CONSENSUS STUDY

Consensus on ONgoing Educational Practices to Improve SGLT2i Adherence in India: Consensus ONE SGLT2i Adherence Group

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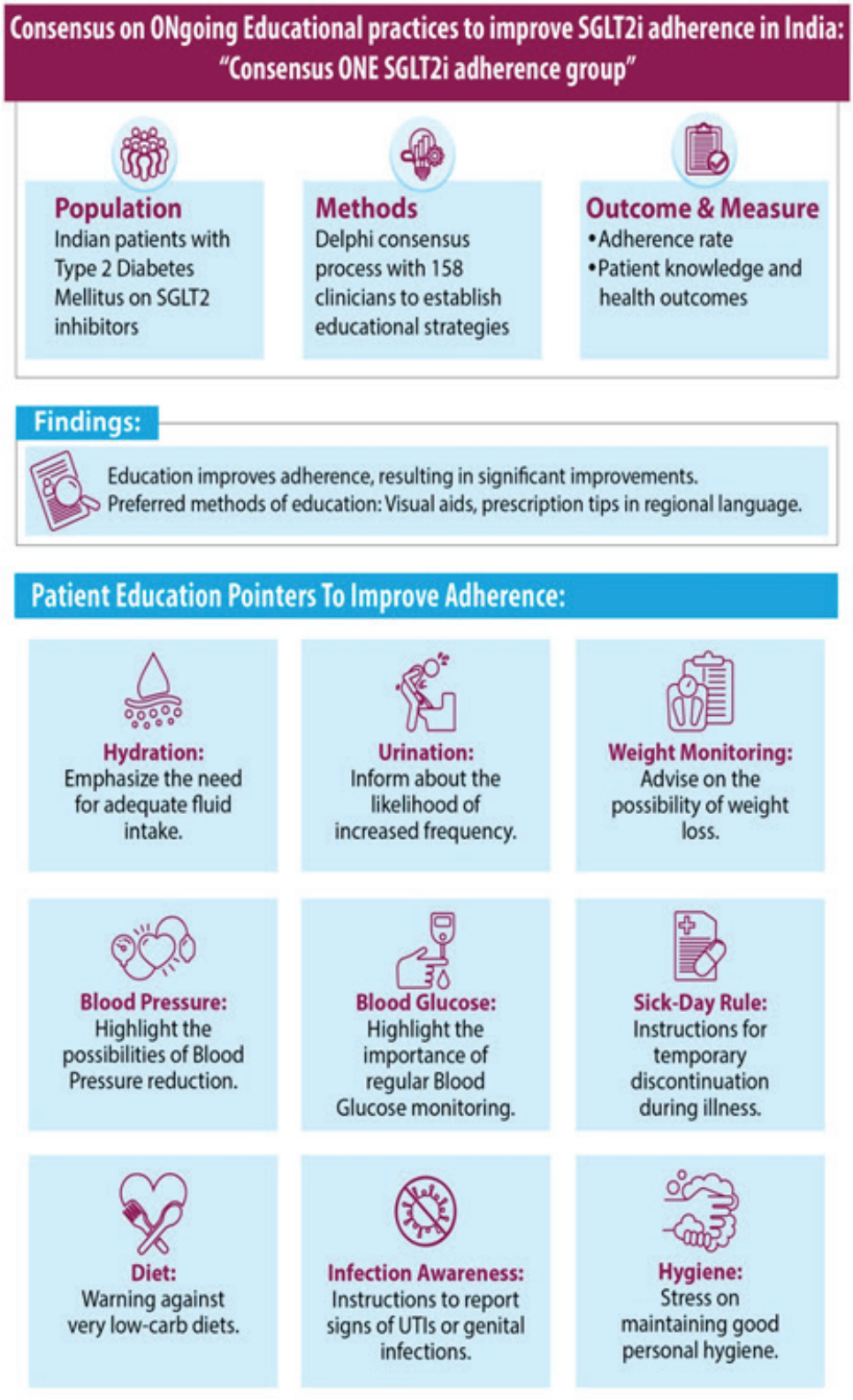
ABSTRACT

