

## Effect of Sodium–Glucose Cotransporter-2 Inhibitors on Serum Uric Acid Levels in Patients with Type 2 Diabetes Mellitus

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### Abstract

**Background:** Diabetes mellitus is a metabolic disorder which is characterized by chronic hyperglycemia that results in defect in insulin secretion, insulin action or both. Insulin is the primary regulator of glucose metabolism, storage and is secreted from pancreatic beta cells, also insulin stimulates glucose uptake in skeletal muscle and fat mediated by GLUT4. SGLT2 inhibitors are class of glucose lowering drugs which promote glucose elimination through urine.

**Objective:** To estimate the serum uric acid levels in type 2 diabetes mellitus patients after starting SGLT-2 inhibitors.

**Methods:** This hospital-based prospective comparative study was conducted in Department of General Medicine at Vydehi Institute of Medical Sciences and Research Centre, Bangalore. and we used simple random sampling technique to recruit 80 patients diagnosed with type 2 diabetes mellitus. Enrolled patients were divided into two groups based on randomization table. Blood samples for assessment of uric acid and creatinine was collected and after 2 weeks of treatment serum uric acid was repeated and the values were compared between the two groups.

**Result:** The mean age of our study participants was  $59.28 \pm 11.97$  years with 67.50% males with an average duration of diabetes recorded  $8.55 \pm 5.04$  years and 37.50% were on insulin treatment. Mean FBS recorded was  $169.10 \pm 42.95$  mg/dL, mean PPBS of  $228.90 \pm 65.98$  mg/dL and a mean HbA1c of  $8.914 \pm 1.85\%$ . 27.50% of them had abnormal urine routine findings, Serum uric acid levels at enrolment were  $7.88 \pm 1.35$  mg/dL and after 2 weeks of treatment it was  $7.39 \pm 1.33$  mf/dl. It was seen that SGLT2 inhibitors significantly reduced serum uric acid levels compared to other oral hypoglycemic drugs.

**Conclusion:** Our study revealed that SGLT2 inhibitors are associated with a significant reduction in mean serum uric acid levels among diabetic individuals. This suggests that SGLT2 inhibitors may be particularly effective in addressing hyperuricemia, a condition that can contribute to complications such as gout and kidney issues.

**Keywords:** Type 2 Diabetes Mellitus, SGLT2 inhibitors, Serum Uric acid levels.

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### Introduction

Diabetes mellitus is a metabolic disorder which is characterized by chronic hyperglycemia that results in defect in insulin secretion, insulin action or both.<sup>1</sup> It is the largest global health emergency of the century and is also ranked among the ten-leading causes of mortality with cardiovascular disease, respiratory disease and cancer. According to World Health Organization (WHO), 74% of the death globally accounted for Non-communicable Diseases (NCDs) as reported in 2023 and diabetes accounted for 17 million deaths, thus it is the ninth leading cause of death globally. By the year 2035 about 592 million subjects are predicted to die of diabetes globally.<sup>1,2,3</sup>

Insulin is the primary regulator of glucose metabolism, storage and is secreted from pancreatic beta cells into the portal circulation and entry of glucose into pancreatic beta cell is by facilitated diffusion through cell membrane glucose transporters (GLUTs), also insulin stimulates glucose uptake in skeletal muscle and fat mediated by GLUT4. Glucose is filtered freely in renal glomeruli and reabsorbed in proximal tubules and SGLT2 is involved in reabsorption of glucose.<sup>4</sup>

SGLT2 inhibitors are class of glucose lowering drugs which promote glucose elimination through urine. SGLTs are integral membrane proteins operating in transport of glucose across membranes,

*pq*

where SGLT1 are expressed in small intestine and SGLT2 are exclusively expressed in kidneys, especially in early proximal tubule and promotes reabsorption of 80-90% of glucose filtered by glomerulus.<sup>5</sup>

Uric acid is a weak acid generated from the metabolism of purine and is recognized as the cause of gout since early 1800s and hyperuricemia or gout is commonly observed among patients with diabetes and also that high circulating uric acid levels may increase risk of type 2 diabetes, metabolic syndromes. Experiments have also shown that raising uric acid with fructose can result in insulin resistance and in addition hyperuricemia is a risk factor of diabetic nephropathy, vascular complications and peripheral neuropathy.<sup>6</sup>

Our study was conducted to understand the effect of sodium glucose cotransporter-2 (SGLT2) inhibitor on the levels of uric acid among type 2 diabetes patients.

