SAFETY AND BENEFITS OF SGLT-2 INHIBITORS IN TYPE2 DIABETES MELLITUS PATIENTS

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Background: This study compares the safety and benefits of three SGLT-2 inhibitors, dapagliflozin, empagliflozin, and remogliflozin in patients with type 2 diabetes mellitus (T₂DM). It evaluates their effects on glycemic control, lipid profiles (total cholesterol, triglycerides, LDL, HDL), and blood pressure, aiming to highlight their benefits beyond glucose lowering in T₂DM management.

Methods: A 12 months prospective, observational, multicenter study was conducted, involving 520 patients with T₂DM selected from a pool of 825 screened individuals. The safety and efficacy of the three SGLT-2 inhibitors were assessed using one-way ANOVA with Graph Pad Prism version 10.2.3. The primary outcome was the comparison of HbA1c reduction, reflecting glycemic control. Secondary outcomes included changes in lipid profiles, blood pressure, and cardiovascular benefits.

Results: Over 12 months, the 520 participants were divided into three groups, each receiving one of the three drugs. Dapagliflozin, Empagliflozin and Remogliflozin showed the most significant reductions in HbA1c, fasting blood sugar (FBS), and postprandial blood sugar (PLBS) (p<0.0001) and demonstrated superior reductions in systolic blood pressure (SBP), and diastolic blood pressure (DBP) (p<0.0001). All three drugs improved a composite endpoint of glycemia, weight, and blood pressure, alongside better lipid profiles (lower total cholesterol, triglycerides, LDL, and higher HDL). Adverse events observed included hypoglycemia, genital

Conclusion: The addition of SGLT-2 inhibitors dapagliflozin, empagliflozin, and remogliflozin to existing treatment regimens offers substantial benefits beyond glycemic control. These drugs not only help regulate blood glucose levels but also significantly reduce cardiovascular and microvascular complications in T₂DM patients. Furthermore, they appear to lower mortality risk in patients with pre-existing cardiovascular conditions.

Key words: SGLT-2 Inhibitors, Diabetes Mellitus, Coronary Artery Disease, Cardiovascular Disease, Dapagliflozin, Empagliflozin, Remogliflozin.

INTRODUCTION:

Diabetes Mellitus is a group of metabolic disorders characterized by chronic hyperglycemia due to deficiency of insulin secretion and/or resistance to insulin action. The chronic hyperglycemia of diabetes is associated with metabolic abnormalities in carbohydrates, lipids, and proteins which results in long-term damage, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels (long term complications of diabetes which include microvascular, macrovascular, and neuropathic disorders) [1,2].

The recommended initial T₂DM management approach includes life style changes and monotherapy (usually with Metformin). If the HbA_{1C} goal has not been met with in approximately 3 months of starting initial therapy, treatment should be intensified by adding a second agent, consider one of the five treatment options combined with Metformin: Sulfonylurea (SU), Thiazolidinediones (TZD), Dipeptidyl Peptidase (DPP-4) inhibitor, Sodium Glucose Co-transporter (SGLT2) inhibitor and 2 injectable agents Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RA) or Basal insulin. Glycaemic control should be reassessed again approximately 3 months, and triple therapy should be considered if the HbA_{1C}target is still not achieved, combination injectable therapy including basal insulin may be considered to be obtaining glycaemic control. In patients with high baseline HbA₁clevels, initial treatment with dual-combination therapy can be considered. The AACE/ACE suggests initial dual therapy (i.e., Metformin plus another agent in addition to lifestyle therapy) for patients with an entry

HbA_{1C} levels $\geq 7.5\%$, whereas the ADA suggests considering initial dual therapy if the entry

HbA_{1C} is $\leq 9\%$ [3].

MATERIAL AND METHODS:

Study Design:

It was a Prospective, Observational and Multicentric study to be conducted in MGM Hospital,

Ajara Hospital and Sri Bhadrakali Diabetic Clinic.

An approval was obtained prior to the study from the Institutional Human Ethics Committee.

The approval number was "KIEC-2023/PHARM D-2023-2024/PROJECT12" and informed

consent was obtained from each patient after having been informed of all the aspects relevant to

the study in their local language.

