

Drug Utilization Patterns Among Complementary and Alternative Medicine Users and Non-Users with Type 2 Diabetes Mellitus

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Received: 14th June, 2026; Revised: 20th July 2026; Accepted: 20th August, 2026; Available Online: 05th September 2026

ABSTRACT

Background: Complementary and alternative medicine (CAM) is increasingly used alongside conventional treatment among patients with type 2 diabetes mellitus. Comparative assessment of drug utilization among CAM and non-CAM users can provide insight into differences in conventional antidiabetic treatment patterns.

Methodology: A prospective observational study was conducted in a tertiary care teaching hospital. All details of patient were recorded in Case Record Form (CRF) which included diabetes-related information. Medication details were collected from patients' prescriptions. The collected prescription data were analyzed using the WHO Core Prescribing Indicators for antidiabetic drugs among the study participants.

Result: The use of oral antidiabetic drug groups was comparable between the CAM and non-CAM groups. Biguanides were the most commonly used drugs in both groups (93.7% vs. 94.9%), followed by sulphonylureas (75.9% vs. 76.7%). However, insulin use was significantly lower in the CAM group than in the non-CAM group (6.9% vs. 14.4%; $p=0.029$).

Conclusion: The study underscores the importance of systematic evaluation of drug utilization and continued monitoring of patients who combine CAM with conventional antidiabetic treatment.

Keywords: Type 2 diabetes mellitus, Complementary and alternative medicine(CAM), Drug utilization; Antidiabetic drugs, Insulin therapy.

How to cite this article: Singh S, Yadav AK, Rathore A, Gupta S, Drug Utilization Patterns Among Complementary and Alternative Medicine Users and Non-Users with Type 2 Diabetes Mellitus *Int J Drug Deliv Technol.* 2026; 16(7): 1613-1618. DOI: 10.25258/ijddt.16.7.176

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by elevated blood glucose levels, resulting from insulin deficiency, resistance, or both around 537 million adults are suffering from diabetes which is predicted to increase about 643 million by 2030 and 783 million by 2045 [1]. India being an epicentre with 73 million diabetic patients after China according to International Diabetes Federation in 2017. By 2045 this figure will be doubled by 134 million [2, 3].

Drug utilization research has been defined by the World Health Organization (WHO) in 1977 as “study of marketing, distribution, prescription and use of drugs in society with special emphasis on the resulting medical and social and economic consequences” [4]. Drug utilization studies provide insight into drug-use and prescribing patterns. Their main aim is to promote the rational, appropriate, cost-effective, and safe use of medicines.

CAM includes two words, “complementary” and “alternative” [5]. Complementary treatments are utilized concurrently with conventional medicine to enhance overall care and improve patient outcomes. Conversely,

alternative treatments are employed as substitutes for conventional approaches. Common CAM therapies include herbal medicines, dietary supplements, yoga, meditation, acupuncture, Ayurveda, homeopathy, and spiritual practices. In type 2 diabetes, they are often used alongside conventional treatment for glycemic control, symptom management, and overall well-being [6].

Diabetes mellitus is a chronic metabolic disorder that often requires lifelong pharmacological therapy and comprehensive lifestyle modification to achieve optimal glycemic control and prevent long-term complications. In addition to conventional antidiabetic medications, many patients use complementary and alternative medicine (CAM) either as an adjunct to or substitute for standard treatment. The concurrent use of CAM with prescribed medications has raised concerns regarding potential herb–drug interactions, medication adherence, treatment outcomes, adverse drug reactions, and unnecessary polypharmacy.

Drug utilization studies comparing CAM users and non-CAM users provide valuable insights into differences in prescribing patterns, medication burden, and the rational use of medicines in these populations. Such evaluations

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can help identify potential safety concerns, promote evidence-based prescribing, and facilitate better communication between healthcare providers and patients regarding CAM use. Therefore, assessing drug utilization using WHO prescribing indicators among diabetic patients who use CAM and those who do not is important for evaluating prescribing practices and optimizing the quality and safety of diabetes management.

MATERIALS & METHODS

Type of Study

A prospective observational study was conducted in a tertiary care teaching hospital.

Study Participants

All patients of type 2 diabetes mellitus ≥ 18 years of age were included. Patient with type 2 Diabetes mellitus with complications and those who refuse to participate in the study were excluded. All patients of type 2 diabetes mellitus attending the endocrine department for routine follow-up visits during the study period were included from July 2022 to February 2023.

Sample size

By following using the given formula **sample size** for the study was calculated.

