PRESCRIBING PATTERN OF ANTIDIABETIC DRUGS AND ITS ADHERENCE TO AMERICAN DIABETES ASSOCIATION GUIDELINES IN PATIENTS OF TYPE 2 DIABETES MELLITUS WITH AND WITHOUT CO-MORBIDITIES IN RURAL TERTIARY CARE HOSPITAL IN CENTRAL INDIA

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ABSTRACT

Objectives: (1) To assess the prescription patterns of antidiabetic drugs in Type 2 diabetes patients in Rural Central India. (2) To assess compliance with American Diabetes Association guidelines for the management of Type 2 diabetes. (3) To assess the clinical and demographic characteristics, such as age, gender, comorbidities, and lifestyle. (4) To assess glycemic control based on glycated hemoglobin (HbA1c) levels. (5) Determine the most commonly prescribed antidiabetic treatments and drug selection factors.

Methods: A retrospective observational study of 120 patients evaluated demographics, lifestyle characteristics, comorbidities, HbA1c, and prescribed antidiabetic treatments, with emphasis on guideline compliance.

Results: The majority of participants (70.87%) were aged 41–60 years, with a near-equal gender distribution. While 89.17% adhered to lifestyle modifications, 54.17% were overweight, and 12.50% were obese. Risk factors included smoking (35.83%) and alcohol consumption (14.17%). HbA1c levels indicated that 55% had moderate glycemic control (6.5–8), though 16.67% had levels above 10. Common comorbidities included hypertension (45.00%), dyslipidemia (35.00%), and cardiovascular disease (22.50%). The most frequently prescribed antidiabetic therapy was the fixed-dose combination of glimepiride and metformin (54%), with insulin therapy used in 30% of cases. Adherence to American Diabetes Association guidelines was high (90%), though 10% showed non-adherence due to patient refusal or off-guideline practices.

Conclusion: The study underscores the importance of holistic diabetes care, addressing lifestyle, pharmacological, and guideline adherence to improve outcomes.

Keywords: Guidelines, Oral anti-diabetic drugs, Fixed-dose combinations, Rural healthcare, Diabetes.

INTRODUCTION

Diabetes is a global disorder due to metabolism. It is marked by chronic higher blood glucose. This results from flaws in insulin exudation, action, or both. The International Diabetes Federation reported that, in 2021, 10.5% of adults had diabetes, which affected about 537 million adults. The new patients are predictable would surge to 783 million by 2044–2045 [1]. India, the "diabetes capital of the world," has 77 million diabetics. This number is predictable to exceed 100 million by the year 2030 [2]. The most prevalent type of diabetes is called type 2 diabetes mellitus (T2DM). It causes serious health problems and death due to complications. These include cardiovascular disease, renal impairment, ocular damage, and neuropathy. These complications harm patients' quality of life. They also raise healthcare costs and the economic burden [3].

Managing T2DM well requires lifestyle changes, patient education, and drugs. The treatment landscape has evolved significantly over the years. There are now more pharmacological options available. These include traditional therapies, such as metformin and sulfonylureas. They also include newer classes, such as glucagon-like peptide-1 (GLP-1) inhibitors and sodium-glucose cotransporter-2 (SGLT2) receptor agonists. Therapy has enhanced, but optimal glycemic management remains difficult, especially in resource-poor areas [4].

Guidelines are provided by the American Diabetes Association (ADA) to improve diabetic patient care worldwide. They are based on evidence. These guidelines stress therapy tailored to each patient. It should consider glycemic targets, comorbidities, hypoglycemia risk, and costs [5]. They also recommend lifestyle changes and careful use of drugs. This is to meet blood sugar targets and lower complication risks. Following these guidelines is crucial. It helps achieve optimal glycemic control and prevents long-term complications [6].

However, real-world adherence to ADA guidelines often varies due to a range of factors. In rural areas, challenges often lead to deviations from recommended practices. These include limited access to healthcare, low health literacy, and economic constraints [7]. Cost is a key factor in drug selection. It often limits the use of newer, more expensive therapies, such as GLP-1 inhibitors and SGLT2 receptor agonists. Furthermore, in resource-limited settings, healthcare providers may use traditional therapies. They are cheaper and more available, despite better options being indicated [8].

