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ASSESSMENT OF ANTI-DIABETIC DRUG UTILIZATION USING WHO PRESCRIBING INDICATORS AND ATC/DDD METHODOLOGY WITH EVALUATION OF A PATIENT INFORMATION LEAFLET IN TYPE 2 DIABETES MELLITUS PATIENTS

Dr. Asha Mathew[1], Bindhu Y. M.[2], Jannie S. Jacob*[2], Kushal C. B.[2], Tasmiya D.[2], Dr. Yeshavanth G.[3]

[1]Assistant Professor, Bapuji Pharmacy College, Davangere.

[2]Pharm D Interns, Bapuji Pharmacy College, Davangere.

[3]Professor and Head, Department of General Medicine, SSIMS & RC, Davangere.

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***Corresponding Author: Jannie S. Jacob**
Pharm D Interns, Bapuji Pharmacy College, Davangere.
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ABSTRACT

Background and objectives: Rational use of antidiabetic medicines is important in patients with diabetes, particularly when comorbidities increase treatment complexity. This study assessed antidiabetic drug utilization and prescribing patterns and evaluated whether a patient information leaflet (PIL) improved knowledge, attitude, and practice (KAP) related to diabetes and its complications. **Methods:** A prospective observational study was conducted among 155 adults with diabetes and comorbidities admitted to a tertiary care hospital over six months. We obtained demographic and prescription data from case records and treatment charts. Antidiabetic utilisation was examined using the Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) approach, and prescribing patterns were assessed using World Health Organization (WHO) core prescribing indicators. A PIL on diabetes and its complications was developed, translated into Kannada, validated, and assessed for readability. Data were analysed using IBM SPSS Statistics version 28; paired t-test and Pearson correlation were used, with $P<0.001$ considered statistically significant. **Results:** Among the 155 participants, 86 (55.4%) were men and 69 (44.5%) were women; 47 (30.3%) were aged 61–70 years. Hypertension was the most frequently reported comorbidity (100/155, 64.5%). Oral hypoglycaemic agents accounted for 126/223 (56.5%) antidiabetic drugs, and insulin for 97/223 (43.4%). Dapagliflozin and regular insulin were the most frequently recorded agents within their respective groups. Brand-name prescribing accounted for 154/170 (90.5%) drugs, while generic prescribing accounted for 16/170 (9.4%). The reported WHO indicators included a mean of 15 medicines per encounter, generic prescribing in 8.08%, antibiotic use in 83.22% of encounters, injection use in 98.06%, and prescribing from the essential medicines list in 50.38%. Among 155 prescriptions assessed for DDD pattern, 118 (76.12%) had a DDD ratio <1, 20 (12.9%) had a ratio of 1, and 17 (10.96%) had a ratio >1. Mean KAP scores increased from 2.57 to 4.66 for knowledge, 2.96 to 4.69 for attitude, and 2.96 to 4.62 for practice after the PIL intervention ($P<0.001$ for each). **Interpretation and conclusions:** The study identified substantial variation from the prescribing patterns expected by WHO core indicators, alongside extensive brand-name prescribing and frequent use of antibiotics and injections. The PIL was associated with marked short-term improvement in diabetes-related KAP scores and was well accepted by participants. Larger, multicentre studies with longer follow-up and clinical outcomes are needed to determine whether these improvements are sustained and translate into better diabetes control.

KEYWORDS: *Diabetes mellitus; Drug utilization; Patient education; Patient information leaflets; Prescribing patterns.*

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterised by persistent hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. The condition represents a major and growing health concern and is frequently associated with other chronic diseases, particularly hypertension and cardiovascular disorders. **(1)** The presence of multiple comorbidities often results in the use of several medications, making evaluating prescribing practices and medication utilisation important in routine diabetes care.[1]

Pharmacological management of diabetes involves oral antidiabetic agents and insulin, used alone or in combination, depending on the patient's clinical status and therapeutic needs. Studies in different healthcare settings have shown considerable variation in the choice and use of antidiabetic medicines.[1] More recent studies have also reported changing prescribing patterns, with newer drug classes increasingly being incorporated into diabetes treatment.[2,3,4] Understanding these patterns is important for evaluating whether medicines are being used appropriately and consistently with rational prescribing principles.