Background: Sodium-glucose cotransporter 2 inhibitors (SGLT2i) directly inhibit the SGLT2 protein in kidney proximal tubules, leading to increased glucose excretion. Medication adherence ensures individuals receive intended therapeutic effects, optimizing overall treatment effectiveness. The primary objective of this consensus study was to pinpoint the prevalent adverse effects associated with SGLT2i and establish optimal clinical practices for educating patients during the initiation of therapy. **Methods:** A diverse panel of experts, consisting of 158 clinicians specializing in diabetes care across India, were invited to engage in a Delphi discussion following an initial online survey conducted via email. Throughout the process, panelists were actively encouraged to offer feedback on the compiled responses, allowing for adjustments in their perspectives. Subsequently, the outcomes of each meeting were consolidated to form final recommendations. **Results:** About 88.24% of participants identified initiating SGLT2i for type 2 diabetes with atherosclerotic cardiovascular disease, heart failure or chronic kidney disease. Considerations for prescribing include eGFR <25 mL/min/1.73 m² (66.46%), a history of urinary tract infection (65.82%), and prior genital mycotic infections. Most (53.71%) preferred tips in prescriptions, and 63.92% consistently educated patients about SGLT2i use, with 64.15% strongly agreeing it alleviates clinical inertia; 68.35% strongly supported regional language education, and 79.11% endorsed QR-based patient education in smart prescriptions (Rx). **Conclusion:** Educating patients in regional languages, leveraging technology and providing printed literature are crucial strategies for overcoming clinical inertia and enhancing medication adherence.

Keywords: Diabetes mellitus, SGLT2i, patient education, technology

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Visual Abstract



Introduction

Diabetes stands as one of the most prevalent chronic diseases globally, with an increasing incidence.[1] India bears a significant burden of type 2 diabetes mellitus (T2DM), standing as the second-highest globally, with a staggering 74.2 million individuals diagnosed. Projections indicate that this already substantial number will escalate to 124.9 million by the year 2045.[2] In India, the overall weighted prevalence of diabetes is 21.1% (oral glucose tolerance test or OGTT [11.4%] and glycated hemoglobin or HbA1c [13.3%]) according to the Indian Council of Medical Research-India Diabetes (ICMR-INDIAB)-17 study.[3] Managing diabetes necessitates lifelong treatment involving medications and consistent follow-up. Adherence to antidiabetic medications is pivotal for achieving optimal glycemic control, thereby mitigating the risk of complications and fostering a more favorable prognosis.[4,5] Essential components of self-care, such as adhering to prescribed diets and medications, monitoring blood glucose levels, practicing foot care, engaging in regular exercise and recognizing symptoms, play a critical role in secondary prevention efforts.[6-8] Embracing these elements is indispensable for individuals in their journey toward effectively managing and preventing the progression of diabetes.

Sodium-glucose cotransporter 2 inhibitors (SGLT2i) represent the latest class of agents approved for managing type 2 diabetes (T2D).[9] Functioning by directly inhibiting SGLT2, a protein situated in the proximal tubules of the kidneys, these inhibitors impede glucose reabsorption in the renal system, leading to increased glucose excretion in the urine. Beyond their primary mechanism, SGLT2i are associated with a spectrum of additional advantages, including the reduction of blood pressure (BP), decreased serum urate levels and facilitation of weight loss. The amalgamation of these effects contributes to their favorable clinical profile.[10] SGLT2i have received global approval for treating T2D in patients who do not achieve sufficient glycemic control with conventional medications.[11] Extensive research on SGLT2i suggests that they may represent a viable first-line option for individuals recently diagnosed with diabetes, even in the absence of apparent associated health issues during the initial phases of the condition.[12]

While these agents have shown effectiveness and demonstrated cardiovascular and renal protection, the utilization of SGLT2i is not devoid of risks. Euglycemic diabetic ketoacidosis (eDKA), genital infections, urinary tract infections (UTIs) and weakness are some of the concerns with SGLT2i, which can be managed through meticulous patient selection, effective counseling and heightened monitoring, especially for individuals at elevated risk.[13-15] However, most of these adverse effects are rare, and the benefits of SGLT2i (glycemic control, cardiorenal protection, reduction in weight, BP and cholesterol) outweigh the risks when used in appropriately selected patients.