India faces unique challenges in managing diabetes, especially in rural areas. There, economic and infrastructure barriers exist. Studies show that T2DM is rising in rural India. It now affects 2–15% of people, depending on the region and population studied [9]. This shows the need for a tailored approach to diabetes care in rural areas. It should focus on cost-effective strategies and better access to healthcare. We must understand the prescribing patterns of anti-diabetic drugs. We should also evaluate adherence to ADA guidelines in such settings. This is a key to finding gaps and improving diabetes care [10].

This study aims to evaluate anti-diabetic drug prescriptions in a Rural Central India tertiary care hospital. It will assess their adherence to the ADA 2021 guidelines among T2DM patients, with and without

comorbidities. The study will analyze present practices to identify gaps. It aims to improve diabetes care in similar settings. The findings will add to the evidence on real-world diabetes management. They will highlight chances to improve treatment outcomes.

METHODS

We included 120 adult patients diagnosed with T2DM who attended the diabetes outpatient department of a rural tertiary care hospital. The sample size is calculated using the Daniel formula, and then prescription data are collected from the medical record section and analyzed.

The design for this study is retrospective observational. The study was conducted over a period of 20 months, ensuring adequate time for data collection and analysis to reflect real-world prescribing patterns in patients with type 2 diabetes mellitus.

Data collection focused on gathering information regarding demographics, medical history, coexisting conditions, and ongoing medication regimens. Prescribing patterns were meticulously evaluated and compared with the 2021 guidelines of the ADA to assess adherence. Key parameters analyzed included:

- Glycated hemoglobin (HbA1c) levels to determine glycemic control
- Therapy costs to assess the economic burden of treatment
- Patient concerns, including treatment adherence and accessibility
- The impact of comorbidities on disease management.

Special attention was given to the concurrent use of antihypertensives and lipid-lowering agents, as these were commonly prescribed alongside anti-diabetic therapies. The study found that economic constraints significantly limited the use of advanced therapeutic options, such as SGLT2 inhibitors and GLP-1 receptor agonists. These findings emphasize the necessity of developing cost-effective, accessible strategies to improve diabetes care in resource-limited rural settings [11,12].

Inclusion criteria

1. Only individuals diagnosed with T2DM will be included
2. Only patients whose clinical data (age, gender, body mass index [BMI], HbA1c levels, prescribed medications, comorbidities, etc.) are available for review.

Exclusion criteria

1. Patients diagnosed with type 1 diabetes mellitus will be excluded
2. Patients with incomplete or missing clinical data, including HbA1c levels, prescribed medications, and comorbidities, will be excluded.

RESULTS

Demographic and baseline characteristics

Out of the 120 study subjects, 55% were men, and their average age was 54. Most participants (78%) were between 40 and 60 years old, while 12.14% were aged 20–40 years, and 16.99% were above 60 years. Overweight individuals comprised 54.17% of the participants, and 12.50% were categorized as obese. Lifestyle modifications, including exercise and dietary adjustments, were adopted by 89.17% of patients, while 10.83% reported no such changes. In addition, 35.83% of participants were smokers, and 14.17% consumed alcohol.

Clinical and comorbidity data

Hypertension was the most prevalent comorbidity, affecting 45% of the participants, followed by dyslipidemia (35%), cardiovascular disease (22.5%), and neuropathy (18.33%). A smaller proportion of patients reported hypothyroidism (7.50%) and fatty liver disease (7.50%). HbA1c levels indicated suboptimal glycemic control in a significant number of patients:

- 55% had levels between 6.5 and 8.0
- 24.17% had levels between 8.1 and 10.0
- 16.67% had levels above 10.0.

Prescribing patterns

Oral antidiabetic agents were prescribed to 70% of the patients, with the glimepiride-metformin fixed-dose combination being the most common (54%). Monotherapy with metformin was prescribed to 4% of the patients. Insulin therapy was administered to 30% of the participants, with short-acting insulin being the most commonly used (52.63%). Insulin glargine and insulin detemir are examples of long-acting insulin, are utilized for better blood sugar control and to reduce nocturnal hypoglycemia.