Study Duration: 1 Year

Inclusion Criteria: Patients aged over 18 years who were being treated for type 2 diabetes

mellitus (T2DM) with SGLT-2 inhibitors, had an HbA1c level greater than 7%, and had co-

morbid cardiovascular conditions.

Exclusion Criteria: Patients diagnosed with type 1 diabetes mellitus (T1DM), those unwilling

to participate, individuals with gestational diabetes mellitus or other forms of diabetes, patients

less than 18 years of age, pregnant women, and lactating women were excluded from the study.

PARAMETERS ASSESSED:

Body Weight, SBP,DBP,FBS,PLBS,HbA1c,Lipidprofiles (TC, TG, HDL,LDL) at base line and

changes after initiation of SGLT-2isfor 6 Months Duration were collected. Primary end point

was change in HbA1C, FBS,PLBS levels Lipid Profile, Blood Pressure and Body weight at

12weeks (3months) and 24weeks (6months) as compared to the baseline levels in all three

SGLT-2 Inhibitors (Dapagliflozin, Remogliflozin and Empagliflozin).

STATISTICAL ANALYSIS:

All the parameters were expressed as Mean ± Standard Deviation (SD). Data analysis was

performed using MS Excel and Graph Pad Prism 10.2.3 Version. Statistical analysis was

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performed using ANOVA one-way method followed by Tukey's multiple comparison test to assess the significant difference between the efficacy parameters pre and post add-on treatment.

RESULTS:

In the present study, included 520 patients according to inclusion criteria and remaining 305 patients excluded based on exclusion criteria. The study was conducted at Ajara hospitals and Sri Bhadrakali clinic, Warangal. In a total of 520 patients 298 patients received Dapagliflozin (n1=298), 121 patients received Remogliflozin (n2=121), 101 patients received Empagliflozin (n3=101).

SAFETY PARAMETERS:

Table 1 represents safety parameters assessed were Genital Infections, Ketoacidosis, Hypotension, Hypoglycaemia, Volume Depletion, Dehydration and Urinary Tract Infections in patients treated with Dapagliflozin, Empagliflozin and Remogliflozin Etabonate.

Table1: Safety parameters of Dapagliflozin, Empagliflozin, Remogliflozin

Safety Parameters	Dapagliflozin	Empagliflozin	Remogliflozin
Genital Infections	16(5.3%)	5(6.2%)	7(4.9%)
Ketoacidosis	30(10%)	21(26.2%)	29(20.4%)
Hypotension	10(3.3%)	3(3.7%)	7(4.9%)
Hypoglycemia	43(14.4%)	25(31.2%)	30(21.1%)
Volume Depletion	12(4%)	6(7.5%)	7(4.9%)
Dehydration	18(6%)	11(13.7%)	8(5.6%)
Urinary Tract Infections	21(7%)	5(6.2%)	12(8.4%)

FBS Comparison of Dapagliflozin, Empagliflozin, Remogliflozin:

Subjects with uncontrolled T₂DM have an elevated Fasting Blood Sugar level (FBS), which indicates hyperglycemia condition in the body. Table 2 represents the comparison of 3 visits of Volume 25, Issue 8, 2025

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Dapagliflozin, Empagliflozin and Remogliflozin. There was a significant change between visit-1, visit-2, visit-3 of Dapagliflozin with P value <0.0001****, <0.0001**** respectively. There was a significant change between visit-1, visit-2, visit-3 of Empagliflozin with P value 0.0007***, <0.0001**** respectively. There was a significant change between visit-1, visit-2, visit-3 of Remogliflozin with P value 0.0001****, <0.0001**** respectively.

Table2: Comparison of FBS values of Dapagliflozin, Empagliflozin and Remogliflozin

S.No.	Drugs	Visit-1	Visit-2	Visit-3	P Value V1-V2	P value V1-V3
1.	Dapagliflozin	145.6±59.1	132.0±41.7	116.7±37.2	<0.0001****	<0.0001****
2.	Empagliflozin	169.7±34.3	144.9±23.7	122.4±20.3	0.0007***	<0.0001****
3.	Remogliflozin	173.8±63.0	144.5±41.2	128.6±37.9	<0.0001****	<0.0001****

PLBS Comparison of Dapagliflozin, Empagliflozin, Remogliflozin:

Subjects with uncontrolled T₂DM have an elevated Post Lunch Blood Sugar level (PLBS), which indicates hyperglycaemia condition in the body. Table 3 represents the comparison of 3 visits of Dapagliflozin, Empagliflozin and Remogliflozin. There was a significant change between visit-1, visit-2, visit-3 of Dapagliflozin with P value <0.0001****, <0.0001**** respectively. There was a significant change between visit-1, visit-2, visit-3 of Empagliflozin with P value 0.0210*, <0.0001**** respectively. There was a significant change between visit-1, visit-2, visit-3 of Remogliflozin with P value 0.0042**, <0.0001**** respectively.