### Material and Methods

This hospital-based prospective comparative study was conducted among Patients diagnosed with type 2 diabetes mellitus at Medicine OPD or admitted in the wards under the department of general medicine and endocrine OPD, at Vydehi Institute of Medical Sciences and Research Centre, Bangalore. Duration of study was 18 months beginning from July 2022 till end of January 2024. The ethical clearance was obtained from the Institutional Ethics Committee.

### Inclusion Criteria:

1. Patients aged more than 18 years.
2. Patients diagnosed with type 2 diabetes mellitus (known and newly detected).
3. Patients willing to participate in the study.

### Exclusion Criteria:

1. Patients with diagnosis of gout.
2. Patients with type 1 diabetes and other type of diabetes (Maturity onset diabetes of the young, Gestational diabetes).
3. Patients with chronic kidney disease with eGFR <60 mL/min/1.73 m<sup>2</sup>.
4. Patients with genitourinary infection.
5. Patients who are on thiazides and uricosuric drugs.

**Sampling technique:** The sampling technique adopted for our study was simple random sampling technique.

### Sample Size Estimation

**Sample size:** Sample size was calculated using the formula for prospective comparative study,

$$n = \sigma^2 \frac{pq}{d^2}$$

where, n = sample size

$$\sigma = 1.96 \text{ (95\% confidence interval)}$$

p = 6.67 (Serum uric acid concentration among diabetic individuals not on SGLT2 inhibitors<sup>7</sup>)

$$q = (100 - p) = 100 - 6.67 = 93.33$$

$$d = 5.5 \text{ (absolute error)}$$

By substituting the above values in the formula, the sample size was calculated to be 79. Finally, the sample size was taken as 80 for our study.

**Method of data Collection:** The patients attending the General Medicine OPD or admitted in the wards of department of General medicine and Endocrine OPD at Vydehi Institute of Medical sciences and research Centre with clinical diagnosis of diabetes mellitus fulfilling the inclusion and exclusion criteria were selected for our study. The patients and their attenders were informed about our study and informed written consent was obtained from them. Based on sample size estimation 80 patients were recruited for our study.

The participants were clinically examined and demographic information and detailed clinical history was sought related to presenting symptoms, habits, history of co-morbidities using a pre-structured questionnaire. The enrolled patients were divided into two groups based on randomization table. In group A, the enrolled type 2 diabetic patients received SGLT-2 inhibitors and in Group B, the enrolled type 2 diabetic patients were on other oral hypoglycemic drugs but not on SGLT-2 inhibitors. The blood samples for assessment of uric acid and creatinine were collected and sent to the laboratory at Vydehi Institute of Medical Sciences and Research Centre at the beginning of the therapy and after two weekss of treatment and all the enrolled patients in both the groups were advised to follow strict diabetic diet.

The following investigations were carried out,

1. Complete blood count.
2. Fasting blood sugar.
3. Post prandial blood sugar.
4. HbA1c.
5. Random blood sugar.
6. Serum uric acid level (at enrolment and after 2 weeks of treatment).
7. Serum creatinine.
8. Blood urea.

## 9. Urine routine and microscopy.

**Data Analysis plan:** The data collected from the patients was coded and entered into MS Excel sheet and master chart was prepared. The data was presented in the form of tables, rates, ratios and percentages. Univariate analysis was reported as mean and standard deviation and associations were established using t test, chi square test and ANOVA test was conducted for multivariate analysis. Pie chart, bar diagram and line diagram were used for graphical representation of data. The association was considered statistically significant if the p value was less than 0.05. EPI software was used for statistical analysis.