Drug utilisation research provides a systematic approach to examining the prescribing, dispensing and use of medicines in clinical practice.[5] The Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) methodology provides a standardised framework for quantifying drug utilisation and allows comparison of medicine use between different populations and healthcare settings.[5] Previous studies using ATC/DDD methodology have demonstrated differences between prescribed daily doses and standard defined daily doses for several antidiabetic medicines, highlighting the usefulness of this approach in evaluating drug utilisation.[5]

In addition to drug utilisation, assessment of prescribing quality is important for promoting rational medicine use. The World Health Organization (WHO) prescribing indicators provide standardised measures for evaluating prescribing practices, including the number of medicines prescribed per encounter, use of generic names, use of antibiotics and injections, and prescribing from an essential medicines list.[6] Studies assessing these indicators have identified variations in prescribing practices and have emphasised the need for continuous monitoring to promote rational and cost-effective medicine use.[6,7]

Patient-related factors are another important component of diabetes management. Adequate knowledge regarding the chronic nature of diabetes, its risk factors, complications, medication use, diet, physical activity and self-monitoring can support appropriate self-care. Health education interventions have been shown to improve diabetes-related knowledge, attitudes and practices among patients.[8] Patient counselling has similarly been associated with improvements in knowledge, medication adherence and quality of life.[9,10]

Patient Information Leaflets (PILs) provide a simple and accessible method of communicating disease-related information to patients. Previous research has demonstrated that appropriately developed and readable PILs can improve patients' knowledge about diabetes and encourage greater confidence in self-management.[11,12] Educational information provided through PILs may therefore complement routine clinical care by reinforcing information regarding the disease, treatment, lifestyle modification and prevention of complications.[12]

Although several studies have examined antidiabetic drug utilisation and prescribing patterns, there remains a need for studies that evaluate drug utilisation, prescribing practices and patient education within the same clinical setting. The

present study was therefore undertaken to assess the utilisation pattern of antidiabetic medicines using the ATC/DDD methodology, evaluate prescribing practices using WHO prescribing indicators, and develop and assess the impact of a PIL on patients' knowledge, attitude and practices regarding diabetes and its complications.

MATERIALS & METHODS

Study design and ethical considerations: A prospective observational study was conducted among adult inpatients with diabetes mellitus at S.S. Institute of Medical Sciences and Research Centre (SSIMS&RC), Davangere, India, over a period of six months. The study assessed antidiabetic drug utilisation and prescribing practices. Also, it evaluated the effect of a patient information leaflet (PIL) on patients' knowledge, attitude, and practices related to diabetes mellitus and its complications.

Ethical approval and consent: Ethical approval was obtained from the Institutional Ethics Committee before commencement of the study. The purpose and procedures of the study were explained to eligible participants, and written informed consent was obtained before their enrolment. Patient privacy and confidentiality were maintained throughout the study.

Study population and sample size: The study population comprised adult inpatients with diabetes mellitus admitted to SSIMS&RC Hospital during the study period. A total of 155 participants were included. The sample size was estimated using a reported prevalence of high risk of diabetes mellitus in India of 11.4%, with an assumed margin of error of 5%. The calculated minimum sample size was 153, and the final sample was increased to 155 participants.

Inclusion criteria: Participants were eligible if they were willing to participate, were aged 20 years or older, and had a history of diabetes mellitus for more than six months.

Exclusion criteria: Patients who were unwilling to participate, those diagnosed with diabetes mellitus for less than six months, and those with gestational diabetes mellitus were excluded from the study.

Study procedure

The study was conducted in three phases. Initially, the literature was reviewed, and the study tools were developed and validated. After obtaining informed consent, demographic details, medical history, diagnosis, and treatment information were collected from patient records, treatment charts, and interviews. Antidiabetic drug utilisation was assessed using the ATC/DDD methodology, and prescribing practices were evaluated using WHO prescribing indicators.

For the educational intervention, a patient information leaflet (PIL) on diabetes mellitus and its complications was developed, translated into Kannada, and validated by healthcare professionals. Participants completed a pre-intervention questionnaire assessing their knowledge, attitude, and practices (KAP), received the PIL with an explanation, and subsequently completed the post-intervention questionnaire. The collected data were coded, entered into Microsoft Excel, and analysed statistically.

Interpretation of statistics

Statistical analysis was performed using IBM SPSS Statistics version 28. Categorical variables were expressed as frequency and percentage, whereas continuous variables were presented as mean ± standard deviation (SD). Pre- and

post-intervention scores were compared using the paired *t-test*, and correlations between variables were assessed using Pearson's correlation. A *P* value <0.001 was considered statistically significant.