Table3: Comparison of PLBS values of Dapagliflozin, Empagliflozin and Remogliflozin:

S.No.	Drugs	Visit-1	Visit-2	Visit-3	P Value	P Value
					V1-V2	V1-V3
1.	Dapagliflozin	221.3±80.6	201.1±63.9	180.5±53.7	<0.0001****	<0.0001****
2.	Empagliflozin	182.6±47.8	157.8±41.3	136.8±34.9	0.0210*	<0.0001****
3.	Remogliflozin	250.7±76.7	211.7±63.3	183.8±58.7	0.0042**	<0.0001****

HbA1c Comparison of Dapagliflozin, Empagliflozin, Remogliflozin:

Subjects with uncontrolled T₂DM have elevated HbA1c levels, which indicate hyperglycemia condition in the body. Table represents the comparison of 3 visits of Dapagliflozin, Empagliflozin and Remogliflozin. There was a significant change between visit-1, visit-2, visit-3 of Dapagliflozin with P value <0.0001****, <0.0001**** respectively. There was a significant change between visit-1, visit-2, visit-3 of Empagliflozin with P value 0.0210*, <0.0001**** respectively. There was a significant change between visit-1, visit-2, visit-3 of Remogliflozin with P value 0.0042**, <0.0001**** respectively.

Table4: Comparison of HbA₁c values of Dapagliflozin, Empagliflozin and Remogliflozin:

S.No.	Drugs	Visit-1	Visit-2	Visit-3	P Value	P Value
					V1-V2	V1-V3
1.	Dapagliflozin	8.1±1.8	7.4±1.3	7.2±1.7	<0.0001****	0.0014**
2.	Empagliflozin	7.6±0.9	6.9±0.8	6.1±0.6	0.0011***	<0.0001****
3.	Remogliflozin	8.6±01.3	7.7±1.1	7.0±0.9	0.0002***	<0.0001****

Systolic BP Comparison of Dapagliflozin, Empagliflozin, Remogliflozin:

Subjects with increased blood pressure, this condition indicates Hypertension with any comorbid cardiovascular disease. Table 5 represents the comparison of 3 visits of Dapagliflozin, Empagliflozin, and Remogliflozin. There was a significant change between visit-1, visit-2, visit-3 of Dapagliflozin with P value 0.0022**, 0.0022**respectively. There was a significant change between visit-1, visit-2, visit-3 of Empagliflozin with P value 0.0410*, 0.0410*, respectively. There was a significant change between visit-1, visit-2, visit-3 of Remogliflozin with P value 0.0027**, 0.0027**respectively.

Table 5: Comparison of Systolic BP of patients using Dapagliflozin, Empagliflozin and Remogliflozin

S.No.	Drugs	Visit-1	Visit-2	Visit-3	P Value	P Value
					V1-V2	V1-V3
1.	Dapagliflozin	130.1±14.8	127.9±14.4	125.9±14.2	0.0022**	0.0022**
2.	Empagliflozin	136±13.2	130.2±10.3	127.1±10.9	<0.0001****	<0.0001****
3.	Remogliflozin	136.1±13.4	130.2±10.2	127.4±11.2	<0.0001****	<0.0001****

Diastolic BP Comparison of Dapagliflozin, Empagliflozin, Remogliflozin:

Subjects with increased blood pressure and this condition indicate hypertension with any comorbid cardiovascular disease. Table 6 represents the comparison of 3 visits of Dapagliflozin, Empagliflozin and Remogliflozin. There was a significant change between visit-1, visit-2, visit-3 of Dapagliflozin with P value 0.0022^{**} , 0.0022^{**} respectively. There was a significant change between visit-1, visit-2, visit-3 of Empagliflozin with P value 0.0410^{**} , 0.0410^{**} , respectively. There was a significant change between visit-1, visit-2, visit-3 of Remogliflozin with P value 0.0027^{**} , 0.0027^{**} respectively.

