

Prescribing pattern of anti-diabetic drugs and adherence to the American Diabetes Association's (ADA) 2021 treatment guidelines among patients of type 2 diabetes mellitus: A cross-sectional study

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ABSTRACT

Background: Glycemic control is the major therapeutic objective in diabetes. Poor glycemic control in diabetes mellitus can be prevented by using rational use of anti-diabetic medication, which needs to be evaluated for effectiveness by prescription pattern studies. The objective of this study was to assess the prescribing pattern and adherence to the American Diabetic Association's (ADA) treatment guidelines in type 2 diabetes mellitus patients in a tertiary care teaching hospital in Uttarakhand, India. **Methodology:** This cross-sectional study was conducted on 206 type 2 diabetic patients who were prescribed anti-diabetic therapy. Patient's demographic details and drugs prescribed, with their dosage, were recorded to study the prescription pattern. **Results:** Oral anti-diabetic drugs were most commonly prescribed in 149 (72.33%) type 2 diabetic mellitus patients. Five of these patients (3.35%) were on metformin monotherapy, whereas majority of patients (81, 54.36%) were on a fixed dose combination of Glimpiride (SU) + Metformin (MET). Forty-five patients (30.20%) were on MET + Dipeptidyl peptidase 4 inhibitors (DPP4I) combination; 5 (3.35%) were on MET + SU + alpha-glucosidase inhibitors (AGI) combination; 7 (4.69%) were on MET + SU + Pioglitazone (PIO) (Thiazolidinediones) combination; 6 (4.02%) were on sodium/glucose cotransporter-2 inhibitors (SGLT2I) and 57 (27.66%) were on insulin therapy. Out of 206 patients, the prescriptions of 185 patients (89.8%) were adherent and of 21 patients (10.19%) were not adhering to ADA 2021 treatment guidelines. **Conclusion:** Oral anti-diabetic agents predominate the prescribing pattern practices for type 2 DM but there was a shift in trend towards the use of fixed-dose combinations (FDC) in the management of type 2 DM, and majority of prescriptions were adherent to ADA treatment guidelines.

Keywords: Adherence American Diabetic Association (ADA) treatment guidelines -2021, Anti-diabetic drugs, oral hypoglycemic agents, prescribing pattern

Introduction

Diabetes mellitus (DM) is one of the commonest metabolic disorders encountered worldwide including in India. It

is characterized by hyperglycemia due to an imbalance in carbohydrates, fats and protein metabolism, resulting in defects in insulin secretion and action or both.^[1] According to the World Health Organization, it is estimated that prevalence of diabetes mellitus will reach 300 million by 2021 from the 5 million it was in 1995. India currently has a population of 62.4 million people with diabetes. This is set to increase to over 100 million by 2030. In India, the prevalence of

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Received: 24-02-2022

Revised: 11-05-2022

Accepted: 17-05-2022

Published: 31-10-2022

Access this article online

Quick Response Code:



Website:
www.jfmpc.com

DOI:
10.4103/jfmpc.jfmpc_458_22

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How to cite this article: Tiwari K, Bisht M, Kant R, Handu SS. Prescribing pattern of anti-diabetic drugs and adherence to the American Diabetes Association's (ADA) 2021 treatment guidelines among patients of type 2 diabetes mellitus: A cross-sectional study. J Family Med Prim Care 2022;11:6159-64.

diabetes among adults has reached 20% in urban areas and approximately 10% in rural areas.^[2]

Various classes of anti-diabetic medicines, such as insulin and oral hypoglycemic agents (OHA), are currently utilized in the treatment of diabetes, and they work through many mechanisms to lower blood glucose levels and maintain optimal glycemic control. Treatment for DM needs to be taken throughout life and is associated with many complications and comorbidities. Diabetes also increases the risk of vascular disease and is frequently associated with hypertension, lipid problems, and obesity leading to polypharmacy. To guide the physicians regarding adequate management, there are several treatment guidelines including those by the American Diabetic Association (ADA) and the Indian Council of Medical Research (ICMR).^[3] The ADA is considered to be the gold standard consensus guidelines for the management of DM,^[4] which are updated from time to time. Since diabetes is one of the most common lifestyle disorders, a majority of the patients are initially managed by a primary care physician. It is important for primary care health providers to follow the treatment guidelines like the ADA guidelines for diabetes management. Hence, there is a need to spread awareness at the level of prescribing physicians concerning the adherence to present guidelines to facilitate the optimum management of the diabetic patient.