In the care of patients with T2D, these challenges lead to poor adherence and persistence, hindering optimal treatment outcomes.[16,17] The World Health Organization (WHO) has categorized reasons for medication non-use into five groups: patient-related factors (e.g., age), socioeconomic aspects (e.g., medication costs), condition-related considerations (e.g., presence of complications), health-system-related factors (e.g., continuity of care) and medication-related issues (e.g., adverse effects).[18] Simultaneously, ineffective communication between patients and health care providers, inadequate knowledge about medications and unclear medication instructions contribute to undermining treatment processes.[19] A multifaceted approach is essential to enhance patient satisfaction and medication adherence levels. This includes simplifying prescribing regimens, implementing educational programs, fostering improved communication between patients and health care professionals, utilizing reminders and addressing treatment costs.[20-22] Studies have indicated that personalized patient education contributes to enhanced glycemic and weight control, accompanied by a reduced risk of hypoglycemia and long-term complications in individuals on SGLT2i therapy.[4,8,23]

This Delphi consensus study aimed to identify the common adverse effects of SGLT2i and to establish the best clinical practices for patient education at the time of the first prescription of SGLT2i therapy, specifically tailored to the Indian context.

Materials and Methods

A diverse panel of experts was created, with 158 clinicians specializing in diabetes care from across India, each bringing varied backgrounds and expertise in managing patients with T2D, heart failure (HF), hypertension and chronic kidney disease (CKD). They were invited to partake in the Delphi discussion, which was preceded by an initial online survey via email. The survey delved into everyday practices, considerations and challenges encountered when prescribing SGLT2i to patients with T2D. To encourage comprehensive

responses, the survey also incorporated open-ended questions. The panelists were actively encouraged to provide feedback on the compiled responses, allowing them to adjust their perspectives accordingly. Subsequently, the responses were meticulously summarized and anonymized. After completing the questionnaire, all experts were invited to participate in 5 separate subgroups to discuss the survey responses and identify the most relevant and standard educational instructions and instruments for patients who were starting their SGLT2i therapy. A joint core committee of 5 members was present in all meetings and moderated the discussion. Finally, all findings from each meeting were combined and collated in the final recommendations and reshared with the participants digitally for any additional feedback. Throughout the entirety of the Delphi process, discussions were conducted with the utmost confidentiality and anonymity, ensuring a secure environment for the participants. The expertise and invaluable contributions of the panelists were duly acknowledged, underscoring the collaborative nature inherent in the Delphi method. The responses collected from the questionnaire were analyzed using quantitative methods. Frequency analysis was used to identify patterns and trends within the data, enabling the identification of predominant responses and variations among the collected data.

Results

A total of 158 clinicians actively participated in this survey. Most participants, constituting 88.24%, identified the most compelling reasons to initiate SGLT2i as the combination of T2D with atherosclerotic cardiovascular disease (ASCVD), HF or CKD. Additionally, a significant portion, 69.62%, regarded uncontrolled T2DM as a key factor. Conditions warranting careful consideration while prescribing SGLT2i were an estimated glomerular filtration rate (eGFR) <25 mL/min/1.73 m² (66.46%) and a history of UTI (65.82%). A significant proportion, totaling 63.92% of participants, confirmed that they consistently educate their patients about the use of SGLT2i and that this could effectively alleviate clinical inertia. Parameters such as the precautions, purpose of therapy, expected results and essential facts were highlighted as crucial aspects of patient education about SGLT2i (Table 1). Most participants (53.71%) preferred incorporating tips into the prescription to complement verbal discussions, closely followed by printed literature (49.71%). Other alternatives, such as handing over a quick response (QR) code sticker (36%) and seeking further explanation from educators, were also acknowledged by participants. Furthermore, a substantial 68.35% of participants strongly agreed that educating patients in regional languages could enhance acceptance and comprehension of the content. Incorporating writing tips directly into the prescription was identified as the most prevalent method used by 53.16% of doctors to reinforce verbal discussions, and it was also considered the most convenient tool for patient education by 59.49% of the respondents. Furthermore, a significant portion of doctors, 32.91%, strongly supported the effectiveness of smart prescription (Rx) QR-based patient education in enhancing adherence to SGLT2i treatments. Significantly, most participants (59.49%) reported consistent observations of enhanced tolerability, treatment adherence, and favorable clinical outcomes following patient education on SGLT2i (Table 1).

