPP-4 inhibitor	25	2
Triple therapy	-	SGLT2 inhibitor+DPP-4 inhibitor	6	0
	Remogliflozin (100 mg)+Vildagliptin (50 mg)+Metformin (500 mg)	SGLT2+DPP-4+Biguanide	77	12
*Other triple therapy ³	-	SGLT2+DPP-4+Biguanide	4	1
Triple+extra DPP-4**	Remogliflozin (100 mg)+Vildagliptin (50 mg)+Metformin (500 mg) (+extra DPP-4)	SGLT2+DPP-4+Biguanide(+extra DPP-4)	131	1

*"Other monotherapy/combinations" include regimens with n≤5 each (low-frequency regimens grouped for readability); **extra DPP-4 refers to a second DPP-4 inhibitor agent. ¹Other Monotherapy include regimens such as dapagliflozin (5 mg), empagliflozin (10 mg), empagliflozin (25 mg), and remogliflozin etabonate (100 mg). ²Other dual therapy includes regimens such as Dapagliflozin (5 mg)+Sitagliptin (100 mg), Dapagliflozin (5 mg)+Sitagliptin (50 mg), and Empagliflozin (10 mg)+Linagliptin (5 mg). ³Other triple therapy include regimen such as Dapagliflozin (10 mg)+Sitagliptin (100 mg)+Metformin (500 mg) and Dapagliflozin (10 mg)+Sitagliptin (100 mg)+Metformin (1000 mg). SGLT2: Sodium-glucose cotransporter-2, DPP-4: Dipeptidyl peptidase-4

Table 3: HbA1c reductions from baseline to week 26 by therapy group

Therapy group	n	Baseline HbA1c (mean)	Week-26 HbA1c (mean)	Mean Δ HbA1c	SD of Δ HbA1c	95% CI of mean Δ HbA1c	Mean reduction (%)
Monotherapy	119	8.44	7.34	1.10	1.14	0.89–1.31	11.75
Dual therapy (Biguanide+DPP4 combined)	169	9.18	7.60	1.58	1.33	1.38–1.78	15.61
Triple therapy (SGLT2+DPP4+Metformin)	81	9.01	7.16	1.85	1.55	1.51–2.19	18.68
Triple+Extra DPP4	131	9.34	7.28	2.06	1.61	1.78–2.34	20.36
Overall comparison		p<0.001					

All continuous values are expressed as mean±standard deviation unless otherwise specified. Differences in mean HbA1c reduction across therapy groups were analyzed using one-way analysis of variance. Values are presented with 95% confidence intervals for mean HbA1c change. SGLT2: Sodium-glucose cotransporter-2, DPP-4: Dipeptidyl peptidase-4, HbA1c: Glycated hemoglobin

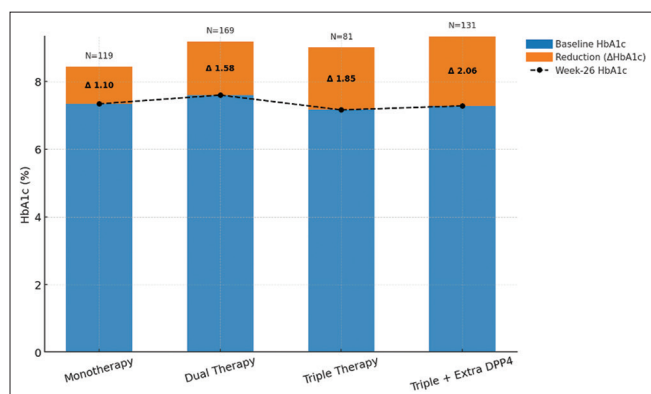


Fig. 1: Mean percentage reduction in glycated hemoglobin (HbA1c) across sodium-glucose cotransporter-2 inhibitor-based therapy groups at Week 26. Differences in mean HbA1c reduction across therapy groups were statistically significant (one-way analysis of variance, p<0.001).