RESULTS

1. Demographic and Clinical Characteristics of Patients

A total of 155 patients with diabetes mellitus were studied. Of these, 55.4% were male patients and 44.5% were female. The age group with the highest number of patients was 61-70 years, accounting for 30.3% of the study population. The 51-60 years age group was the next largest group, with 28.3% of patients. The most common co-morbid conditions were hypertension (100 patients), the number of patients with cardiovascular disease was 69 and renal diseases (35 patients).

Most patients stayed in the hospital for less than five days, which accounted for 65.1% of the participants. Regarding the duration of diabetes, the largest group had been living with the condition for more than 6 months to 5 years, accounting for 42.5%. This was followed by patients with a duration of 6–10 years, who accounted for 33.5%. Monotherapy was prescribed more often than combination therapy. Looking at the number of anti-diabetic drugs prescribed, two-drug therapy was the most common pattern at 36.1%, followed by single-drug therapy at 32.2%.

2. Anti-diabetic Drug Utilization Pattern

There was a significant difference between brand-name prescribing and generic prescribing. Brand-name prescriptions made up 90.5% of all prescriptions, while generic-name prescriptions only made up 9.4%. The number of prescriptions for anti-diabetics was 223. Out of these, 56.5% of the prescriptions were for oral hypoglycaemic agents, and 43.4% were insulin.

The most common oral hypoglycaemic agent used was SGLT-2 inhibitors (38.2%). 22% of patients were prescribed biguanides, and 22% of patients were prescribed DPP-4 inhibitors. The sulfonylurea group comprised 13.2% of prescriptions, whereas the use of the thiazolidinedione group and alpha-glucosidase inhibitors and glinide derivatives was less frequent. The most prescribed insulin preparations were short-acting insulin (67.7%), followed by long-acting insulin (21.2%) and intermediate-acting insulin (8.6%). Dapagliflozin (ATC code: A10BK01) was the most frequently used oral antidiabetic drug. Regular insulin (ATC code: A10AB01) was the insulin preparation used most often. The class size distribution is shown in Table 1 and Figure 1.

Table 1: Distribution of anti-diabetic drug classes and frequently prescribed drugs with corresponding ATC classification.

DRUG CATEGORY	DRUG CLASS	FREQUENTLY PRESCRIBED DRUG (ATC CODE)	FREQUENCY (n)	PERCENTAGE (%)
Oral hypoglycemic agents (n=68)	**SGLT-2 inhibitors**	Dapagliflozin (A10BK01) Empagliflozin (A10BK03)	25 1	38.2
	DPP-4 inhibitors	Linagliptin (A10BH05) Sitagliptin (A10BH01) Vildagliptin (A10BH08) Teneligliptin(A10BH0)	10 3 3 1	22.0
	Biguanides	Metformin (A10BA02)	15	22.0
	Sulfonylureas	Gliclazide (A10BB09) Glimepiride (A10BB12)	5 4	13.2
	Thiazolidinediones	Pioglitazone (A10BG03)	1	1.47
	Alpha-glucosidase	Acarbose (A10BF01)	1	1.47

	inhibitors			
	Glimin derivatives	Imiglimin	1	1.47
Insulin therapy (n=127)	**Short-acting insulin**	Regular insulin (A10AB01)	86	67.7
	Long-acting insulin	Insulin glargine (A10AE04) Insulin detemir (A10AE05)	26 1	21.2
	Intermediate-acting insulin	Insulin isophane (A10AC01) Insulin lente (A10AC02)	10 1	8.6
	Rapid-acting insulin	Insulin Actrapid (A10AB01) Insulin aspart (A10AB05)	2 1	2.36