**Definition of study variables:**

## A. Blood sugar levels:

## I. Fasting blood sugar

- Normal: <100 mg/dL
- Impaired: 100 to 125mg/dL
- Diabetes: >126 mg/dL

## II. Post-prandial blood sugar

- Normal: <140 mg/dL
- Impaired: 140 to 199 mg/dL
- Diabetes: >200 mg/dL

## III. HbA1c

- Normal: <5.6%
- Borderline: 5.7-6.4%
- Diabetes: >6.5%

## B. Serum uric acid levels:

- I. Normal range among men is between 3.5 to 7.2 mg/dL
- II. Normal range among women is between 2.6 to 6 mg/dL.

**Results****Table 1: Age wise distribution of study subjects.**

| Sl. No        | Age (in years) | OHD + SGLT2       | OHD               |
|---------------|----------------|-------------------|-------------------|
|               |                | Frequency (%)     | Frequency (%)     |
| 01            | <40 years      | 05 (12.50%)       | 04 (10%)          |
| 02            | 41 to 50 years | 05 (12.50%)       | 07 (17.50%)       |
| 03            | 51 to 60 years | 06 (15%)          | 06 (15%)          |
| 04            | 61 to 70 years | 17 (42.50%)       | 17 (42.50%)       |
| 05            | >71 years      | 07 (17.50%)       | 06 (15%)          |
| Total         |                | 40 (100%)         | 40 (100%)         |
| Mean $\pm$ SD |                | 59.35 $\pm$ 11.48 | 59.20 $\pm$ 12.58 |

Findings from Table 1 show that, mean age of our study subjects in OHD + SGLT2 group was 59.35  $\pm$  11.48 years with 12.50% aged less than 40 years, 12.50% aged in between 41 to 50 years, 15% aged in between 51 to 60 years, 42.50% aged in between 61 to 70 years and rest 17.50% aged more than 71

years and in OHD group mean age was 59.20  $\pm$  12.58 years with 10% aged less than 40 years, 17.50% aged in between 41 to 50 years, 15% aged in between 51 to 60 years, 42.50% aged in between 61 to 70 years and rest 15% aged more than 71 years.

**Table 2: Gender wise distribution of study subjects**

| Sl. No | Gender  | OHD + SGLT2   | OHD           |
|--------|---------|---------------|---------------|
|        |         | Frequency (%) | Frequency (%) |
| 01     | Males   | 23 (57.50%)   | 31 (77.50%)   |
| 02     | Females | 17 (42.50%)   | 09 (22.50%)   |
| Total  |         | 40 (100%)     | 40 (100%)     |

Findings from Table 2 reveal that, in OHD + SGLT2 group 57.50% were males and 42.50% were females

and in OHD group 77.50% were males and 22.50% were females.

**Table 3: Distribution of study subjects based on duration of diabetes.**

| Sl. No        | Duration of diabetes (in years) | OHD + SGLT2           | OHD                   |
|---------------|---------------------------------|-----------------------|-----------------------|
|               |                                 | Frequency (%)         | Frequency (%)         |
| 01            | <5 years                        | 16 (40%)              | 13 (32.50%)           |
| 02            | 6 to 10 years                   | 15 (37.50%)           | 13 (32.50%)           |
| 03            | >11 years                       | 09 (22.50%)           | 14 (35%)              |
| Total         |                                 | 40 (100%)             | 40 (100%)             |
| Mean $\pm$ SD |                                 | 8.20 $\pm$ 5.22 years | 8.90 $\pm$ 4.89 years |

Findings from Table 3 depict that, in OHD + SGLT2 group mean duration of diabetes was  $8.20 \pm 5.22$  years with 40% having diabetes for duration less than 5 years, 37.50% in between 6 to 10 years and rest 22.50% had duration of diabetes for more than 11 years and in OHD group mean duration of diabetes was  $8.90 \pm 4.89$  years with 32.50% having diabetes for duration less than 5 years, 32.50% in between 6 to 10 years and rest 35% had duration of diabetes for more than 11 years.

50% of our subjects with diabetes were on treatment with oral hypoglycemic drugs along with SGLT2 inhibitors and rest 50% were on oral hypoglycemic drugs, but without SGLT2 inhibitors.

In both OHD + SGLT2 and OHD group 37.50% of the diabetic subjects were on insulin treatment and rest 62.50% were not on insulin treatment.