Concomitant medications

In addition to antidiabetic therapies, 29% of the participants were prescribed antihypertensive agents. Lipid-lowering drugs, primarily statins, were prescribed to 18.6% of patients to mitigate cardiovascular risks. Gastrointestinal drugs, such as pantoprazole, were commonly prescribed (15%), possibly to manage the side effects of antidiabetic drugs. Vitamins and minerals, including ferrous salts and multivitamins, were prescribed to 5.6% of participants to address nutritional deficiencies.

Compliance with ADA guidelines

Overall compliance to the 2021 ADA guidelines was observed in 90% of the cases. Non-adherence (10%) was attributed to:

- 6%: Inappropriate use of insulin therapy in patients with HbA1c <10 and no signs of catabolism
- 3%: Patients with HbA1c >10 refusing insulin therapy despite medical recommendations
- 1%: Off-guideline prescriptions, such as DPP-4 inhibitors for patients with HbA1c <6.5 or sulfonylurea combinations in individuals with a history of recurrent hypoglycemia.

From Table 1, the preponderance of participants (70.87%) were of advanced age 41–60 years, with 12.14% aged 20–40 years and 16.99% aged >61 years. The gender distribution showed 51.46% males and

Table 1: Demographic distribution of study participants (n=120)

Demographic distribution	Number of patients (n=120)	Percentage
Age: 20–40 years old	15	12.14
Age: 41–60 years	85	70.87
Age: >61 years	20	16.99
Gender: Male	62	51.46
Gender: Female	58	48.54
Exercise and dietary adjustments: With adjustments	107	89.17
Exercise and dietary adjustments: Without adjustments	13	10.83
BMI range: Normal (18.5–24.9)	40	33.33
BMI range: Overweight (25–30)	65	54.17
BMI range: Obese (>30)	15	12.50
Risk factors: Smoking	43	35.83
Risk factors: Alcohol	17	14.17
Risk factors: Other	24	20.00
HbA1c levels: <6.5	5	4.17
HbA1c levels: 6.5–8	66	55.00
HbA1c levels: 8–10	29	24.17
HbA1c Levels: >10	20	16.67
Comorbidities: Hypertension	54	45.00
Comorbidities: Dyslipidemia	42	35.00
Comorbidities: Hypothyroidism	9	7.50
Comorbidities: Obesity	11	9.17
Comorbidities: Neuropathy	22	18.33
Comorbidities: Fatty liver	9	7.50
Comorbidities: CVD	27	22.50
Comorbidities: Other	9	7.50

BMI: Body mass index, CVD: Cardiovascular disease, HbA1c: Glycated hemoglobin

48.54% females. Most participants (89.17%) adhered to exercise and dietary adjustments, while 10.83% did not. Regarding BMI, 54.17% were overweight, 33.33% had a normal BMI, and 12.50% were obese.

Risk factors included smoking (35.83%), alcohol consumption (14.17%), and other factors (20.00%). HbA1c levels indicated that 55% of participants had levels between 6.5 and 8, 24.17% between 8 and 10, and 16.67% above 10. Comorbidities were common, with hypertension (45.00%), dyslipidemia (35.00%), and cardiovascular disease (22.50%) being the most prevalent. Other conditions included neuropathy (18.33%), obesity (9.17%), hypothyroidism (7.50%), fatty liver (7.50%), and miscellaneous conditions (7.50%).

From Table 2 data, anti-diabetic drugs, including secretagogues, sensitizers, incretin-based therapies, and alpha-glucosidase inhibitors, were prescribed most frequently (29%, n=63). Antiplatelet agents, such as aspirin and clopidogrel, were the second most common (18.6%, n=70), followed by gastrointestinal drugs (15%, n=25) and lipid-lowering agents (9.5%, n=21). Vitamins and minerals were prescribed to 5.6% (n=12), while antimicrobials accounted for 3.4% (n=13). Antihistamines, drugs acting on the nervous system, and levothyroxine were each prescribed to approximately 4.8% of patients (n=10). Anti-inflammatory and analgesic drugs were the least prescribed (4.6%, n=10).