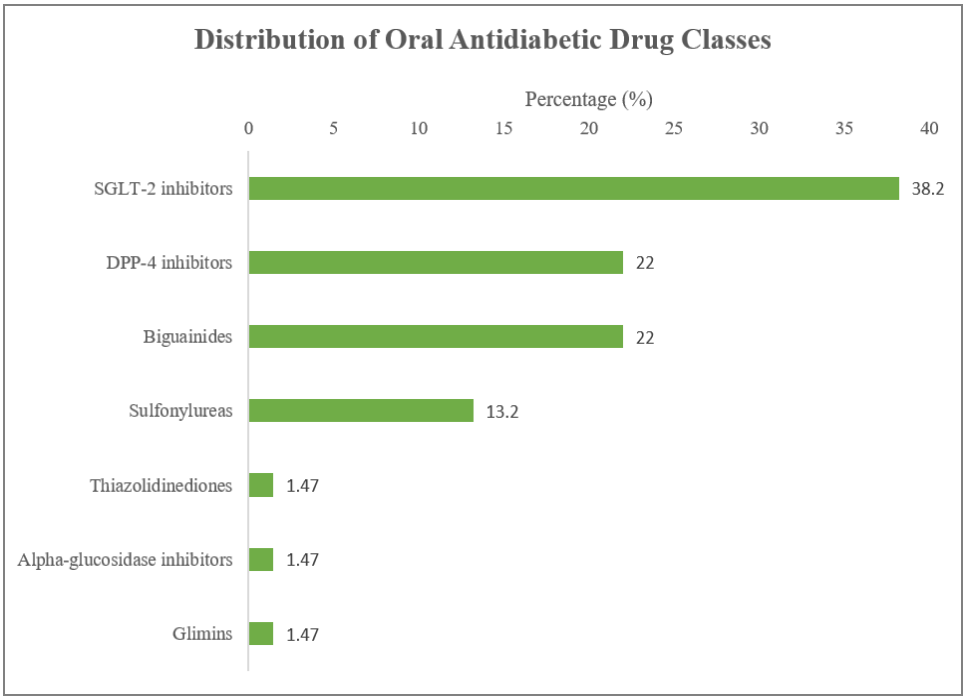

Fig. 1: Distribution of oral antidiabetic drug classes among the study population.

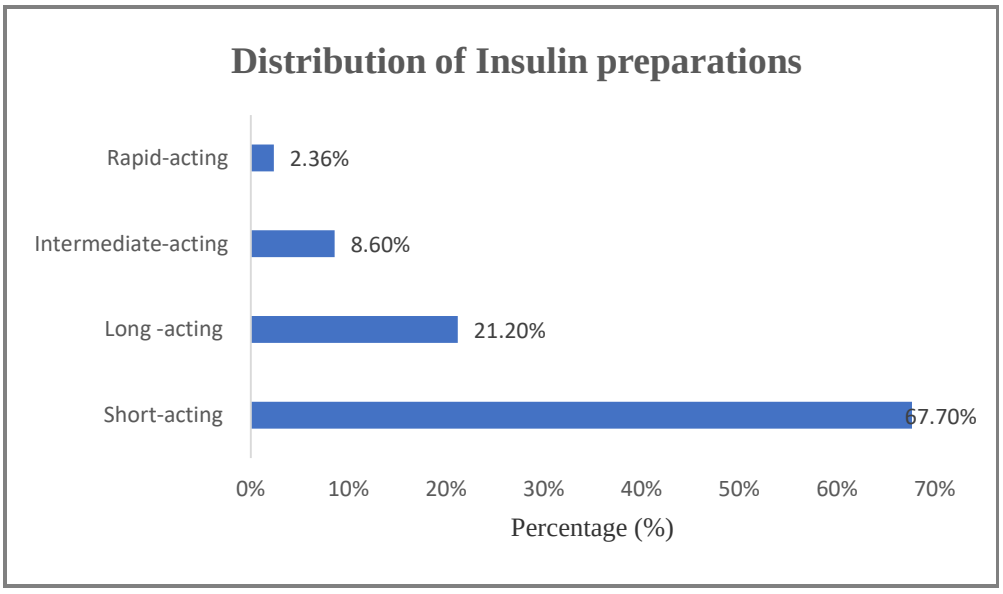

Fig. 2: Distribution of insulin preparations by duration of action among the study participants.

3. Defined Daily Dose (DDD) Analysis

The average defined daily dose (DDD) of patients on monotherapy was 87.467. For combination therapy, these values were a little higher at 88.434. When all anti-diabetic therapy was considered together, the average DDD was 87.9. Most prescriptions, accounting for 76.12%, had DDD values below 1. DDD values equal to the standard DDD were seen in 12.9% of prescriptions, while 10.96% had values above the standard DDD.

Table 2: Defined daily dose (DDD) analysis among anti-diabetic treatment patterns and prescriptions.