SGLT2-based treatment result, while gliclazide add-on showed small reductions from the fact that it was used in people with lower baseline HbA1c. Interpretation of these findings is also limited due to relatively small the number of patients in each subgroup.

DISCUSSION

This multicentric observational study presents real-world evidence of the effectiveness of SGLT2 inhibitor-based regimens in a wide range of

therapeutic intensities in Indian patients with T2DM. A positive and consistent relationship between intensity of response was seen, with trends of reductions of HbA1c from monotherapy to dual therapy, triple therapy, and intensified triple therapy. This trend is consistent with previously made clinical observations regarding the dependence of the glucose lowering activity of the SGLT2 inhibitors on the complexity of the regimen and the glycemic burden at baseline.

Dual therapy with SGLT2 inhibitor plus metformin or DPP-4 inhibitor resulted in significant higher HbA1c reductions than SGLT2 inhibitor monotherapy. This is biologically possible, as each class follows different pathophysiological mechanisms. The SGLT2 inhibitors promote glucose excretion in the urine insulin-independent [10], metformin mainly inhibits glucose production in the liver and DPP-4 inhibitors enhance glucagon-independent insulin secretion and lower glucagon levels [11,12]. When taken together, these classes combine to cover several aspects of the Ominous Octet and provide better glycemic results. These results are in agreement with strong clinical and pharmacologic evidence of additive benefits of combination therapy in the management of T2DM [13–15].

The greatest improvements in the present study were observed in triple therapy (SGLT2+DPP-4 inhibitor+metformin) and a maximized version with another DPP-4 inhibitor added. These groups showed not only the highest reductions in HbA1c (1.85% and 2.06%, respectively) but also higher baseline glycemic levels, which may be seen more commonly in the real-world of practice in India. Several studies have shown that persons with more severe hyperglycemia have greater absolute HbA1c reductions with aggressive combination therapy [16]. The results seen in the present study support modern treatment algorithms such

Table 4: Impact of additional oral agents (glimepiride, gliclazide, and voglibose) on HbA1c reduction across SGLT2-based regimens

Therapy group	Add-on drug	n	Baseline HbA1c (mean)	Week-26 HbA1c (mean)	Mean Δ HbA1c	SD of Δ	Mean reduction (%)
Monotherapy	Glimepiride	32	8.64	7.31	1.33	1.32	13.54
	Gliclazide	22	7.75	7.24	0.51	0.74	5.77
	Voglibose	3	8.44	7.57	0.87	1.00	9.39
Dual therapy	Glimepiride	59	9.55	7.95	1.60	1.08	15.64
	Gliclazide	9	8.40	7.70	0.70	1.11	7.45
	Voglibose	17	9.30	7.84	1.46	0.95	14.70
Triple therapy	Glimepiride	3	9.77	7.10	2.67	0.87	26.96

HbA1c values and changes are presented as mean±standard deviation; These subgroup analyses involve limited sample sizes and should be interpreted with caution; furthermore, the "Triple+Extra DPP-4" group is not shown because no additional oral agents beyond the intensified regimen were prescribed. HbA1c: Glycated hemoglobin, SGLT2: Sodium-glucose cotransporter-2

as RSSDI 2025 recommendations [9] and ICMR guidelines [2], which recommend the early initiation of dual or triple therapy when HbA1c is >8–8.5% or in case of treatment failure for desired glycemic targets.

Insulin was prescribed as an adjunct therapy in almost 10% of the participants, mostly among those with a longer time of the disease, or more significant uncontrolled hyperglycemia. The modest but meaningful incremental reduction of HbA1c seen in these patients of 0.30–0.40% is consistent with previous data demonstrating the increased glycemic control with the combination of SGL2 inhibitors with insulin with minimal or no increased risk of hypoglycemia [17,18].