Table 1. Response by Clinicians to Survey Questions

Questions	Response	Response by doctors N = 158*
1. In your practice, what are the compelling reasons to consider SGLT2i for your patients?	Uncontrolled T2DM	110 (69.62)
	T2DM + ASCVD/HF/CKD	141 (89.24)
	HF	80 (50.63)
	CKD	65 (41.14)
	Any other	2 (1.27)
2. According to you, which of the following conditions are you watchful about before initiating SGLT2i?	Past UTI	104 (65.82)
	eGFR <20 mL/min/1.73 m2	79 (50)
	Past genital mycotic infections	46 (29.11)
	Elderly patients	63 (39.87)
	Active diabetic foot	105 (66.46)
	Any other	1 (0.63)

3. Do you think that patient education on the use of SGLT2i can reduce the inertia towards its clinical use?	Strongly agree	102 (64.15)
	Agree	53 (33.54)
	Neither agree nor disagree	3 (1.9)
	Disagree	0 (0)
	Strongly disagree	0 (0)
4. In your practice, how frequently do you educate your patients on the use of SGLT2i?	Always	101 (63.92)
	Frequently	48 (30.38)
	Sometimes	8 (5.06)
	Rarely	0 (0)
	Never	0 (0)
5. In your opinion, which of the following parameters are important for patient education about the use of SGLT2i?	Purpose of therapy	29 (18.35)
	Expected result/outcomes	20 (12.66)
	Must know facts	22 (13.92)
	Precautions to be taken	39 (24.68)
	All of the above	114 (72.15)
4. In your practice, how frequently do you educate your patients on the use of SGLT2i?	Always	101 (63.92)
	Frequently	48 (30.38)
	Sometimes	8 (5.06)
	Rarely	0 (0)
	Never	0 (0)
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	Must know facts	22 (13.92)
	Precautions to be taken	39 (24.68)
	All of the above	114 (72.15)

6. Which of the following tools have you used to substantiate your verbal discussion?		84 (53.16)
	Written tips in the prescription	82 (51.9)
	A printed literature	51 (32.28)
	A QR code sticker that gives access to the educational info in the regional languages	
	Ask my educator/counselor/pharmacist to explain further	58 (36.71)
	I have not used any tool	11 (6.96)
7. Which of the following tools do you find most convenient for patient education while initiating SGLT2i?	Tips mentioned in the prescription	94 (59.49)
	Handing over printed literature	91 (57.59)
	Handing over a QR code sticker–which gives them access to the educational information in their regional language	58 (36.71)
	Asking my educator/counselor/pharmacist to explain further	53 (33.54)
8. Do you think that patient education in regional languages can help to improve acceptance and understanding of the content among patients?	Strongly agree	108 (68.35)
	Agree	45 (28.48)
	Neither agree nor disagree	5 (3.16)
	Disagree	0 (0)
	Strongly disagree	0 (0)
9. Do you think that smart Rx QR based patient education can enhance adherence to SGLT2i treatment among your patients?	Strongly agree	52 (32.91)
	Agree	73 (46.2)
	Neither agree nor disagree	26 (16.46)
	Disagree	6 (3.8)
	Strongly disagree	0 (0)
10. In your practice, did you observe an improvement in tolerability, treatment adherence and clinical outcomes after providing patient education regarding the use of SGLT2i?	Always	94 (59.49)
	Frequently	56 (35.44)
	Sometimes	8 (5.06)
	Rarely	0 (0)
	Never	0 (0)

Data presented as n (%).

*N = 158 unless otherwise specified.