PARAMETER	CATEGORY	VALUES
Average DDD	**Monotherapy** **Combination therapy** **Overall average DDD**	87.467 88.434 87.900
Distribution of DDD value	**DDD < 1** **DDD = 1** **DDD > 1** **Total**	118 (76.12%) 20 (12.90 %) 17 (10.96%) 155 (100%)

3. WHO Prescribing Indicators

The WHO prescribing indicators showed that an average of 15 medicines were prescribed per encounter. The high number of medicines may be related to the presence of several co-morbid conditions among the hospitalized patients. Generic prescribing was only 8.08%, with brand-name prescribing being more common in the tertiary care setting. Antibiotics were prescribed in 83.22% of encounters, and injections were prescribed in 98.06%. The use of antibiotics may be related to the treatment of infections, while the high use of injections may be linked to insulin administration and the need for injectable treatment during acute inpatient care. Medicines included in the essential medicines list accounted for 50.38% of the prescriptions. The findings are shown in Table 3 and Figure 2.

Table 3: Analysis of prescriptions using WHO prescribing indicators.

WHO PRESCRIBING INDICATORS	OBSERVED VALUE	OPTIMAL VALUE
Average number of medicines per encounter	15	1.6–1.8
% of Medicines prescribed by generic name	8.08%	100%
% of Encounters with an antibiotic prescribed	83.22%	20–26.8%
% of Encounters with an injection prescribed	98.06%	13.4–24.1%
% of Medicines prescribed from the essential medicines list	50.38%	100%

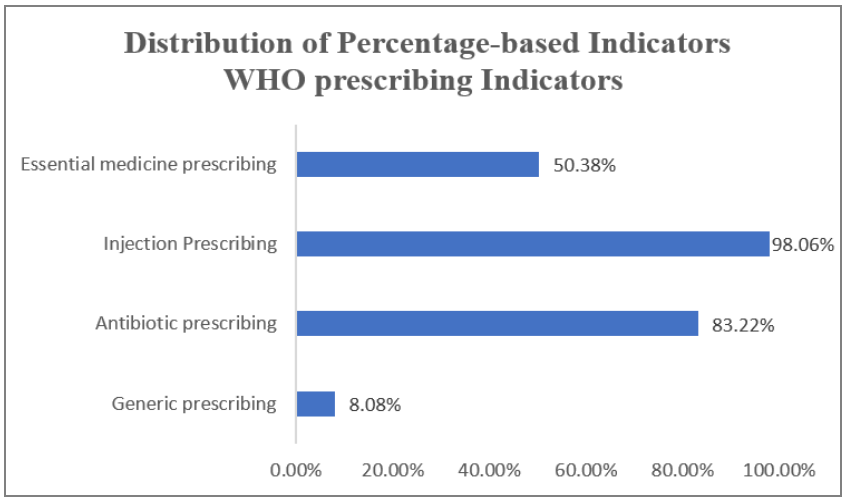

Fig. 3: Distribution of percentages based on WHO prescribing indicators, showing observed proportions of generic prescribing, antibiotic prescribing, injection prescribing and prescribing from the essential medicine list.

4. Effect of Patient Information Leaflet (PIL) on Knowledge, Attitude and Practice

The educational intervention was done in the form of a patient information leaflet (PIL) to enhance patients' knowledge, attitude, and practices on diabetes and prevention of diabetes complications. After the intervention, the patients' knowledge of diabetes as a chronic disease, its complications, symptoms, risk factors, and diagnosis increased. There were also improvements in their attitudes towards the long-term management of diabetes, dietary changes, physical activity, regular blood sugar monitoring, and early seeking of medical advice. In addition to changes in habits, changes were seen in daily routines, which consisted of a well-balanced diet, adequate sleep and rest, physical activity, healthy behaviours, proper food, foot care, and medication. Table 4 shows the pre-test and post-test scores.

A paired t-test revealed that there was a statistically significant difference between the baseline and post-intervention scores on all three domains of KAP, $p<0.001$. The mean knowledge score increased from 2.57 to 4.66 following the intervention. The mean attitude score increased from 2.96 to 4.69, and the mean practice score increased from 2.96 to 4.62. Better scores indicate better awareness and self-care of patients in preventing diabetic complications as a result of piloting the counsellors and awareness sessions.

Table 4: Pre- and post-intervention comparison of knowledge, attitude, and practice with paired t-test analysis.