The magnitude of HbA1c reduction in the present study (1.10–2.06%) is proportionate with, and in some instances larger than, reductions in randomized clinical studies of SGLT2 inhibitors [6-8,19,20,21]. This difference is probably related to increased baseline levels of HbA1c in the Indian population and to the routine use of multidrug regimens in practice. These findings underscore the importance of SGLT2 inhibitor targeted approaches in the real-world of diabetes management in India, especially in settings where early degradation of β cells and the rapid glycemic deterioration are routine.

The use of additional agents especially glimepiride, gliclazide, and voglibose gives the impression of prescribing patterns typical of Indian clinical practice. Glimepiride add-on therapy showed similar HbA1c decreasing effects as the absence of sulfonylurea addition, suggesting that this derivative of glimepiride can also be combined with SGLT2-based regimens. Gliclazide commonly was used in patients with relatively lower baseline levels of HbA1c, which explains the more modest absolute decrements observed. Although the number of the voglibose users was small, their results justify modest additive benefit. These subgroups observations point to the need to personalize therapy based on baseline glycemia, comorbidities, and treatment tolerability.

Overall, the present study highlights the importance of early and rational increase of agents with complementary mechanisms of action as opposed to the delayed stepwise approach. The real-world improvements that were seen with SGLT2-based dual and triple combinations exhibit their utility in helping the Indian patient achieve and maintain glycemic targets. By targeting some of the components of the Ominous Octet at the same time, these regimens may help with improved long-term glycemic durability and possibly even diabetes-related complications [22,23].

CONCLUSION

This multicenter real-world study proves that there is substantial and clinically significant HbA1c lowering from SGLT2 inhibitor-based regimens in Indian adults with diabetes mellitus type 2. A clear incline of benefit was observed with glycemic improvements having increased from monotherapy to dual therapy further to triple and even intensified triple combinations. The largest reductions were seen when SGLT2-inhibitors were combined with metformin and DPP-4 in patients who started therapy with higher HbA1c levels at the baseline. The use of insulin led to more incremental benefit in people who needed more glycemic support.

The role of adjunctive agents such as glimepiride, gliclazide, and voglibose was reflected by individualized prescription based on baseline glycemic status. Marginal, but supportive reductions in these therapies have not diminished the overall efficacy of SGLT2 inhibitor centered regimens.

Overall, the results highlight more current recommendations by RSSDI 2025 and ICMR for early on rational combination therapy as per patients need. SGLT2-targeted treatment strategies become viable, scalable, and highly effective in improving glycemic outcomes in the Indian clinical practice. While these findings offer important real-world insights, they are drawn using a small number of centers in particular parts of India and may not be completely generalizable to all healthcare settings in India.

LIMITATION

This study has some limitations to its the observational design such as risks of confounding and selection bias, the relatively short follow-up period/period of 26 weeks, the lack of a control group, the potential for regression to the mean, unassessed variability in dosing, and adherence and small sample sizes in the subgroup analyses.

FUTURE PERSPECTIVES

Future research should be comparative effectiveness studies of SGLT2 inhibitor-based regimens compared with other glucose lowering strategies, as well as long-term prospective studies to evaluate the durability of the glycemic control and cardio-renal outcomes. Further possible study examining the sequencing of treatment and examining adherence in the real-world to appraise possible individual therapy in different patient subgroups and clinical settings.

ETHICAL APPROVAL

Approved by the Institutional Ethics Committee of Vishwaraj Hospital. (Approval Letter dated April 08, 2023).

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AUTHORS' CONTRIBUTIONS

- Mr. Bharat Kshirsagar: Conceptualization, study design, data collection, data analysis, interpretation of results, manuscript drafting, and final approval.
- Dr. Aman Upaganlawar: Study supervision, methodological guidance, and critical revision of the manuscript.
- Dr. Kishor Londhe: Clinical data contribution, patient management oversight, and manuscript review.
- Dr. Namdev Jagtap: Clinical data contribution, patient management oversight, and manuscript review.

All authors read and approved the final manuscript.

CONFLICTS OF INTEREST

No conflicts of interest declared.

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