**Table 4: Distribution of study subjects based on associated co-morbidities.**

| Sl. No | Associated co-morbidities | OHD + SGLT2   | OHD           |
|--------|---------------------------|---------------|---------------|
|        |                           | Frequency (%) | Frequency (%) |
| 01     | Nil                       | 31 (77.50%)   | 28 (70%)      |
| 02     | Hypertension              | 09 (22.50%)   | 09 (22.50%)   |
| 03     | Dyslipidemia              | 00 (0)        | 02 (5%)       |
| 04     | CVDs                      | 01 (2.50%)    | 01 (2.50%)    |
| 05     | Thyroid disorders         | 03 (7.50%)    | 03 (7.50%)    |

In OHD + SGLT2 group 77.50% did not have any associated co-morbidities, 22.50% had hypertension, 2.50% had CVDs and 7.50% with thyroid disorders. In OHD group 70% did not have any associated co-morbidities, 22.50% had hypertension, 5% had CVDs and 7.50% with thyroid disorders.

habitual behavior, whereas 7.50% were smokers, 5% of them had habit of alcohol consumption and rest 12.50% of them had habit of both smoking and alcohol consumption. In OHD group 75% were not on any habitual behavior, whereas 10% were smokers, 5% of them had habit of alcohol consumption and rest 10% of them had habit of both smoking and alcohol consumption.

In OHD + SGLT2 group 75% were not on any

**Table 5: Distribution of study subjects based on Fasting Blood Sugar levels.**

| Sl. No        | Fasting Blood Sugar levels | OHD + SGLT2        | OHD                |
|---------------|----------------------------|--------------------|--------------------|
|               |                            | Frequency (%)      | Frequency (%)      |
| 01            | <110 mg/dL                 | 04 (10%)           | 04 (10%)           |
| 02            | 111 to 125 mg/dL           | 03 (7.50%)         | 03 (7.50%)         |
| 03            | >126 mg/dL                 | 33 (82.50%)        | 33 (82.50%)        |
| Total         |                            | 40 (100%)          | 40 (100%)          |
| Mean $\pm$ SD |                            | 171.88 $\pm$ 44.44 | 166.35 $\pm$ 41.26 |

In OHD + SGLT2 group mean fasting blood sugar level recorded was  $171.88 \pm 44.44$  mg/dL and in OHD group it was  $166.35 \pm 41.26$  mg/dL and in both

the groups 10% recorded FBS less than 110 mg/dL, 7.50% had FBS in the range between 111 to 125 mg/dL and rest 82.50% had FBS more than 126 mg/dL.

**Table 6: Distribution of study subjects based on Post Prandial Blood sugar levels.**

| Sl. No        | Post-prandial blood sugar | OHD + SGLT2        | OHD                |
|---------------|---------------------------|--------------------|--------------------|
|               |                           | Frequency (%)      | Frequency (%)      |
| 01            | <140 mg/dL                | 04 (10%)           | 03 (7.50%)         |
| 02            | 141 to 199 mg/dL          | 09 (22.50%)        | 14 (35%)           |
| 03            | >200 mg/dL                | 27 (67.50%)        | 23 (57.50%)        |
| Total         |                           | 40 (100%)          | 40 (100%)          |
| Mean $\pm$ SD |                           | 230.45 $\pm$ 67.12 | 227.33 $\pm$ 64.82 |

In OHD + SGLT2 group mean PPBS was  $230.45 \pm 67.12$  mg/dL with 10% having PPBS value less than 140 mg/dL, 22.50% in between 141 to 199 mg/dL, 67.50% had more than 200 mg/dL and in OHD

group it was  $227.33 \pm 64.82$  mg/dL with 7.50% recorded PPBS less than 140 mg/dL, 35% had PPBS in the range between 141 to 199 mg/dL and rest 57.50% had PPBS more than 200 mg/dL.