From Fig. 1, it can be noted about the Prescription Pattern of Antidiabetic Agents. Among study participants, the most commonly prescribed antidiabetic agent was the fixed-dose combination of glimepiride and metformin (54%). Monotherapy with metformin accounted for 4%, while insulin therapy was used by 30% of patients, with short-acting insulin being the most common (52.63%), while long-acting insulin accounted for 47.37%.

Adherence to ADA Guidelines (2021): The majority of patients (90%) adhered to the ADA 2021 guidelines, while 10% demonstrated non-adherence due to inappropriate insulin use, patient refusal, or off-guideline prescribing practices (Fig. 2).

DISCUSSION

This study provides an extensive overview of T2DM population, clinical, and pharmacological profile in a rural tertiary care hospital in Central India. The findings indicate guideline-based treatment approaches and multifactorial pathogenesis of diabetes, which are applicable to real-life rural populations.

The highest percentage of 41–60 years old patients (70.87%) confirms the established epidemiologic trend in which the risk of T2DM increases with aging due to the cumulative effect of lifestyle risk factors, reduced physical activity, and insulin resistance with aging. Similar trends have also been reported in Indian studies by Kalra et al. and Das

et al., once again confirming the age group to be the top priority for the intervention and screening program [13,14].

The near equal gender split observed in our research (51.46%, men; 48.54%, women) reflects no significant gender difference in T2DM prevalence among the study population. This is similar to that reported by ICMR-INDIAB and other population-based studies [15,16].

Lifestyle changes, primarily food control and physical activity, are the pillars of the control of diabetes. In our research, 89.17% of patients adhered to such changes, indicating high awareness and concordance. The 10.83% incidence of non-compliance, however, indicates the importance of organized educational interventions spanning behavioral and cultural domains, particularly in rural areas where myths and the unavailability of diabetes educators continue [17].

The obesity prevalence was also high, as over 54% of the respondents were overweight and 12.5% obese. The pathogenesis of insulin resistance and glycemic control has long been determined to be induced by obesity. The findings necessitate a programmatic community-based intervention for diabetic patients' weight management in the rural setting [18].

Risk factors and lifestyle

The existence of modifiable risk factors—smoking (35.83%) and alcohol consumption (14.17%)—emphasizes the necessity of targeted lifestyle counseling. The existing evidence from Int J Pharm Pharm Sci emphasizes that smoking and alcohol intake are highly correlated with increased drug-related problems and poor glycemic control in patients with T2DM [19]. Similarly, a 2024 IJAP study established a high correlation between adherence to lifestyle, income, and medication adherence, reemphasizing the role of behavior-based interventions [20].

Glycemic control

55% in our cohort had moderate control (HbA1c 6.5–8%), while **16.67%** had poor control (HbA1c >10%), suggesting the need for intensified intervention. A Kerala-based IJCPR survey concurs with this trend, and it was demonstrated that poor drug compliance and poor lifestyle are significant predictors of high HbA1c [21].

Comorbid conditions

High hypertension (45%), dyslipidemia (35%), heart disease (22.5%), neuropathy (18.33%), and obesity (9.17%) prevalence highlights the interrelated metabolic and cardiovascular risks [13].

Treatment trends

Metformin–glimepiride fixed-dose combinations were found to dominate prescriptions (54%), consistent with Indian rural prescribing patterns reported in Diabetologia and DiabetolMetab Syndr [15,16]. Insulin was prescribed to 30% of patients, with short-acting insulin being preferred (52.63%) to manage postprandial hyperglycemia.