Table6: Comparison of Diastolic BP of patients using Dapagliflozin, Empagliflozin and Remogliflozin

S.No.	Drugs	Visit-1	Visit-2	Visit-3	P Value	P Value
5.110.	Diugs	V 151t-1	V 1811-2	V 1811-3		
					V1-V2	V1-V3
1.	Dapagliflozin	82.4±11.6	80.8 ± 10.4	79.7 ± 8.0	0.0046**	0.0046**
2.	Empagliflozin	84.2±7.7	80.5±6.9	80.0±7.2	0.0005***	0.0005***
3.	Remogliflozin	84.0±7.6	80.2±7.0	80±7.5	<0.0001****	<0.0001****
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HDLCHOLESTEROL COMPARISON OF DAPAGLIFLOZIN, EMPAGLIFLOZIN, REMOGLIFLOZIN:

Subjects with T2DM have lower levels HDL Cholesterol levels which can increase the risk of developing Coronary Artery Disease (CAD). Table 7 represents the comparison of 3 visits of Dapagliflozin groups, Empagliflozin groups, Remogliflozin. There was a significant change between visit-1, visit-2 & with P -values 0.0004,<0.0001 respectively. There was a significant change between visit-1, visit-2 & with P -values, <0.0001. <0.0001 respectively.

There was a significant change between visit-1, visit-2 & with P -values, <0.0001. <0.0001 respectively.

Table7: Comparison of HDL Cholesterol Values in Dapagliflozin, Empagliflozin and Remogliflozin

S.No.	Drugs	Visit-1	Visit-2	Visit-3	P Value	P Value
					V1-V2	V1-V3
1	Dapagliflozin	41.2±11.2	42.9±9.51	44.6±10.9	0.0004	<0.0001
2	Empagliflozin	40.98±11.0	41.48±11.6	42.35±11.7	< 0.0001	<0.0001
3	Remogliflozin	35.1±3.71	41.69±4.2	47.8±5.5	<0.0001	<0.0001

TOTAL CHOLESTEROL COMPARISON OF DAPAGLIFLOZIN, EMPAGLIFLOZIN, REMOGLIFLOZIN:

Subjects with type 2 diabetes mellitus have elevated levels of Total Cholesterol which indicates an increased risk of CAD. Table 8 represents the comparison of 3 visits of Dapagliflozin groups Empagliflozin groups and Remogliflozin. There was a significant change between visit-1, visit-2, & visit-3 with P -values <0.0001**** respectively. There was a significant change between visit-1, visit-2, & visit-3 with P -values <0.0001****, <0.0001**** respectively. There was a significant change between visit-1, visit-2, & visit-3 with P -values <0.0001****, <0.0001**** respectively.

Table 8: Comparison of Total cholesterol Values in Dapagliflozin, Empagliflozin and Remogliflozin

S.No.	Drugs	Visit-1	Visit-2	Visit-3	P Value	P Value
					V1-V2	V1-V3
1	Dapagliflozin	0	153.2±35.5	144.0±34.5	<0.0001	<0.0001
2	Empagliflozin	146.7±46.1	129.2±41.3	112.8±37.6	<0.0001	<0.0001
3	Remogliflozin	209.1±31.8	186.4±32.9	163.0±35.2	<0.0001	<0.0001

TRIGLYCERIDES COMPARISON OF DAPAGLIFLOZIN, EMPAGLIFLOZIN, REMOGLIFLOZIN:

Subjects with type 2 diabetes mellitus have elevated levels of Triglycerides which indicates an increased risk of CAD. Table 9 represents the comparison of 3 visits of Dapagliflozin groups, Empagliflozin groups, Remogliflozin. There was a significant change between visit-1, visit-2, & visit-3 with P -values0.0004 <0.0001. <0.0001 respectively. There was a significant change between visit-1, visit-2, & visit-3 with P -values<0.0004****, <0.0001****, <0.0001**** respectively. There was a significant change between visit-1, visit-2, & visit-3 with P -values<0.0004****, <0.0001****, <0.0001**** respectively.