$n = z^2pq / d^2$ where n = number of sample, z = 1.96% for 95% confidence level, p = proportion of the prevalence, d = precision of the prevalence estimate (5%)

The prevalence of 39% based on previous study is used to calculate sample size with confidence level 95%, response distribution 50% and margin of error 5% recommended sample size is 377 [7]. Allowance of 10% for missing, losses to follow up. Corrected sample size obtained is 414. Total sample collected was 436 patients and after lost to follow up 215 Non- CAM and 174 CAM patients were analyzed.

Ethical Consideration

The study was conducted after approval from Institutional Human Ethics Committee of Geetanjali Medical College & Hospital dated 26th March 2022. A written informed consent for participation in the study was obtained from all the participants before commencement of the study. The participants were informed about purpose, procedure and their rights. They were also assured that information will be strictly confidential.

Data Collection

All details of patient were recorded in **Case Record Form (CRF)** which included diabetes-related information. Medication details were collected from patients' prescriptions. Information regarding all prescribed medications was recorded, including number of antidiabetic medications prescribed, the generic or brand name of the drug and route of administration, Details of fixed-dose combination (FDC) therapies were also documented. The collected prescription data were analyzed using the WHO Core Prescribing Indicators for antidiabetic drugs among the study participants.

Statistical Analysis

The collected data was entered into a Microsoft Excel sheet by the investigator on the same day to minimize any potential data entry bias. Discrete or qualitative data were presented as proportions, and the significance of differences in proportions was evaluated using the chi-square test. A 95% confidence level i.e. p value < 0.05 was considered to be statistically significant.

RESULT

The use of oral antidiabetic drug groups was comparable between the CAM and non-CAM groups. Biguanides were the most commonly used drugs in both groups (93.7% vs. 94.9%), followed by sulphonylureas (75.9% vs. 76.7%).

Table 1: Comparison of Drug Groups Usage Between CAM and Non-CAM Groups

Drug groups	CAM (n=174)		Non- CAM (n=215)		p value
	Number	Percentage	Number	Percentage	
Biguanides	163	93.7	204	94.9	0.771
Sulphonylureas	132	75.9	165	76.7	0.933
α -glucosidase inhibitors	105	60.3	120	55.8	0.426
Dipeptidyl peptidase 4 inhibitors	97	55.7	101	47	0.106
Thiazolidinediones	7	4	4	1.9	0.331
Sodium-glucose cotransporter 2 (SGLT2) inhibitors	68	39.1	82	38.1	0.932
Insulin	12	6.9	31	14.4	0.029*

* P value > 0.05 is considered as statistically significant

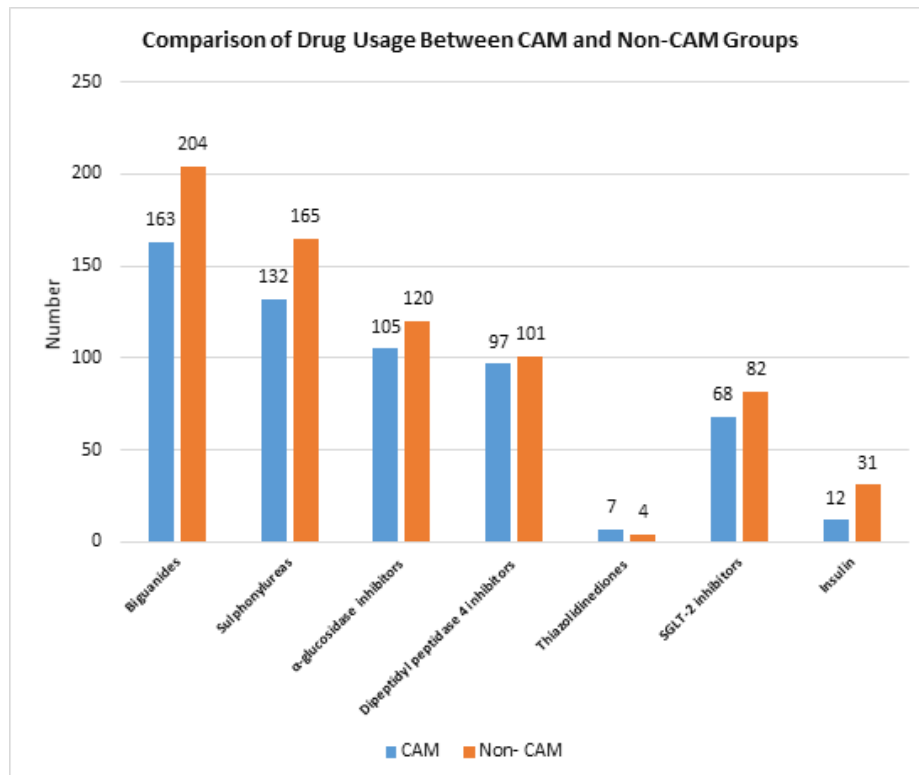


Figure 1: Comparison of Drug Groups Usage Between CAM and Non-CAM Groups

Drug use was comparable between the CAM and non-CAM groups. Metformin was the most commonly used drug in both groups (93.7% vs. 94.9%), followed by glimepiride (73.0% vs. 74.0%) and voglibose (59.2% vs. 52.1%). No significant between-group differences were observed for any individual oral antidiabetic drug,

including metformin, sulphonylureas, α-glucosidase inhibitors, thiazolidinediones, SGLT2 inhibitors, or DPP-4 inhibitors (all $p > 0.05$). However, insulin use was significantly lower in the CAM group than in the non-CAM group (6.9% vs. 14.4%; $p = 0.029$).

