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Research Article

ASSESSMENT OF EFFECTIVENESS OF SODIUM-GLUCOSE TRANSPORT PROTEIN-2 INHIBITORS IN TYPE-2 DIABETIC PATIENTS IN A TERTIARY CARE HOSPITAL – A LONGITUDINAL PROSPECTIVE STUDY

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ABSTRACT

Objectives: The main aim of the study was to assess the effectiveness of the sodium-glucose transport protein-2 inhibitors (SGLT-2i) in type 2 diabetic patients.

Methods: This was a prospective and longitudinal study conducted in a tertiary care center. During the study period, the data were collected from 200 diabetic patients, out of which 80 patients were followed up. Data collection form and informed consent were obtained from each patient.

Results: Out of 200 patients, 84 (42%) were female while 114 (58%) being male aged between 50 and 70 years had a higher prevalence of type 2 diabetes mellitus. Dapagliflozin was administered to 54 (67.5%) of the 80 patients, while empagliflozin was administered to 26 (32.5%). A total of 32 patients receiving dapagliflozin had baseline glycated hemoglobin (HbA1c) values of 7.6–9.0%, followed by >9% (n=16) and 6.5–7.5% (n=6), respectively. Sixteen patients receiving empagliflozin had baseline HbA1c values of 7.6–9.0%, followed by >9 (n=8) and 6.5–7.5% (n=2). After the start of the medicine, an average of gradual reduction of HbA1c was found to be 1.47%, while the study focused on the same.

Conclusion: SGLT-2i showed its action in lowering the blood glucose in patients who were adherent to the treatment regimen along with diet and exercise.

Keywords: Sodium-glucose transport protein-2 inhibitors, Efficacy, Uncontrolled diabetes, Glycated hemoglobin.

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INTRODUCTION

Worldwide, diabetes mellitus (DM) is on the rise, primarily in developing nations like India. According to estimates, the number of people with diabetes worldwide was 9.3% (463 million) in 2019, going to be 10.2% (578 million) by 2030 and 10.9% (700 million) by 2045 [1]. India is thought to have 77 million diabetic patients living. About 60% of individuals with diabetes do not have their condition under control. To attain adequate glycemic control and avoid or postpone the complications associated with diabetes, they need to improve their continuous therapy. Sodium-glucose transport protein-2 inhibitors (SGLT-2i) significantly enhanced the management of diabetes [2]. They offer effective weight loss and glycemic control. The control of glucose reabsorption and preservation of the body's general metabolic balance are largely dependent on the kidneys. The SGLT-2i dapagliflozin, canagliflozin, and empagliflozin are approved by the Food and Drug Administration (FDA) and can be used in India for clinical purposes. They can be used alone or in conjunction with other anti-diabetic medications to treat type 2 diabetes. Numerous prospective and randomized trials have demonstrated the effectiveness of these medications in reducing weight and promoting optimal glycemic control [3]. The most often reported side effect of SGLT-2i in clinical studies including these medications is genitourinary infection. Patients with diabetes already have a higher risk of genitourinary infections, and using SGLT-2i may make this issue worse.

The first SGLT-2i approved on March 29, 2013, was canagliflozin, which is recommended for adult patients with type 2 DM to help control blood glucose in addition to diet and exercise [4]. It has also been demonstrated to lower the risk of end-stage renal disease, cardiovascular (CV) death, heart failure hospitalization, and albuminuria in individuals with diabetic nephropathy. In addition, it lowers the risk of adverse CV events in type 2 diabetes subjects with underlying CV disease.

The FDA approved dapagliflozin in January 2014. In addition to diet and exercise, the medication is recommended for adult patients with type 2 diabetes to enhance blood glucose control. Additional indications include lowering the risk of hospitalization and CV mortality in adult individuals with underlying heart failure, as well as limiting the hospitalization related to heart failure in type 2 DM patients suffering from CV-related ailments [5].