Prescribing pattern has changed recently due to availability of various newer drugs in the market for the management of type 2 DM. So, the study of prescribing patterns may prove to be an exploratory tool for primary health care physicians. The aim of this study was to examine the current prescribing pattern of anti-diabetic drugs and adherence to standard treatment guidelines provided by the ADA in 2021.

Methods

Study Designs and Settings: This cross-sectional study was conducted by the departments of pharmacology and medicine, over a period of 12 months, after taking requisite approval from the Research Review Board and Institutional Ethics Committee.

Methodology: Subjects included 206 adult patients with type 2 DM presenting to diabetic OPD and who had received anti-diabetic agents for more than 6 months. Newly diagnosed, gestational diabetics, serious comorbid patients and those receiving anti-diabetic therapy for less than 6 months duration were excluded from the study. Patients were assessed once during the period. The details regarding demographic data, relevant medical history, associated comorbidities and details regarding drug therapy were elicited. The prescription pattern was analyzed and adherence to treatment guidelines was done by comparing with the 2021 ADA guidelines. Various parameters involved for checking prescription adherence to ADA guideline such as Hb1Ac, drug cost, patient concerns about treatment, adherence to therapy-morbidities were considered.

Statistical methods: Descriptive statistics were used to describe the results. Data were represented as percentages.

Results

Baseline demographic

Baseline demographic characteristics of study subjects are represented in Table 1. Out of 206 subjects, 51.45% of patients were male, and the mean age of the study subjects was 52.06 years. The majority of study participants belonged to the age group of 41–60 years, 88.83% patients were on lifestyle and diet modifications, and 11.16% patients were not adhering to lifestyle and diet modifications. Among 206 patients, 53% were overweight. 36% of subjects were smokers, and 15% were alcoholics. A majority of the population, 54.85% had HbA1c ranging between 6.5 and 8. Majority of patients (45.14%) were suffering from HTN followed by dyslipidemia (35%) and cardiovascular disease (22.33%).

Table 2 shows the distribution of type of insulin received by the study subjects. Among 57 patients receiving insulin, 52.63% of study subjects were on short-acting insulin (regular).

Table 1: Demographic distribution of study subjects (n=206)

Demographic distribution	Number of Patients (n=206)	Percentage (%)
Age (in years)		
20-40	25	12.13
41-60	146	70.87
>61	35	16.99
Gender		
Male	106	51.45
Female	100	48.54
Exercise and Diet Modification		
With lifestyle and diet modification	183	88.83
Without lifestyle and diet modification	23	11.16
BMI range		
Normal (18.5-24.9)	68	33.00
Overweight (25-30)	111	53.88
Obese (>30)	27	13.10
Risk Factors		
Smoking	74	36
Alcohol	30	15
Other	41	20
HbA1c Levels		
<6.5	9	4.36
6.5-8	113	54.85
8-10	50	24.27
>10	34	16.50
Comorbidities		
Hypertension	93	45.14
Dyslipidemia	72	34.95
Hypothyroidism	15	7.28
Obesity	19	9.22
Neuropathy	38	18.44
Fatty Liver	16	7.76
CVD	46	22.33
Other	15	7.28

Figure 1 shows that 72.33% of the study subjects received oral anti-diabetic agents whereas insulin was prescribed to 27.66% of study subjects. Most commonly prescribed were oral anti-diabetic drugs in type 2 DM patients. 3.35% of patients were on metformin monotherapy, whereas the majority of patients (54.36%) were on a fixed-dose combination of glimepiride + metformin.

Table 3 shows the prescribing pattern of concomitant medication received by study participants. Anti-hypertensive medications were most common concomitant agents received, by 28.9% of patients.

Figure 2 demonstrated that 89.8% of prescriptions adhered to the 2021 ADA treatment guidelines, and 10.19% of prescriptions did not adhere to the guidelines. The main reasons for non-adherence were as follows: 57 patients were on insulin therapy of which 5.82% had HbA1c <10, and there was no evidence of catabolism (weight loss) requiring insulin therapy. Prescription of insulin in these patients was suggestive of non-adherence to ADA treatment guideline. 2.42% of patients whose HbA1c was >10 refused to start insulin therapy and therefore were also indicative of non-adherence to the ADA guidelines. 0.97% of patients had HbA1c <6.5, but they were on the dipeptidyl peptidase 4 inhibitors (DPP4I) combination therapy; 0.97% of patients were having previous multiple hypoglycemic events, but as they were on combination therapy of metformin and sulfonylurea, it was suggestive of non-adherence to the ADA guideline.