PARAMETERS		SL. NO	TOTAL SCORE	MEAN	Std. DEVIATION	MEAN DIFFERENCE	Std. Deviation DIFFERENCE	PAIRED t- TEST	P-VALUE	REMARKS
KNOWLEGDE	PRE	155	399	2.57	0.92276156	-2.09	0.0912	-298.57	P<0.001	SIGNIFICANT
	POST	155	723	4.66	0.83149023					
ATTITUDE	PRE	155	460	2.96	0.8478 6128	-1.73	0.048	- 576.6	P<0.001	SIGNIFICANT
	POST	155	728	4.69	0.7995 4154					
PRACTICE	PRE	155	460	2.96	0.83	-1.66	0.83	- 25.15	P<0.001	SIGNIFICANT
	POST	155	717	4.62	0					

5. Correlation Between Knowledge, Attitude and Practice

Pearson's correlation analysis of the post-test scores showed a weak negative relationship between knowledge and attitude, with $r= -0.090$ and $p<0.001$. Knowledge and practice showed a strong negative correlation, with $r= -0.768$ and $p<0.001$. A moderate negative correlation was found between attitude and practice, with $r= -0.529$ and $p<0.001$. The negative correlations may be related to differences between patients in terms of age, long-standing habits, and individual motivation. The correlation results are presented in Figure 4.

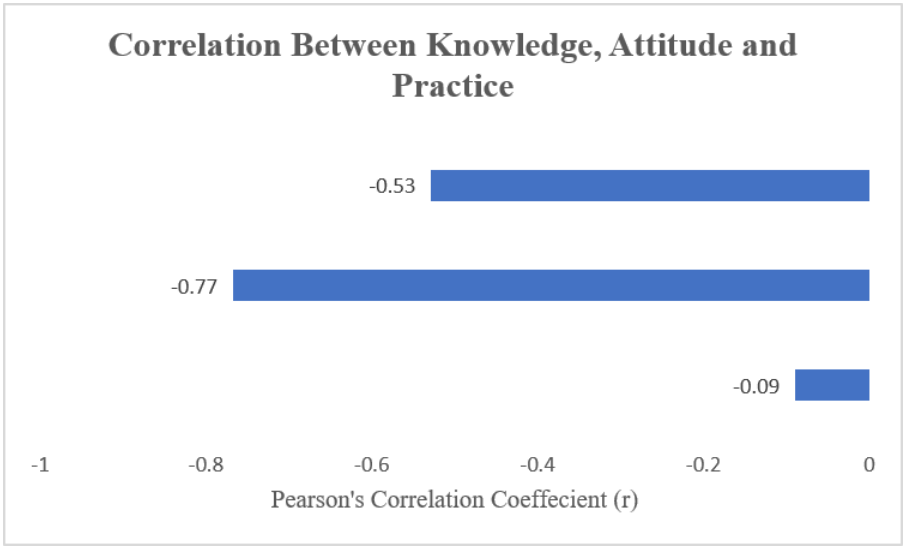

Fig. 4: Correlation between Knowledge, attitude, and practice scores.

7. Patient Feedback on the Questionnaire and PIL

All participants found the questionnaire readable and easy to understand. In the feedback on the PIL, 76.7% of the participants rated the material as "good". This suggests that most of the patients were comfortable with the educational material and found it useful.

DISCUSSION

Diabetes Mellitus (DM) is a chronic metabolic condition marked by increased blood glucose levels and abnormalities in the metabolism of proteins, fats, and carbohydrates due to deficiencies in insulin production, insulin action, or both [(1)]. Drug Utilization research helps to understand how certain medicines are being used by different groups of people based on their age, gender, or health conditions across hospitals and other parts of the healthcare system, which may help to amend the drug policy of a healthcare system. Information on drug utilization patterns can help design a drug policy and review the healthcare budget.[13]

In total, 155 patients were enrolled in the study, among whom 86 (55.4%) were males, and 69 (44.5%) were females. The male predominance seems to align with what **Rini Ponnachan *et al.*** [(1)] reported, and also with **Sandeep Lahiry *et al.***, who showed a higher number of male patients. As for age distribution, most of the patients were in the 61–70-year age group (30.0%), while the smallest proportion was seen in the 20–30-year age group (1.9%). Comparable results were noted by **Sandeep Lahiry *et al.***, where most participants were within the 60- 70-year age group, suggesting a higher prevalence of T2DM in older adults.[5]

Among the 155 study participants, a total of 290 comorbid conditions were identified. Hypertension was the most prevalent comorbidity (100), followed by cardiovascular diseases (69), renal diseases (35), respiratory diseases (25), thyroid disorders (8), and other comorbid conditions (53). These findings are consistent with those reported by **Mohd Mahmood *et al.*** [14] In their prospective observational study, they also identified hypertension and cardiovascular diseases as the most common comorbidities among patients with DM.