The third SGLT-2i which the FDA has approved was empagliflozin, in August 2014. Besides diet and exercise, empagliflozin is recommended for adult patients with type 2 diabetes to enhance the management of blood glucose. The adverse effects related to CV in type 2 DM patients were declined, thereby reducing the admission to hospital due to heart failure. There was a reduction in atherosclerotic CV disease (ASCVD) as evident from the mortality and improved CV outcomes [6]. By encouraging the kidneys to eliminate glucose from the body through urine, SGLT-2i reduces blood sugar. All SGLT-2i are given orally (by mouth) and function essentially in the same way. When used in conjunction with type 2 diabetes and chronic kidney disease (CKD), SGLT-2i can effectively reduce the progression of renal disease, lower heart failure, and lessen the risk of kidney failure and mortality. SGLT-2i also shields the kidneys in non-diabetic individuals with CKD. Research indicates that certain drugs in this class may also lower a patient's chance of developing heart failure if they have a history of heart disease. They have also been demonstrated to lessen the necessity of heart failure hospital stays [7].

More than 40 years ago, glycated hemoglobin (HbA1c) was first shown to be an "unusual" hemoglobin in diabetes patients. Following that finding, a number of modest studies were carried out linking it to measures of glucose, leading to the hypothesis that HbA1c may be utilized as an objective indicator of glycemic management. HbA1c was introduced into clinical use in the 1980s and subsequently has become a cornerstone of clinical practice [8]. The average plasma glucose for the previous 8–12 weeks is reflected in the HbA1c. It does not require any prior preparation, like fasting, and may be done at any time of day. Because of these characteristics, it is the test of choice for evaluating glycemic control in diabetics. Recently, there has been a lot of interest in using it to screen people who are at high risk of developing diabetes and to diagnose diabetes. A glucose substitute has long been sought for the diagnosis of diabetes, mostly because to the inconvenience of testing fasting plasma glucose (FPG) levels or doing an oral glucose tolerance test (OGTT), as well as daily variability in glucose levels. The American Diabetes Association (ADA) and an international committee now advise using HbA1c to diagnose diabetes [9,10].

HbA1c levels are suggested by the ADA for the diagnosis of DM. Together with FPG, the HbA1c test can be used to predict the development of diabetes in the future. Nevertheless, few intervention trials have looked at the efficacy of HbA1c in predicting the onset of type 2 diabetes whose baseline HbA1c levels were 5.7% or below [11]. The present study was focused on the effectiveness of the SGLT-2i to target HbA1c, thereby analyzing the glycemic control.

METHODS

Study region, time frame, and design

The study was a prospective, longitudinal, and observational study which was conducted in a Tertiary Care hospital, Hyderabad. It was carried out for a period of 18 months from October 2022 to March 2024.

Determination of sample size

In all, 200 patients (n=200) were involved in this investigation.

Study criteria

Inclusion criteria

Outpatients with DM type-2 undergoing treatment in the sugar clinic.

Exclusion criteria

Patients with DM type-1, patients with a history of renal dysfunction, urinary tract infection, pediatrics, pregnant woman, and patients in intensive care unit.

Study procedure

A data collection form was designed to collect the required data. The patient demographics, laboratory parameters, medication reconciliation, and prescribed treatment were collected. The data regarding the reduction in HbA1C, body weight, and FBS were collected. The effect of SGLT-2i on lipids would be observed and analyzed.

Ethics

The present observational study was conducted on 200 subjects in the Department of Endocrinology, bearing protocol number as EC. Ref No: 321/2023 at Vijayakrishna Multispeciality Hospital, Suryapet – 508214, Telangana State, India.

Data analysis

MS Excel will be used for collecting the data. The patient's details will be noted as case numbers and only their initials will be used. All the data collection forms will be kept strictly confidential. Statistical evaluation will be performed with mean, standard deviation, and Pearson's correlation using the Statistical Package for the Social Sciences version 23.0. Baseline data, adverse events, and distribution of SGLT-2i were analyzed with a Chi-squared test (qualitative variables). The results were analyzed and subjected to analysis of variance.