**Table 7: Distribution of study subjects based on HbA1c levels.**

| Sl. No        | HbA1c                  | OHD + SGLT2     | OHD             |
|---------------|------------------------|-----------------|-----------------|
|               |                        | Frequency (%)   | Frequency (%)   |
| 01            | <7% (good control)     | 07 (17.50%)     | 09 (22.50%)     |
| 02            | 7 to 8% (fair control) | 12 (30%)        | 06 (15%)        |
| 03            | >8% (poor control)     | 21 (52.50%)     | 25 (62.50%)     |
| Total         |                        | 40 (100%)       | 40 (100%)       |
| Mean $\pm$ SD |                        | 8.91 $\pm$ 1.81 | 8.92 $\pm$ 1.89 |

Findings from Table 7 show that, in OHD + SGLT2 group mean HbA1c level recorded was  $8.91 \pm 1.81\%$  with 17.50% recorded HbA1c less than 7%, 30% in the range between 7 to 8% and rest 52.50% had HbA1c more than 8% and in OHD group mean

HbA1c level recorded was  $8.92 \pm 1.89\%$  with 22.50% recorded HbA1c less than 7%, 15% in the range between 7 to 8% and rest 62.50% had HbA1c more than 8%. These findings suggest that HbA1c levels were comparable between the two groups.

**Table 8: Distribution of study subjects based on serum uric acid levels.**

| Sl. No | Serum Uric Acid levels (mg/dL) | Mean | SD   |
|--------|--------------------------------|------|------|
| 01     | At enrolment                   | 7.88 | 1.35 |
| 02     | After 2 weeks                  | 7.39 | 1.33 |

At enrolment mean serum uric acid levels was  $7.88 \pm 1.35$  mg/dL and after 2 weeks, the mean serum uric acid levels was  $7.39 \pm 1.33$  mg/dL. Findings from Table 8 indicate that, in OHD + SGLT2 group mean serum creatinine levels were  $0.91 \pm 0.21$  mg/dL and mean blood urea levels was  $26.77 \pm 10.55$  mg/dL among our subjects and in OHD group mean serum

creatinine levels was  $1.66 \pm 1.47$  mg/dL and blood urea levels was  $27.49 \pm 11.10$  mg/dL. Findings from the urine routine findings reveal that, in OHD + SGLT2 75% of them had normal urine routine findings and 25% had abnormal urine routine findings and in OHD group 70% had normal and 30% had abnormal urine routine findings.

**Table 9: Association between serum uric acid levels and diabetes treatment type.**

| Sl. No                 | Diabetes treatment                               | Serum Uric Acid levels after 2 weeks |      | p-value            |
|------------------------|--------------------------------------------------|--------------------------------------|------|--------------------|
|                        |                                                  | Mean                                 | SD   |                    |
| 01                     | Oral hypoglycemic drugs with SGLT2 inhibitors    | 6.98                                 | 1.25 | 3.0146 (0.0035) *  |
| 02                     | Oral hypoglycemic drugs without SGLT2 inhibitors | 7.81                                 | 1.28 | 0.3711 (0.7116) NS |
| t test value (p value) |                                                  | 2.9341 (0.0044) *                    |      |                    |

(NS is Not significant, \* is significant, at p value <0.05)

Table show that mean serum uric acid levels after 2 weeks among patients receiving oral hypoglycemic drugs with SGLT2 inhibitors was  $6.98 \pm 1.25$  mg/dL and among those on oral hypoglycemic drugs without SGLT2 inhibitors was  $7.81 \pm 1.28$  mg/dL and this difference was statistically significant indicating that SGLT2 inhibitors had a significant role in lowering serum uric acid.

### Discussion

In this prospective and comparative study of measurement of uric acid following finding were observed and compared.

Our study recorded a mean age of  $59.28 \pm 11.97$  years with 11.25% aged less than 40 years, 27.50% aged between 41 and 60 years and 61.25% aged 61 years or above with 67.50% being males and 32.50% females.