Discussion

Clinical characteristics of study subjects

A total of 206 type 2 DM subjects were evaluated, and it was observed that males outnumbered the females, and the pattern was similar to the other studies.^[5] Body fat distribution varied by gender, with a higher proportion of visceral and hepatic fat compartments in males being linked to insulin resistance.

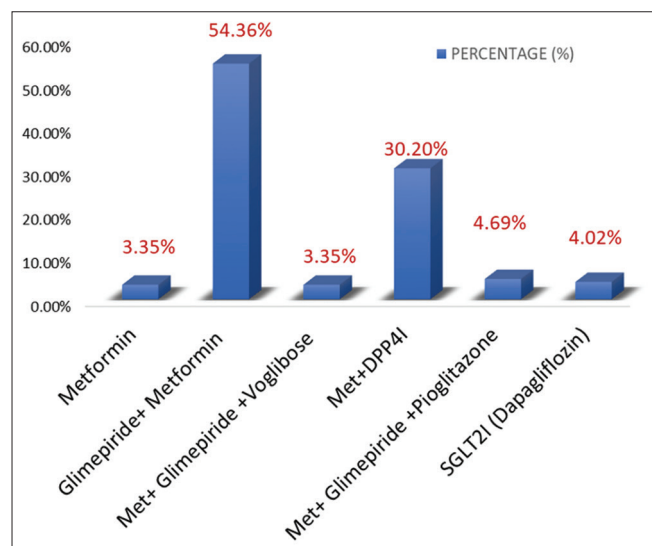


Figure 1: Prescribing pattern of an oral anti-diabetic agent in study subjects (n = 149)

Females have higher subcutaneous and peripheral fat, both of which are linked to insulin sensitivity and protective against type 2 DM. As a result, females are less likely to develop type 2 DM.^[6] In our study, 36% of patients were smokers, and 15% were alcoholics. Smoking and alcoholism disturb the blood

Table 2: Prescribing pattern of type of insulin received by the subjects (n=57)

WHO ATC code	Type of Insulin	No. of (57) Patients	Percentage (%)
A10A	Insulin and analogues		
A10AB,	Fast-acting	8	14.03%
A10AB04	Insulin aspart	4	7.01%
A10AC04	Insulin lispro		
A10AB04	Insulin lispro Lispro		
A10AC	Short-acting	30	52.63%
A10AC01	Regular (human)		
A10D01	Intermediate-acting	7	12.28%
A10DO2	Insulin mixtard		
A10AE	Long-acting	7	12.08%
A10AE04	Insulin glargine	1	1.75%
A10AE05	Insulin detemir		

Table 3: Prescribing pattern of concomitant medication received by study subjects (n=206)

WHO ATC code	Class of drugs	Frequency (%*)	No. of other than anti-diabetic drug prescribed (n=377)
C02	Anti-hypertensive drugs:	28.9%	109
C09CA07	ACEIs/ARBs	15%	57
C07AA05	Beta-blockers	3.44	13
C08GA02	Calcium channel blockers	6.66	25
C03EB01	Furosemide	1.8	7
C03EB01	Other diuretics	1.8	7
N02BG	Analgesic and anti-inflammatory	4.6%	17
N06AA09	Central nervous system drugs	4.77	18
N04BA01	Amitriptyline	2.65	10
	Levodopa	2.1	8
H03AA01	Levothyroxine	4.77	18
B03AE04	Vitamins and minerals	5.57	21
	Ferrous salts, Neurobin	2.65	10
	Multivitamin	2.91	11
C10AA01	Lipid-lowering agents	9.54	36
C10BA04	HMG-CoA reductase inhibitors (statins)	4.77	18
	Fibrates (gemfibrozil) other	4.77	18
J01CR02	Antimicrobial	3.45	13
J01MA02	Amoxicillin	2.38	9
	Ciprofloxacin	1.07	4
R06AE07	Antihistamines	4.77	18
D04AA33	Cetirizine	3.18	12
	Diphenhydramine	1.59	6
A02BC02	Gastrointestinal drugs	15	57
A07DA03	Pantoprazole	6.63	25
	Racecadotril	8.4	32
B01AC04	Antiplatelet	18.56	70
	Aspirin + Clopidogrel	18.56	70