RESULTS

In the current study, for a period of about 18 months, a total number of 200 patients were evaluated, out of which 84 patients (42%) were females and 114 (58%) were males. When the different age groups were assessed, patients whose age was between 50 and 70 years of age suffered more in number with type 2 DM as presented in Table 1.

With regard to the duration of existence of type 2 DM in patients, it was analyzed that about 44% (n=88) of the patients suffered with diabetes for 5–10 years, followed by <5 (n=39) and >10 years (n=17), depicted in Table 2 and Fig. 1.

In the treatment options when SGLT-2i were prescribed, the number of patients which were dependent on dapagliflozin was 158 (79%), followed by 42 (21%) patients that were relying on empagliflozin, as represented in Table 3 and Fig. 2.

In the treatment of type 2 DM, two SGLT-2i – dapagliflozin and empagliflozin – were prescribed. In the present study, 200 patients were given with dapagliflozin and empagliflozin, and only 80 patients were thoroughly subjected to follow-ups. Out of 80 patients, 54 (67.5%) patients were treated with dapagliflozin and 26 (32.5%) patients were treated with empagliflozin. Baseline HbA1c was recorded and it was found that 7.6–9.0% in 32 patients treated with dapagliflozin, followed by >9% (n=16) and 6.5–7.5% (n=6), respectively. Empagliflozin-treated patients were 16 with a baseline HbA1c of 7.6–9.0% followed by >9 (n=8) and 6.5–7.5% (n=2). There was no statistical difference ($p=^{NS}0.892$) between both the treatments (Table 4 and Fig. 3).

Table 1: Demographics of gender and age in years by frequency (n) and percentage

Age in years	Number of patients, n (%)	Distribution of sex	
		Females, n (%)	Males, n (%)
<50	60	26 (30.9)	34 (29.8)
50–70	130	54 (64.2)	74 (64.9)
>70	10	4 (4.9)	6 (5.3)
Chi-square: 0.04		Total: 84 (42)	Total: 114 (58)
df: 2		Mean: 28	Mean: 38
$p=^{NS}0.976$		SD: 20.46	SD: 27.9

Every data point was presented as Mean±SD, with a significance level of $^{NS}p<0.976$; NS=non-significant, SD: Standard deviation

Table 2: Duration (years) of type 2 diabetes mellitus in patients by frequency (n) and percentage

Duration of DM in years	Number of patients, n (%)
<5	78 (39)
5–10	88 (44)
>10|	34 (17)
	Total: 200
	Mean: 66.66
	SD: 23.45

DM: Diabetes mellitus, SD: Standard deviation

Table 3: Number of patients treated with dapagliflozin and empagliflozin by frequency (n) and percentage

Type of SGLT-2 inhibitors	Number of patients, n (%)
Dapagliflozin	158 (79)
Empagliflozin	42 (21)
	Total: 200
	Mean: 100
	SD: 58

SD: Standard deviation, SGLT-2: Sodium-glucose transport protein-2

In the present study, in the treatment of type 2 DM when SGLT-2i was given, the reduction in the HbA1c was recorded. Dapagliflozin was administered to 52 (65%) patients and empagliflozin was prescribed to 28 (35%) and regular follow-ups were conducted. The treatment was calculated in terms of months and days (Tables 5 and 6), with dapagliflozin, the least duration was found to be 3 months with 2.1–3.0% reduction in HbA1c (n=4), followed by 5 months (HbA1c - 4.1–4.0 in 4 patients), 5 months and 9 days (HbA1c - 0–1 in 26 patients), respectively. Finally, treatment for 9 months and more was found in around 16 patients with a decline of 1.1–3.0 in HbA1c, and the values were found to be significant (*p<0.044).

With empagliflozin, the duration was found to be 8 months and above 0.0–3.0% reduction in HbA1c (n=28).