Table 9: Comparison of Triglycerides Values in Dapagliflozin, Empagliflozin and Remogliflozin

S.No.	Drugs	Visit-1	Visit-2	Visit-3	P Value V1-V2	P Value V1-V3
1.	Dapagliflozin	167.1±6.7	146.1±42.2	129.6±35.0	<0.0001****	<0.0001****
2.	Empagliflozin	147.5±71.6	131.9±59.2	120.1±59.3	<0.0001****	<0.0001****
3.	Remogliflozin	180.4±43.3	155.3±42.6	127.1±34.6	0.0004***	<0.0001****

LDL CHOLESTEROL COMPARISON OF DAPAGLIFLOZIN, EMPAGLIFLOZIN, REMOGLIFLOZIN:

Table10: Comparison of LDL Cholesterol Values in Dapagliflozin, Empagliflozin and Remogliflozin

S.No.	Drugs	Visit-1	Visit-2	Visit-3	P Value	P Value
					V1-V2	V1-V3
1	Dapagliflozin	113.6±40.0	99.1±31.9	86.7±26.2	<0.0001	<0.0001
2	Empagliflozin	94.4±27.6	86.4±23.6	77.3±24.2	<0.0001	<0.0001
3	Remogliflozin	161.1±21.1	134.7±21.0	107.9±22.2	<0.0001	<0.0001

DISCUSSION:

The present study includes 520 patients who were treated with different oral therapies. In T₂DM goals of therapy include elimination of symptoms and arrest or slow down the development of complications. Many Oral Hypoglycaemic Agents (OHA) are available for the treatment of T₂DM, despite the availability of multiple classes and combination of OHA the clinical Management of T₂DM is currently suboptimal, with the majority of patients failing to achieve and maintain target glycaemic levels. Many newer and novel OHA are available for the treatment of T₂DM. Recent studies had shown the importance of SGLT-2 Inhibitors in the management of T₂DM. Remogliflozin, Dapagliflozin, Empagliflozin by inhibiting glucose reabsorption, offers a potential treatment for T2DM as monotherapy and in combination with existing therapies. A study was conducted to assess the Safety and Benefits of SGLT-2 Inhibitors (D+E+R) for 520 patients with T₂DM and to find out the extra cardiovascular benefits by using these drugs. Comparison of 3 types of Oral hypoglycaemic agents was done on control of patients with Type-2 Diabetes Mellitus. Also, additional benefits were also identified like effect on lipid profile and weight loss. The findings demonstrate that treatment with SGLT-2 Inhibitors resulted in a significant mean reduction in all glycaemic parameters. Though body weight showed mean reduction the SBP showed expected reduction, with expected significant DBP reduction from baseline. We have also seen a significant reduction in

these SGLT-2 Inhibitors like Dapagliflozin, Empagliflozin and Remogliflozin.

In the Study, Efficacy parameters of (D+E+R) are as follows: 520 patients during visit I had no significant reduction in the blood glucose levels (FBS, PLBS). All the subjects of Dapagliflozin n = 298 during visit & visit 3 had significant reduction in the blood glucose levels (FBS, PLBS). Results obtained from the study showed that Efficacy in Controlling or maintaining blood glucose levels was based on mean values obtained from applying descriptive analysis. Current showed improvement in blood glucose levels i.e., FBS, PLBS & HbA1c which in comparable with the study of Dapagliflozin in patients with T2DM, Current study was comparable with study done by Saleem, 2017 [4]. involving introduction of Dapagliflozin in to diabetic therapy by replacing the non-SGLT-2 Inhibitors the same study also revealed that efficacy of Dapagliflozin as therapeutic option or in combination therapy shown statistically improvements in glycaemic control and blood pressure which coincides with the present study. Another study done by Sanz et al., 2015 [5] also reveals the decrease in BP in the patients with glycemia which also coincides with our study. The same study done by Saleem, 2017 [4] also reveals that there is a positive significant change in the levels of lipids like LDL and HDL in the patients who were treated with Dapagliflozin as their hypoglycaemic agent which also coincides with the study. Dapagliflozin therapy was well tolerated, although events suggestive of genital infections, UTI and of volume depletion were seen which also coincides with a study done by Liakos et al., 2015 [6] where they have observed increased cases of genital infections and UTIs in cases of Dapagliflozin than in placebo.