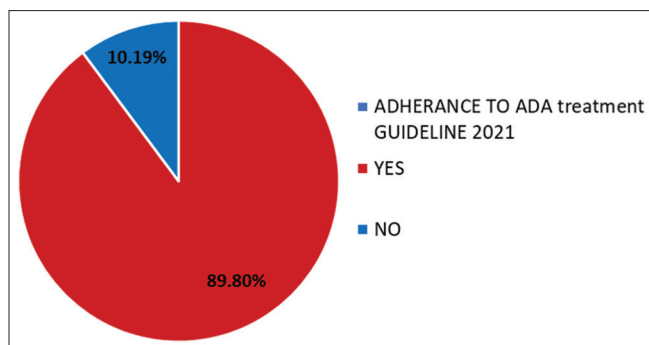


Figure 2: Adherence to treatment guidelines (ADA 2021) among the study subjects ($n = 206$)

flow and metabolic actions in the body, and that may lead to diabetic complications in patients with type 2 DM. Alcohol intake also increases the risk of chronic inflammatory disorder of the pancreas.^[7] In our study, the age group of 41–60 years comprised of 70.87% of the patients, which is in concordance with the earlier published literature where 75% of patients were in the age group 41–60 years. This may be because of a sedentary lifestyle, and a rise in stress levels and ageing, causing an increase in the prevalence of diabetes mellitus in this age group. Moreover, these patients also have a higher chance of developing various other chronic complications associated with type 2 DM.^[8]

Associated comorbidity in study patients

DM is a chronic metabolic disorder often associated with various comorbidities. In our study, hypertension was the most common comorbidity followed by dyslipidemia. Hypertension is associated with increased stiffness of large arteries, which often precedes macrovascular events. Various studies reported similar observations where hypertension was the commonest comorbidity reported in 22.69%–49.18% of patients.^[7–9] Another study showed similar results where hypertension was the commonest comorbidity reported in 51% of patients with diabetes mellitus, and dyslipidemia was the second most common comorbidity followed by cardiovascular disease, hypothyroidism, and urinary tract infection.^[1]

Prescription pattern

In our study, a total of 597 medications were prescribed in 206 patients, and the average number of medications per prescription was 2.89. Out of 206 prescriptions, most were on combination therapy with oral anti-diabetic drugs and 66.66% of patients were on a fixed-dose combination (FDC) of oral anti-diabetic medication. A similar prescribing pattern of FDC was found in other studies which reported 60% and 71.06% of FDC prescription.^[10,11] The reason behind the change in prescribing patterns is that pharmacotherapy for diabetes mellitus has dramatically changed in the last few years. The prescription trend is shifting toward FDCs that simplify the treatment regimen by reducing pill burden compared with the same combination delivered as separate pills.

In our study, 9 patients (4.36%) had a HbA1c of less than 6.5. Only 3.35% were on metformin monotherapy with lifestyle modification in our study, which was in contrast to other studies which reported that 69.42%–78.61% of patients were on metformin monotherapy.^[12] Less number of study subjects were on monotherapy with metformin as compared to other studies. It could be attributed to our inclusion criteria, which required patients to have been on anti-diabetic medication for more than six months, so most of them were on combination therapy to achieve their optimal glycemic level.^[5] In our study, the most commonly prescribed dual drug therapy was (glimepiride + metformin) which was 54.36% of the patients and second most common oral anti-diabetic combination was metformin + DPP4I which was 45 patients (30.20%), and 3.35% of patients were on metformin monotherapy.

A similar prescription pattern was found in other studies in which 53.3% of patients were on metformin + glimepiride followed by metformin + DPP4I in 22.402% of patients.^[12–14] In our study, most of the patients were on dual drug therapy to achieve their optimal glycemic level. It could be attributed to the fact that our institute is a tertiary health care center that receives most of the referral patients and metformin is prescribed as a monotherapy only when the patients are newly diagnosed and able to achieve optimal glycemic levels within three months. Moreover, the inclusion criteria of our study required patients on anti-diabetes medication for more than six months. The prescription pattern of another study was different from our study in which the most common dual combination therapy was metformin + DPP4I, the most common triple combination was metformin + DPP4I + sulfonylureas, and quadruple combination was metformin + DPP4I + sulfonylurea + thiazolidinediones.^[15] This is because the cost was an important barrier for prescribers in our study, and only 4.02% of a patient were on SGLT-2 inhibitors, which were costly compared to other drugs and in addition to therapy, increases the cost of combined therapy, which could be a suggestive of less prescription of this agent in our study.