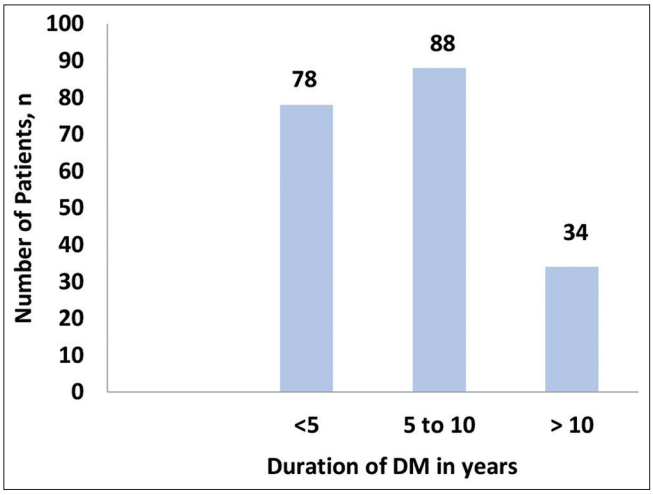

Fig. 1: Duration (years) of type 2 diabetes mellitus in patients by frequency (n)

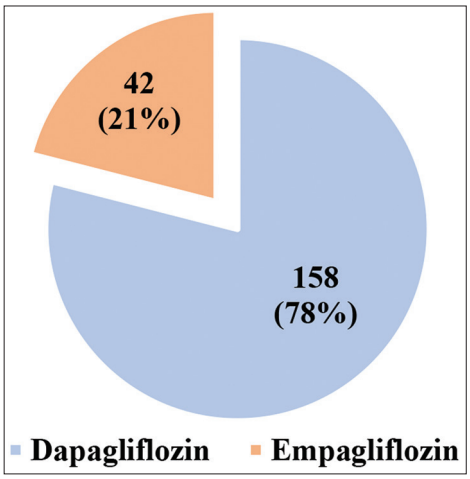

Fig. 2: Number of patients treated with dapagliflozin and empagliflozin by frequency (n) and percentage

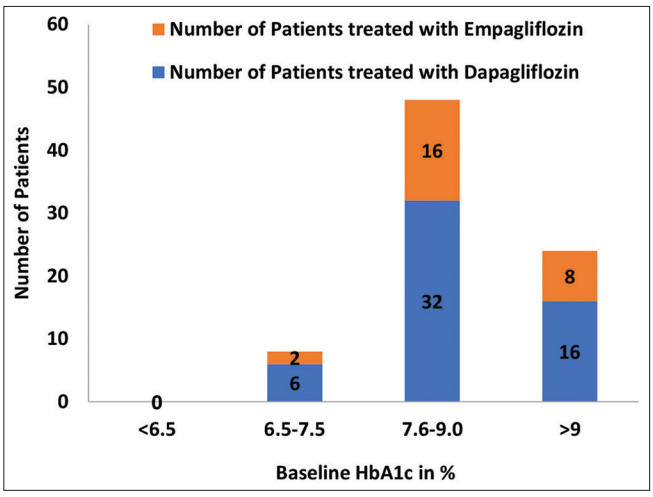

Fig. 3: Number of patients presented with baseline glycated hemoglobin (n=80), treated with dapagliflozin and empagliflozin

DISCUSSION

According to projections, 77 million people in India had diabetes in 2019, and by 2045, that number is predicted to reach over 134 million. About 57% of these people never receive a diagnosis [12]. The majority of cases of diabetes are type 2, which can cause multiorgan complications that can be roughly categorized as microvascular and macrovascular problems.

Table 4: Number of patients presented with baseline HbA1c (n=80), treated with dapagliflozin and empagliflozin

Baseline HbA1c in %	Number of patients treated with dapagliflozin, n (%)	Number of patients treated with empagliflozin, n (%)
<6.5	0	0
6.5–7.5	6 (11.11)	2 (7.69)
7.6–9.0	32 (59.2)	16 (61.5)
>9	16 (29.69)	8 (30.81)
Chi-square: 0.227	Total: 54 (67.5)	Total: 26 (32.5)
df: 2	Mean: 13.5	Mean: 6.5
p=^{NS}0.892	SD: 12.11	SD: 6.22

Every data point was presented as Mean±SD, with a significance level of ^{NS}p<0.892; NS: Non-significant, SD: Standard deviation, HbA1c: Hemoglobin