Hu X, et al, reported a total of 1938 diabetic individuals enrolled in their study with 56% of them being males and rest 44% were females with mean age recorded  $50.20 \pm 11.45$  years.<sup>6</sup> Yuan

T, et al, reported in their study the mean age to be  $54 \pm 9.61$  years with 62.50% of them being males, whose findings were quite similar to that of ours.<sup>7</sup> Ferreira JP, et al, also revealed findings similar to that of ours where mean age recorded was  $65.30 \pm 7.8$  years among those who were on treatment with SGLT2 and among those who were not on SGLT2 mean age recorded was  $63 \pm 8.7$  years with 86.40% males and 70.50% males respectively.<sup>8</sup>

Fralick M, et al, reported that the mean age recorded was 54 years with 52% of them being females.<sup>9</sup> Chino Y, et al, reported a younger age group with mean age recorded  $26.50 \pm 5.5$  years.<sup>10</sup>

Our study recorded a mean duration of diabetes to be  $8.55 \pm 5.04$  years with 36.25% having a duration for less than 5 years, 35% had duration in between 6 to 10 years and rest 28.75% had duration of diabetes for more than 11 years and 37.50% of them were on insulin treatment.

Ferreira JP, et al, reported that 3.4% of them had diabetes for a duration less than 1 year, 12.60% in

between 1 to 5 years, 23.50% in between 6 to 10 years and 60.50% had diabetes for a duration of more than 10 years.<sup>8</sup>

In our study, 73.75% did not report any associated co-morbidities, while 22.50% had hypertension, 2.50% had dyslipidemia, 7.50% had thyroid disorders, 8.75% were smokers, 5% had a history of alcohol consumption and 11.25% had both smoking and alcohol consumption.

Hu X, et al, reported that in their study 48.35% of them had history of smoking, 51.65% had history of alcohol consumption and 41.15% of them had hypertension as associated co-morbidity.<sup>7</sup> Ferreira JP, et al, reported that in their study almost all

(95.60%) had associated hypertension.<sup>8</sup> Fralick M, et al, reported that two thirds of their diabetic subjects were hypertensive as well.<sup>9</sup>

The mean serum uric acid level in our study was  $7.88 \pm 1.35$  mg/dL and mean serum uric acid levels after 2 weeks among patients receiving oral hypoglycemic drugs with SGLT2 inhibitors was  $6.98 \pm 1.25$  mg/dL and among those on oral hypoglycemic drugs without SGLT2 inhibitors was  $7.81 \pm 1.28$  mg/dL. Hu X, et al, recorded a mean plasma uric acid concentration of  $6.67 \pm 1.09$  mg/dL without SGLT2 and  $5.15 \pm 0.54$  mg/dL with SGLT2 inhibitors.<sup>7</sup>

| Study                                                | Serum uric acid before treatment with SGLT2 | Serum uric acid after treatment with SGLT2 |
|------------------------------------------------------|---------------------------------------------|--------------------------------------------|
| Our study (2-week treatment)                         | $7.88 \pm 1.35$ mg/dL                       | $6.98 \pm 1.25$ mg/dL                      |
| Hu X, et al. <sup>6</sup> (3 months treatment)       | $6.67 \pm 1.09$ mg/dL                       | $5.15 \pm 0.54$ mg/dL                      |
| Yuan T, et al. <sup>7</sup> (1 week treatment)       | $347.75 \pm 32.53$ $\mu$ mol/L              | $273.25 \pm 43.18$ $\mu$ mol/L             |
| Ferreira JP, et al. <sup>8</sup> (12-week treatment) | $6.4 \pm 1.7$ mg/dL                         | $5.9 \pm 1.6$ mg/dL                        |
| Chino Y, et al. <sup>10</sup> (4-week treatment)     | $8.15 \pm 1.49$ mg/dL                       | $5.90 \pm 0.54$ mg/dL                      |

## Conclusion

In our study, we observed a significant reduction in mean serum uric acid levels in diabetic individuals who were treated with SGLT2 inhibitors. This reduction in uric acid was noteworthy and points to the effectiveness of SGLT2 inhibitors in addressing elevated uric acid levels in this patient population.

This suggests that SGLT2 inhibitors may offer a beneficial role beyond their primary use, providing an additional therapeutic advantage in managing elevated uric acid levels.

The ability of SGLT2 inhibitors to reduce serum uric acid levels could be particularly valuable for diabetic patients who also struggle with hyperuricemia or gout and conditions associated with high uric acid levels.

Therefore, SGLT2 inhibitors should be considered a favorable option for such patients, contributing to an improved overall management strategy for diabetes and associated metabolic issues.

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