Table 2: Comparison of Drug Usage Between CAM and Non-CAM Groups

Drugs	CAM		Non- CAM		p value
	Number	Percentage	Number	Percentage	
Biguanides					
Metformin	163	93.7	204	94.9	0.771
Sulphonylureas					
Glimepiride	127	73	159	74	0.921
Gliclazide	5	2.9	6	2.8	0.796
α-glucosidase inhibitors					
Acarbose	2	1.1	8	3.7	0.204
Voglibose	103	59.2	112	52.1	0.194
Thiazolidinediones					
Pioglitazone	7	4	4	1.9	0.331
Sodium-glucose cotransporter 2 (SGLT2) inhibitors					
Empagliflozin	2	1.1	0	-	0.388
Dapagliflozin	66	37.9	82	38.1	0.95
Dipeptidyl peptidase 4 inhibitors					
Sitagliptin	72	41.4	76	35.3	0.266
Viladgliptin	19	10.9	23	10.7	0.925
Linagliptin	3	1.7	0	-	0.177
Tenaligliptin	3	1.7	2	0.9	0.811
Insulin	12	6.9	31	14.4	0.029*

*P value > 0.05 is considered as statistically significant

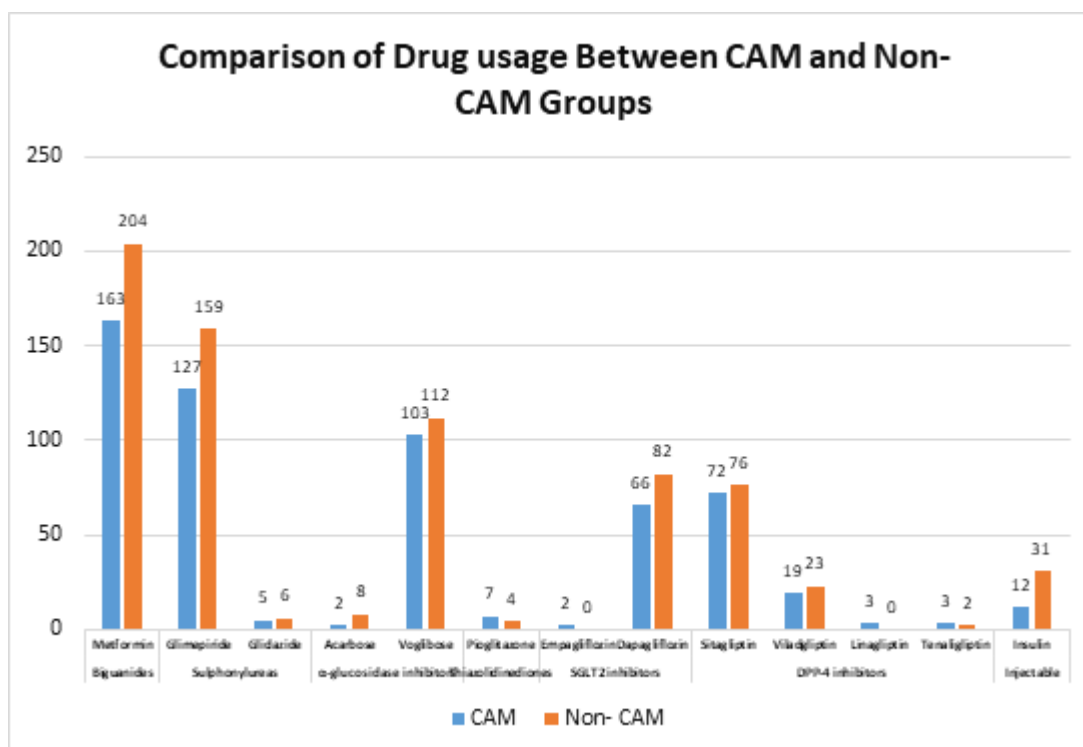


Figure 2: Comparison of Drug usage Between CAM and Non-CAM Groups

Table 3: WHO core indicators for antidiabetic medications

S. No.	Drug use indicators for antidiabetic medications	
1	The average number of antidiabetic drugs per prescription	3.31
2	Percentage of drugs prescribed by generic name	1.53%
3	Percentage of encounters with injectable drug prescribed	3.33%
4	The percentage utilization of scheduled drugs from the NLEM	56.17%
5	Average number of FDCs per prescription	1.4

In current study, the average number of antidiabetic drugs prescribed per encounter was 3.31. Only 1.53% of the drugs were prescribed by their generic names. Injectable antidiabetic medications were prescribed in 3.33% of encounters. Regarding essential drug utilization, 56.17% of the antidiabetic drugs were from the NLEM. Additionally, the average number of FDCs per prescription was 1.4.