Table 5: Number of patients presented with HbA1c (n=54), treated with dapagliflozin

Reduction in HbA1c (%)	Number of patients, n (%)	Average duration of treatment (months)
0.0–1.0	27 (50)	5.9
1.1–2.0	13 (24)	9.4 (in 1 patient 25 months)
2.1–3.0	4 (7.6)	3
3.1–4.0	6 (11)	9
4.1–4.0	4 (7.4)	5
Chi-square: 9.777	Total: 54 (67.5)	
df: 4	Mean: 10.4	
p<0.044*, significant	SD: 8.33	

Every data point was presented as mean±SD, with a significance level of p<0.044*, significant. SD: Standard deviation, HbA1c: Hemoglobin

Table 6: Number of patients presented with HbA1c (n=26), treated with empagliflozin

Reduction in HbA1c (%)	Number of patients, n (%)	Average duration of treatment (months)
0.0–1.0	9 (34.6)	8
1.1–2.0	11 (42.3)	8.1
2.1–3.0	6 (23.1)	8.3
Chi-square: 4.619	Total: 26 (32.5)	
df: 3	Mean: 9.33	
p=^{NS}0.2019	SD: 2.49	

Every data point was presented as mean±SD, with a significance level of ^{NS}p<0.2019; NS: Non-significant, SD: Standard deviation, HbA1c: Hemoglobin

In addition to genetics and family history, the risk factors for diabetes include age, ethnicity, obesity and physical inactivity, bad diet, and behavioral patterns. One can avoid or postpone the start of problems from diabetes by maintaining appropriate blood pressure, blood sugar, and blood lipid levels. To stop the diabetes epidemic and lower the number of complications associated with diabetes in India, improved health promotion and primary prevention are therefore urgently needed at both the individual and national levels [13].

The most recent family of oral anti-hyperglycemic medications to be licensed for the management of DM is known as SGLT-2i. The safety and effectiveness of this class of drugs have advanced significantly in the last few years. SGLT-2i helps people with type 2 diabetes moderately lower their increased blood glucose levels by promoting the renal excretion of glucose [14]. SGLT-2i is drugs that decrease glucose without the help of insulin and have a distinct mode of action. These drugs are quickly making a name for themselves in the treatment of diabetes, especially in light of new research on their advantages and effectiveness. In patients with type 2 diabetes who are unwilling or unable to begin insulin therapy, SGLT-2i may represent an additional treatment option for individuals who need further lowering of blood glucose and who have acceptable risk profiles [15]. The present study contained an assessment of the effectiveness of SGLT-2i in type 2 diabetic patients. This is a longitudinal and prospective study with follow-ups that were carried out in tertiary care hospital.

The demographic data in the present study showed that males in age group between 50 and 70 years were accounted for 58% while females were 42%. These observations were consistent with the previous studies that men who had high levels of sex hormone binding globulin and low levels of free testosterone were developed with high risk of diabetes. In the current study, patients with age groups between 50 and 70 years were occupied with more than 60%. One of the main risk factors for prediabetes and diabetes is advanced age, hence the results were consistent with the study. About 88 patients were suffered with diabetes in the past 5–10 years, and this duration might be attributed to the development of poor glucose control, requiring to depend on multiple medications.

To avoid complications related to diabetes, maintaining good glycemic control is a crucial part of diabetes care. Major guidelines now advise SGLT-2i following lifestyle modifications. Metformin is even recommended as first-line therapy for obese diabetic patients with ASCVD and diabetic kidney disease, as significant trials have demonstrated its efficacy in these patients [16]. Due to their unique beta cell sparing effect and oral activity, SGLT-2i is favored. With regard to the treatment, both the drugs – dapagliflozin and empagliflozin – were prescribed for the diabetic patients accordingly. Dapagliflozin was administered to 79% of the patients, while Empagliflozin was given to 42 patients.