Table 2: The study's concurrent drug prescription pattern subjects (n=120)

Code of WHO ATC	Drug class	Frequency (%)	Number of drugs prescribed (n=120)
C02, C09CA07, C07AA05, C08GA02, C03EB01	Anti-Diabetic drugs: Secretagogues, sensitizers, incretin-based therapies, alpha-glucosidase inhibitors	29.0	63
N02BG	Anti-inflammatory and Analgesic	4.6	10
N06AA09, N04BA01	Drugs acting on the nervous system: Amitriptyline, levodopa	4.8	10
H03AA01	Levothyroxine	4.8	10
B03AE04	Minerals and vitamins: Ferrous salts, neurobion, multivitamins	5.6	12
C10AA01, C10BA04	Agents that reduce lipids: Fibrates (gemfibrozil), HMG-CoA reductase inhibitors (statins)	9.5	21
J01CR02, J01MA02	Antimicrobials: Amoxicillin, ciprofloxacin	3.4	13
R06AE07, D04AA33	Cetirizine and diphenhydramine are antihistamines	4.8	10
A02BC02, A07DA03	Gastrointestinal medications: Racecadotril with pantoprazole	15.0	25
B01AC04	Antiplatelet agents: Aspirin+clopidogrel	18.6	70

WHO: World Health organization, ATC: Anatomical therapeutic chemical
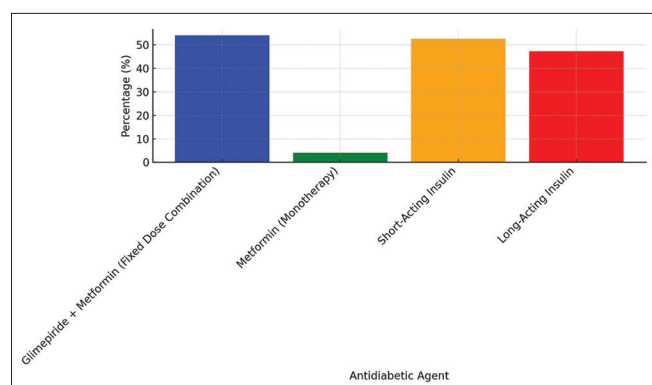
Fig. 1: Prescription patterns of an oral antidiabetic medication among study participants (n=120)
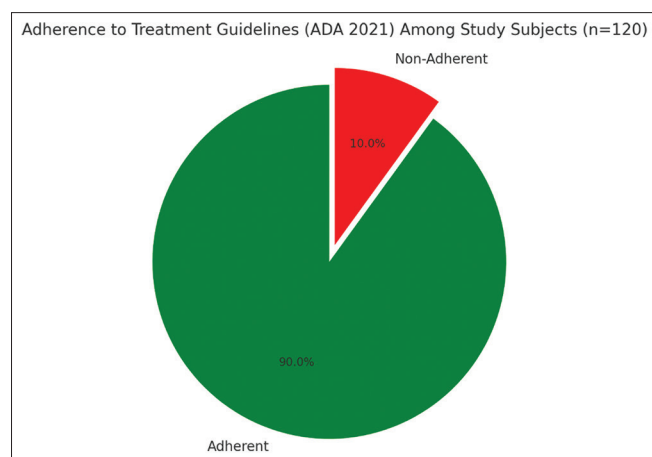
Fig. 2: Study participants' compliance with American Diabetes Association 2021 treatment guidelines (n=120)

Guideline adherence

We monitored 90% compliance with ADA 2021 standards, although a minor 10% variance suggests scope for improvement through ongoing medical education, audit processes, and patient support schemes.

CONCLUSION

The study provides a comprehensive overview of the population, clinical, and therapeutic traits of patients who have diabetes, emphasizing the multifaceted Opportunities and Difficulties with Diabetes management. The findings highlight that most of patients fall within the 41–60 age group, with a nearly balanced gender distribution. Adherence to exercise and dietary adjustments was high, yet obesity and overweight remain prevalent concerns. Common risk factors, such as smoking, alcohol consumption, and comorbidities, such as hypertension and dyslipidemia underscore the complexity of diabetes care.

The prescription pattern reflects a strong reliance on evidence-based therapies, with a preference for fixed-dose combinations of glimepiride and metformin and adherence to the ADA 2021 guidelines by most patients. However, gaps in glycemic control for a subset of participants, along with non-adherence to lifestyle and medication recommendations, highlight the need for more personalized interventions.

ETHICAL CONSIDERATIONS

The research received approval from the Institutional Ethics Committee of Datta Meghe Institute of Higher Education and Research (Deemed to be University), under reference number DMIHER(DU)/IEC/2024/134.

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