DISCUSSION

The present study assessed the pattern of antidiabetic drug utilization among patients with type 2 diabetes mellitus using CAM and those receiving conventional treatment alone.

Biguanides were the most commonly prescribed among CAM users and Non-CAM users, which aligns with findings from Desai et al. Metformin and glimepiride emerged as the most frequently prescribed medications in both the CAM and non-CAM groups, consistent with established treatment guidelines and previous research [8, 9].

CAM users exhibited a slightly higher preference for α -glucosidase inhibitors and DPP-4 inhibitors, which may indicate a tendency towards safer therapies aimed at managing postprandial blood sugar levels. DPP-4

inhibitors, particularly sitagliptin, were utilized slightly more by CAM users (41.4% compared to 35.3%), indicating a higher acceptance of newer oral medications. Among the α glucosidase inhibitors, voglibose was favoured over acarbose, aligning with the observations made by Lee et al. due to its superior tolerance [10].

Thiazolidinediones remained infrequently prescribed, reflecting global usage trends. In contrast the study conducted by Mandal et al. highlighted an interesting trend showing an increased prescribing rate of thiazolidinediones (TZDs) among healthcare providers [11].

The use of SGLT2 inhibitors, especially dapagliflozin, was comparable in both groups, corroborating the findings of Wilding et al. regarding its widespread clinical use [12].

Notably, insulin usage was lower among CAM users, as compared to in Non-CAM users. Study conducted by Ogbera et al. insulin usage did not differ between CAM users from non-CAM users. Some CAM modalities may be perceived by patients as supporting glycaemic control, which could potentially reduce the need for insulin [13]. These trends reveal similar medication choices while also highlighting subtle distinctions in therapeutic preferences between CAM and non-CAM users.

The present study reveals several significant insights regarding the use of antidiabetic medications. Average Number of Antidiabetic Drugs per Prescription (3.31) was more as compared to the results reported by Agarwal et al. and Hannan et al., which found an average of 1.4 and 1.71 respectively [14,15]. The current study's average reflects common polypharmacy patterns, although clinical guidelines typically advise reducing polypharmacy whenever feasible.

The relatively low proportion of drugs prescribed by generic name (1.53%) is consistent with the findings reported by Gorantla et al. and Kaur et al. indicating a preference for prescribing branded formulations in the study setting [16,17]. The fact is, generic medications can provide the same treatment and benefits as brand-name drugs, but at a fraction of the cost. Prescribing more of them is a simple step that could have a big positive impact.

The low proportion of encounters with injectable drugs (3.33%) is consistent with the findings reported by Alqurashi et al. but falls short of the global prevalence of injectable therapies in diabetes management, which ranges from 15-20% as noted by Cambell et al. [18, 19]. This rate is notably lower compared to the findings of the Mandal et al. study, potentially due to the increased prevalence CAM therapies in managing diabetes [11]. As patients turn to CAM approaches to control their blood sugar levels, there may be a reduced need for prescribing insulin and other injectable medications.

Utilization of drugs from the National List of Essential Medicine (NLEM) (56.17%) corresponds with the findings of Jhaj et al, who reported a similar utilization rate, indicating compliance with essential drug recommendations, although there remains potential for enhancement. NLEM is a vital resource that identifies the most critical, safe, and cost-effective medicines for addressing the primary healthcare needs of the population [20].

A comprehensive analysis of prescriptions in our study indicated an average of 1.4 FDCs per prescription which is lower than Gupta et al. a meticulous investigation conducted by Pushpa et al. unveiled that an alarming 16% of all medications prescribed were in the form of FDCs [21, 22]. When patients are concurrently using herbal/CAM products, clinicians may prefer individual conventional agents to facilitate monitoring and modification of therapy.

CONCLUSION

The present drug utilization study provided an overview of antidiabetic prescribing patterns among CAM and non-CAM users with type 2 diabetes mellitus. Oral antidiabetic drugs, particularly metformin-based regimens, were commonly utilized, while insulin use was comparatively lower among CAM users. The study underscores the importance of systematic evaluation of drug utilization and continued monitoring of patients who combine CAM with conventional antidiabetic treatment.

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