Among 155 participants, most patients (65.1%) had a hospital stay of less than 5 days, while 30.9% stayed for 6-10 days. Regarding diabetes duration, the majority (42.5%) had diabetes for > 6 months to 5 years, followed by 33.5% with a duration of 6-10 years. Of the 155 prescriptions, 125 were for monotherapy, and 97 were for combination therapy. Among the 155 participants, 50 (32.2%) were prescribed one medication, 56 (36.1%) were prescribed two medications, 31 (20%) were prescribed three medications, and 18 (11.6%) were prescribed more than four medications.

Out of 68 OHA prescriptions, SGLT-2 inhibitors were the most often prescribed, followed by metformin and DPP-4 inhibitors. In the case of 127 insulin prescriptions, short-acting insulin was the most frequently prescribed, followed by long-acting. Similar results about the use of metformin were also reported by **Sudha Vengurlekar *et al.*** [15]

The study findings revealed that the average DDD for monotherapy was 87.467, whereas combination therapy showed a slightly higher average DDD of 88.4344. This indicates that when two or more antidiabetic drugs were used together, the defined daily dose required was marginally higher compared to monotherapy. The overall average DDD was 87.9.

Among 155 prescriptions analysed, 76.1% had a DDD ratio of less than 1, indicating that the described daily dose was lower than the WHO-defined daily dose. Only 12.9 % of prescriptions had a DDD ratio equal to 1, reflecting adherence to the WHO-recommended DDD, while 10.9% had a ratio greater than 1, indicating doses exceeding the standard

DDD. Overall, the findings demonstrate that underdosing was the most common prescribing pattern, with comparatively fewer patients receiving doses that matched or exceeded the WHO-DDD.

The findings revealed that the average number of medicines prescribed per encounter was 15, which significantly exceeds the WHO-recommended value of 1.6–1.8, indicating a marked prevalence of polypharmacy in the study setting. Additionally, only 8.08% of medicines were prescribed by their generic name, well below WHO expectations, suggesting a strong bias toward brand-name prescribing. Alarmingly, 83.22% of encounters included an antibiotic prescription, raising concerns of potential overuse and contributing to antibiotic resistance. Furthermore, 98.06% of encounters involved an injection, far surpassing WHO recommendations, which points to possible irrational or unnecessary injection use. Finally, only 50.38% of medicines were prescribed from the essential medicines list (EML), indicating suboptimal adherence to national and international guidelines.

The study demonstrated that Patient Information Leaflets (PIL) significantly improved the knowledge, attitude, and practice (KAP) of diabetes patients regarding disease management and complications. Knowledge improved substantially, with increased awareness of diabetes as a chronic condition, its complications, risk factors, and symptoms. Attitude scores also demonstrated significant improvement, particularly in enhancing patients' understanding of the lifelong nature of Diabetes, the importance of maintaining a healthy diet and engaging in regular physical activity, the need for regular monitoring, limiting the consumption of sugary foods, and seeking timely medical care. Similarly, practice-related behaviours improved, including adherence to a healthy diet, regular physical activity, avoidance of harmful habits, routine foot care, and medication compliance. These findings indicate that structured educational interventions through PILs can effectively enhance patient understanding and self-management of diabetes, thereby reducing the risk of complications and improving long-term outcomes. Similar results were reported by **Nethaji Ramanilgam *et al.*,**[9] who found that pharmacist counselling significantly improved knowledge, attitude, practice, quality of life, and medication adherence among diabetes patients.

To conclude, the study provides valuable insights into drug utilization and prescribing patterns in diabetes management. A high prevalence of polypharmacy was observed, along with concerns regarding underdosing, low generic prescribing, and excessive use of antibiotics and injections, reflecting deviations from WHO prescribing standards. The study also demonstrated the effectiveness of patient information leaflets (PILs) in significantly improving patients' knowledge, attitude, and practice (KAP) towards diabetes and its complications. Enhanced awareness of disease management, lifestyle modifications, self-monitoring, and medication adherence was noted following the intervention. These findings highlight the importance of rational prescribing and structured patient education in improving therapeutic outcomes and reducing the burden of diabetes.

Declaration by Authors

Ethical approval: Approved

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