The subjects of Empagliflozin n=101 during visit 2 & visit 3 had a significant reduction in the blood glucose levels (FBS, PLBS) Results obtained from the study showed that efficacy in controlling or maintaining blood glucose levels was based on the values obtained from applying descriptive statistics. Current study showed improvement in blood glucose levels i.e., FBS, PLBS which in comparable with the study. Empagliflozin as a treatment replacing other non-SGLT-2 Inhibitors reduced HbA₁c with significantly lower risk of hypoglycaemia and a

significantly smaller proportion of patients who are suffering with cardiovascular disease have been beneficial in decreasing the risk of serious illness. Long term treatment of Empagliflozin provided sustained glycaemic and weight control (-2 to -3kgs) and was also tolerated with lower risk of hypoglycaemia and cardiovascular risk in patients with type 2 diabetes. In the present study, we found that higher baseline HbA₁c levels, better renal function, and shorter T2DM duration were predictive markers for more effective lowering of glucose levels using Empagliflozin. In addition, the predictiveclinical parameters for body weight reduction were higher BMI and lower baseline HbA₁c levels. Another study done by **Deepak** *et al.*, **2021** [7] Empagliflozin a SGLT-2 inhibitor is a promising drug for reduction in HbA₁c value and obese patients with T2DM, who are inadequately controlled in triple drug therapy and are reluctant to insulin therapy. A study done by Empagliflozin has proven to have decrease the blood pressure (2.5 to 5mmHg) when compared to placebo which coincides also with our study. A study have shown **Ozcelik** *et al.*,2020 [8]Patients treated with Empagliflozin have significantly developed genital infections, UTI, volume depletion and dehydration. There was common side effect of hypoglycaemia which was shown throughout the study.

Remogliflozin is one of the newer SGLT-2 inhibitors, introduced to improve not only glycaemic control but also to exploit a battery of its other pleotropic effects. SGLT-2 facilitates the reabsorption of filtered glucose from the Proximal convoluted tubules by around 90% Therefore, the treatment by these agents, significantly reduces the Reabsorption of the filtered glucose load, thereby increasing the renal excretion of glucose. Accumulating evidence has demonstrated the efficacy of the drug as mono and add on therapy in T2DM.During visit 1there was no significant reduction in the blood glucose levels (FBS, PLBS). The subjects n=121 during visit 2 & visit 3 had significant reduction in the blood glucose levels (FBS, PLBS), Results obtained from the study showed that Efficacy was based on mean values obtained from applying descriptive statistics. Current study showed improvement in maintaining blood glucose levels i.e., FBS & PLBS by the introduction of Remogliflozin or by replacing other

non-SGLT-2 Inhibitors by Remogliflozin in patients with T₂DM. HbA₁c levels were better in patients with Remogliflozin than that of other non-SGLT-2 Inhibitors. The present finding is as is the study done on Indian patients which shows that Remogliflozin treatment resulted in a significant mean reduction from baseline in HbA₁c, FBS and PLBS. Study on Remogliflozin also shown a significant reduction in the systolic BP (-9.8mmHg; p<0.0001) and diastolic BP (-4mmHg; p<0.001). Remogliflozin have shown weighted mean difference on serum triglycerides and total cholesterol in the Type 2 DM patients who are treated with Remogliflozin compared to the other non-SGLT-2 Inhibitors which here coincide with our study. Our study also shown a significant decrease in LDL-C (-54mg/dl; p<0.0001) and increase in HDL-C (+11.2mg/dl; p<0.0001). Another study done on the safety of Remogliflozin by **Dharmalingam** *et al.*, **2020** [9]. Remogliflozin shown the incidence of AEs like hypoglycaemic events, UTIs and Genital and fungal infections which therefore also coincides with our study where Dizziness caused due to hypoglycaemic events is the mostly seen AE throughout our study followed by genital infections and UTIs.

CONCLUSION: On the basis of the results, addition of SGLT-2 Inhibitors like Dapagliflozin, Empagliflozin and Remogliflozin to the currently available treatment options is projected to not only control the blood glucose levels but also further helps in decrease the CV and microvascular complications associated with T₂DM and It also proven to decrease risk of mortality in the patients who were with pre-existing CV conditions.

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