Discussion

SGLT2i constitute an evolving class of antidiabetic agents with the potential to play a central role in comprehensive diabetes management, owing to their diverse beneficial effects. The 2024 Standards of Care from the American Diabetes Association (ADA)[24] and the Expert Consensus Statement of 2023 by the American College of Cardiology[25] recommend the utilization of SGLT2i as the primary choice for glucose control, particularly in individuals at high risk for established heart disease. In 2023, a consensus statement by the American Association of Clinical Endocrinologists (AACE) recommended SGLT2i as the initial therapy for individuals with T2D who have, or are at high risk of ASCVD, HF and/or CKD.[26,27] Notable clinical trials, including DECLARE-TIMI 58[28], DEFINE-HF[29], DELIVER[30], DAPA-CKD[31], DAPA-HF[32], have consistently demonstrated the cardiovascular and renal benefits associated with SGLT2i. Most participants in this study indicated that the predominant factor driving the initiation of SGLT2i was the presence of T2D, ASCVD, HF or CKD. The initiation of SGLT2i therapy is intended to improve cardiovascular outcomes,

reduce the risk of hospitalizations related to HF and confer renoprotective effects.

The initiation of SGLT2i for the first time is generally not recommended for individuals with an eGFR below 20 mL/min/1.73 m² (note that the specific threshold may vary depending on the individual agent). However, for patients already on this medication, continuation may be considered. Caution is advised in cases of a history of genital or UTIs when contemplating using SGLT2i. Patients should be counseled to temporarily discontinue SGLT2i during episodes of acute illness that may potentially lead to dehydration.[10] Additionally, the use of SGLT2i is contraindicated in individuals with severe renal impairment, end-stage kidney disease (ESRD) or those requiring dialysis.[33] Following the provision of patient education on SGLT2i, most participants consistently noted enhancements in tolerability, treatment adherence and clinical outcomes. A study conducted by Atolagbe et al[34], Kardaş Kin et al[35] revealed that medication adherence significantly improved after the educational intervention within a month of the study's initiation.

According to Halkoaho and colleagues, the primary components of self-care in patients with diabetes encompass medication management, nutritional practices, glucose monitoring, physical exercise, oral health care and foot care.[36] Empowering individuals to manage diabetes effectively necessitates a diverse range of education modalities. These include in-person workshops or classes, counseling sessions, patient support groups, distributing printed educational materials (pamphlets, brochures, newspapers and booklets in local languages), webinars and training community health workers to deliver diabetes education. Health care providers can diminish inertia toward the clinical use of SGLT2i by delivering comprehensive patient education.[37] This includes elucidating the mechanism of action, highlighting aspects such as the increase in urine output and the excretion of excess glucose in urine.[21,38] Additionally, conveying treatment goals is essential, emphasizing SGLT2i's role in enhancing glycemic control, reducing the risk of cardiovascular events and providing renoprotective effects. Ensuring a clear understanding of dosage instructions and stressing the importance of consistent medication intake is pivotal. Patient education should also cover potential adverse effects, the necessity for regular monitoring and the significance of follow-up appointments. It is imperative to inform patients about positive outcomes associated with medication use and the potential reduction in complications through adherence. Furthermore, health care providers should actively encourage open communication, addressing patients' concerns or misconceptions about SGLT2i. This collaborative and informative approach fosters better patient understanding, adherence and overall engagement with the prescribed treatment. Patient education in the local language ensures clear communication, enhances engagement and empowers patients by delivering health care information in a familiar language. In this study, most participants strongly agreed that educating patients in their regional language significantly enhances acceptance and understanding among the population.

Embedding patient education guidance within the prescription for SGLT2i ensures the timely delivery of critical information as patients commence their medication regimen. Clear and succinct tips help comprehend the medication's purpose, proper administration procedures and potential side effects. Understanding the medication and its potential repercussions is a motivational factor, encouraging patients to adhere to the prescribed regimen. Including tips covering aspects such as nutrition, hygiene and hydration positively influences patients, motivating them to adopt and sustain healthier lifestyle practices. When patients grasp the correlation between their lifestyle choices and the efficacy of the SGLT2i, they are more likely to implement positive changes. Furthermore, educating patients about potential side effects or warning signs enables early detection and prompts timely reporting, contributing to proactive health care management (Table 2).