In our study, 57 patients (27%) were on insulin therapy, which was similar to the prescription pattern for insulin in other studies in which short-acting insulin was most commonly prescribed in 56.1% patients as it can help to achieve better glycemic control.^[14]

Other medications prescribed in study subjects

Most widely prescribed medications in our study apart from anti-diabetic agents were ACEi/ARB, aspirin, atorvastatin, and clopidogrel. 28.9% of anti-hypertensive medications were prescribed, and a similar prescribing pattern of medications apart from anti-diabetic drugs was found in another study.^[11] These results suggested a link between diabetes and cardiovascular illness. In our study, 88.83% of patients were advised with lifestyle and diet modifications; 11.6% were not compiling to change their lifestyle.^[3] According to ADA guidelines, if the HbA1c target is not met after around 3 months, metformin can

be supplemented with any of the following six therapy options which depends on drug-specific effects and patient variables and underlying problems. In our study, 54.36% of patients were on metformin and glimepiride dual combination therapy and HbA1c was in the range of 6.5–8, suggestive of adherence to ADA treatment guidelines.

Adherence to ADA guidelines (2021)

30.20% of patients on DPP4I + metformin had HbA1c of 6.5–8, and according to the ADA guidelines, it is a second-line drug for combination therapy to prevent hypoglycemic shock if no other risk factors are present, if cost is not a barrier to the prescriber. The result of our study shows that DPP4I was the second most commonly prescribed combination, and it was less than the previous study.^[16] Because cost was the most significant obstacle for the prescriber in our study, strict adherence to ADA treatment guidelines was not possible. According to ADA guidelines, HbA1c is >10%, insulin therapy should be considered or if HbA1c <10% is associated with catabolism.

After comparison of all underlying parameters and patient's HbA1c value in our study, we concluded that 89.8% of prescriptions adhered to the ADA guidelines and 21 patients' (10.19%) prescriptions were not adherent to the guidelines. Adherence to ADA treatment guidelines is higher compared to other studies where lesser adherence was reported, ranging from 78% to 83.6%.^[14–17] This better adherence to treatment guidelines can be attributed to the fact that our institute is a tertiary care center that has a dedicated diabetes clinic to provide adequate diabetic management, as well as dietary advice for patients' lifestyle and diet modifications. Patient awareness clinics are held to inform patients about hypoglycemia symptoms or other symptoms, and proper insulin administration training is provided. Apart from this, various training activities are undertaken frequently to update clinicians about the latest breakthroughs and guidelines.

The significance of following the treatment guidelines is that the primary care physician can provide evidence-based management to all the patients. Hence educational sessions are recommended for updating the knowledge of primary care physicians regarding the recent recommendation for optimum management of diabetic patient.

Limitation of present study

The present study has certain limitations. This study being a cross-sectional study, only the anti-diabetics agents prescribed at that particular time were recorded that could not access the control of diabetes with a prescribed anti-diabetics agent since there was no follow up. In our study, adherence to ADA treatment guidelines was assessed based on HbA1c at the time of the study. It may have reflected the biased interpretations as the duration of the therapy was not taken into consideration. The sample size was also less due to the COVID-19 pandemic; we could not enroll more patients, so further prospective follow-up studies can help to validate the result of this study. So, this is the first study to our

knowledge in our region looking into the treatment adherence as per treatment guidelines. There were no studies done in the past to assess the compliance of diabetic management with recently recommended ADA guidelines. This result highlighted that frequent of health care providers regarding updated guidelines can lead to better adherence to treatment protocols.

Conclusions

Diabetes mellitus is a chronic disease associated with many comorbidities and complications. Oral antidiabetics agents still dominate the prescribing pattern but there was a shifting trend towards the use of fixed-dose combination (FDC) in the managements of type 2 DM and 185 prescriptions (89.8%) were adherent to ADA treatment guidelines. Metformin + sulfonylurea combination was the most commonly prescribed agent followed by metformin + teneligliptin combination. 27.66% of prescriptions were insulin, the second most commonly prescribed medication for type 2 DM. Glimepiride + metformin combination suggests a more rational mode of prescribing for the Indian scenario. In our study most of prescriptions were adherent to ADA treatment guidelines by comparing various parameters like comorbidities, patient's clinical needs, patient's optimal glycemic value, economic condition and awareness of the treatment. Therefore, through our study, we recognized that attempts should be made to create awareness about the prescribing trends and prescription of more drugs according to ADA treatment guidelines to enhance adherence to treatment that would help in improving the quality and efficacy of type 2 DM therapy.

Summary

- Majority of diabetic patients were male in the age group of 41–60 years and were on lifestyle and diet modifications, as recommended for diabetics.
- Majority of type 2 diabetes patients were receiving oral anti-diabetic medication out of which more than half of these patients were on fixed-dose combination of glimepiride + metformin.
- 89.8% of prescriptions adhered to the 2021 American Diabetic Association treatment guidelines.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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