Out of 200 patients, follow-ups were conducted in 80 patients, among whom the baseline HbA1c was recorded as 7.6–9.0 in 32 (59.2%) patients who were kept on dapagliflozin and 61.5% (n=16) on empagliflozin. HbA1c has been suggested by the ADA as a potential replacement for fasting blood glucose in the diagnosis of diabetes [17]. The anticipated half-life of red blood cells is 2–3 months, and the analysis of HbA1c in blood gives information about an individual's average blood glucose levels for the preceding 2–3 months, also HbA1c is a significant indicator of long-term glycemic management [17]. In addition to offering a trustworthy indicator of persistent hyperglycemia, HbA1c has a strong correlation with the likelihood of developing long-term diabetic problems. In individuals with or without diabetes, elevated HbA1c has also been identified as a separate risk factor for coronary heart disease and stroke. The HbA1c test is now considered a dependable biomarker for the diagnosis and prognosis of diabetes due to the valuable information it provides. As a standard of care for diagnosing and tracking diabetes, particularly type 2 diabetes, the HbA1c test is now advised [18].

In place of criteria based on FPG (FPG ≥7.0 mmol/L), the ADA has recently proposed HbA1c with a cut-point of ≥6.5% for the diagnosis of diabetes. There is a substantial correlation between HbA1c levels and FPG. For the diagnosis of diabetes, FPG, 2-h post-glucose load plasma glucose, and OGTT are advised only in situations where HbA1c testing is not feasible because of assay unavailability, patient conditions that prevent its interpretation, or pregnancy [19]. HbA1c is currently regarded as the test of choice for chronic diabetes treatment since it offers a trustworthy measurement of chronic glycemia and has a strong correlation with the risk of long-term diabetes problems. Still up for debate, though, is the HbA1c cut-point from a diagnostic standpoint [20,21]. In the current study, follow-ups were done after the patient was kept on dapagliflozin and it was noticed that 40 patients were observed to have a reduced HbA1c of 0–2.0% after 5–9 months of treatment, whereas 26 patients were found to have a decreased HbA1c of 0–3% who were treated with empagliflozin for about 8 months.

A relatively recent family of medications known as SGLT-2i functions without the need for insulin. By inhibiting the SGLT-2 transporters in the proximal renal tubule, they prevent the reabsorption of filtered glucose and cause an excessive amount of glucose loss in the urine. HbA1c was demonstrated to be significantly reduced in all early SGLT-2i trials, with an average reduction of 0.6–1.2, depending on the baseline degree, according to a study, the results of which were consistent with the current study results [22,23]. In the present investigation, there was a reduction in HbA1c in a significant manner without events of hypoglycemia or hyperglycemia; however, the safety of the drugs needs to be analyzed as type 2 DM is a chronic lifestyle disorder which need to be under close vicinity.

CONCLUSION

These difficulties play a major role in the rise in early morbidity and mortality among diabetics, which lowers life expectancy and increases the financial and other expenditures associated with the disease, placing a heavy financial strain on the Indian health care system. Of the 14 medication groups authorized to treat type 2 diabetes, SGLT-2i is the most recent. Other than decreasing blood sugar, this class has a lot of positive benefits. With dapagliflozin and empagliflozin treatment, there was reduction in the HbA1C significantly. Baseline analysis of HbA1C was assessed and it can be concluded that both had shown a reduction in the same in % wise. For patients with type 2 diabetes, SGLT-2i significantly tends to enhance health outcomes and avoid the escalation of diabetes-related health disparities. For those with type 2 diabetes, SGLT-2i is helpful medications for lowering blood glucose levels. They can be combined or used as monotherapy. Because of this, a wide range of patients can benefit from this class of drugs that have their distinct mode of action as complementary to both insulin and other oral antidiabetic treatments.

Limitations

This was a prospective study with a few drawbacks associated. The study could not obtain complete data on the patient population. As the study was an outpatient study, laboratory reports of the patient population were difficult to record. Out of 200 patients, follow-ups were done subsequently from only 80 patients, additionally HbA1c could not be obtained for all patients. Regular follow-ups were not maintained by the patients for which data collection became a challenge.

CONFLICTS OF INTEREST

The authors declared no conflicts of interest.

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Nil.

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