Emerging trends in educational programs are embracing technology with the introduction of digital apps, online resources, social media platforms and tools like QR codes. The "Prevention, Awareness, Counseling and Evaluation" (PACE) Diabetes Project, specifically the PACE-6 study, highlights the effectiveness of these innovations. The study demonstrates that through direct public education and mass media campaigns, awareness about diabetes and its complications can be significantly enhanced, even citywide.[39] QR codes were utilized in health care education to enhance participant engagement, specifically in simulation training[40], safer use of medications by elderly patients[41] and patient instructions.[42] Printed educational materials offer an accessible, cost-effective and convenient solution in health care environments. Their distribution aims to enhance health care professionals' awareness, knowledge, attitudes and skills, with the ultimate goal of positively impacting patient health outcomes.[43]

Table 2. Guidance for Patients on SGLT2i Therapy: Suggestive Prescription Instructions and Detailed Discussions

To Print	To Discuss
Maintain daily fluid hydration	This medication may increase your body's water loss, emphasizing the importance of maintaining adequate hydration by drinking enough water.
You might experience frequent urination initially, which is okay.	This medication may result in an increased frequency of urination, which is a normal response as it aids your body in eliminating excess sugar.
You might experience weight loss, which is okay.	• You might notice some weight loss due to the loss of glucose in the urine, which results in the loss of calories, as glucose is an energy source. • Monitor your weight at home and communicate any significant changes in weight or other concerns to your health care team.
You might experience a reduction in blood pressure, which is okay.	• You might notice a reduction in BP due to the loss of sodium and water along with glucose in the urine. • Regularly check your BP at home and promptly inform your doctor if you observe unusually low BP or experience sensations of lightheadedness or dizziness.
You might experience a reduction in blood glucose, which is okay.	• Regularly monitor your blood glucose levels at home, as this medication may lead to a reduction in blood glucose. • If you notice low blood glucose levels, promptly inform your doctor. • In case of insulin therapy, consult your doctor to adjust the dose in case of hypoglycemia.
If you are unable to eat due to conditions such as fever, infection, poor appetite, nausea, vomiting or diarrhea, avoid this medication.	• Follow the "sick-day rule". • You can restart the medication once you are able to consume food and fluids. • If you persistently feel unwell, contact your doctor, as you may require blood tests to rule out any complications.
If you have a scheduled surgery that necessitates a period of fasting or "nothing by mouth" (This means refraining from eating or drinking anything for several hours before the scheduled surgical procedure) discontinue this medication.	Discontinue this medication 3 to 4 days prior to minimize the risk of postoperative ketoacidosis (blood becomes acidic due to ketone bodies) and UTIs.
Refrain from eating extremely low-carbohydrate and ketogenic diets	They may elevate the risk of diabetic ketoacidosis.
If you observe a wound, ulcer, or skin breakdown on your feet or legs, consult your doctor	Refrain from taking the medication and promptly notify your doctor.
If you encounter pain or a burning sensation during urination, consult your doctor	Notify your doctor, as further evaluation and potential medication may be necessary.
If you observe redness or itching in the genital area or experience a foul-smelling vaginal or penile discharge, consult your doctor	Inform your doctor. You may require a topical or oral medication to address a potential underlying infection.
Maintain good perineal hygiene	• Keep the genital area clean. • Washing of genital organs followed by urination or defecation. • Use of routine hygienic wipes or sprays • Women should be advised to wash from front to back. • Uncircumcised males should retract the prepuce before washing. • Use clean water for washing or mild soap if required. • Alcohol-based disinfectant should not be used for washing.

Giguère et al[44], in their systematic review, found that while these materials can lead to modest improvements in the practices of health care professionals, their effect on patient outcomes remains unclear and warrants further investigation.

Conclusion

In conclusion, addressing SGLT2i adherence in India requires tailored educational practices. The multifaceted approach, encompassing the use of technology, personalized counseling and community engagement, offers a promising avenue for enhancing medication adherence. Moreover, the study underscores the pivotal role of patient education in overcoming clinical inertia, as evidenced by its positive impact on patients' acceptance and understanding of SGLT2i therapy. QR-based patient education in regional languages, prescription tips and printed literature can enhance adherence and acceptance. By prioritizing patient education, health care providers can bridge gaps in awareness, empower individuals in their diabetes management journey and foster a proactive approach to treatment adherence.

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