

DOI: <https://dx.doi.org/10.18203/2319-2003.ijbcp20260436>

Original Research Article

## Assessment of prescribing pattern, adverse drug reactions and drug information sources in middle aged diabetic hypertensives at a tertiary care hospital in central India: a prospective observational study

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**Received:** 06 January 2026

**Accepted:** 03 February 2026

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### ABSTRACT

**Background:** Prescription pattern studies are powerful exploratory tools to ascertain the role of drugs in society. Aim of this study is to analyze the prescription pattern and adverse drug reactions (ADRs) of type-2 diabetes mellitus (T2DM) with co-existing hypertension in a tertiary care hospital and fulfill the drug information needs of the physician and give feedback to the prescribers to improve quality of healthcare.

**Methods:** An observational cross-sectional study is conducted in general medicine OPD at tertiary care hospital in central India after approval of IEC for a period of 1 year and 6 months. The data of prescriptions of patients having T2DM with co-existing hypertension and patient specific queries on drug information were collected and interpreted using WHO Core drug use prescribing indicators, JNC 8 and American diabetes association 2021 guidelines for hypertensive diabetic patients. Suspected ADRs reporting forms were analyzed by ADR causality and severity assessment scales.

**Results:** Study population included 160 patients with T2DM and co-existing hypertension. Most common antidiabetic class of drugs prescribed was biguanides (79.4%) followed by sulfonylureas (76.3%). Insulin was prescribed to 25% of the study population. Calcium channel blockers (CCB) (41.3%) were the most prescribed antihypertensive class of drugs followed by ACE inhibitors (37.5%). Polypharmacy was seen in 29.4% of the study population. In the study population, number of patients with drug information queries were 56 (35%), commonest queries being adverse effects and dosage of drugs. ADRs reported were only 12 (7.5%) of 160 patients, hypoglycemia (3.75%) being most common under study, indicating under reporting.

**Conclusions:** In this study, monotherapy was more often prescribed than the combination drug therapy. biguanides (metformin) and CCBs (amlodipine) were the most frequently prescribed agents among oral hypoglycemics and antihypertensive. Diabetes and hypertension when coexist multiply the risk of many hazardous complications which can be kept in check by rational prescribing using WHO drug use indicators and adhering to recent standard treatment guidelines. Pharmacovigilance awareness at every level of health care system regarding ADR reporting is of utmost importance.

**Keywords:** WHO indicators, Diabetes mellitus, Hypertension, Drug information queries, Rational prescription, Polypharmacy

## INTRODUCTION

Prescription pattern studies have their primary goal to evaluate the elements involved in the prescription, distribution, administration, and consumption of drugs as well as the associated events (positive or negative). The world health organization (WHO) defines utilization of drugs as marketing, distribution, prescription and use of medications in a society while taking into account any potential medical, social, or financial consequences.<sup>1</sup>

DM is a chronic condition that is becoming a significant cause of morbidity and mortality. Recent studies of WHO revealed increase in prevalence of DM from 108 million in 1980 to 463 million individuals 2021 worldwide. India being termed as “diabetes capital of world” (>77 million diabetics and is set to rise in future). Globally 50% of the people with DM have co-existing hypertension.<sup>2</sup> Diabetes death rates by age increased by 3% between 2000 and 2019.<sup>3</sup> The development of hypertension in diabetes patients not only makes treatment more difficult and expensive, but it also significantly increases multiplicative risk for both macrovascular and microvascular complications.<sup>4,5</sup>

The coexistence of T2DM and hypertension, often referred to as "diabetic hypertension" or the "double burden," is a clinical scenario characterized by the concurrence of these two chronic conditions in an individual. Epidemiological studies have reported a higher prevalence of hypertension among individuals with T2DM, with estimates ranging from 40-60%, as compared to the general population.<sup>6,7</sup> Conversely, patients with hypertension also face a significantly increased risk of developing T2DM.<sup>8</sup> This bidirectional relationship underscores the importance of a comprehensive approach in managing these patients, considering both cardiovascular risk factors.

Effective long-term therapy typically involves the use of a variety of medications in varied combinations. Prescription study is an effective tool to constitute guidelines for improving drug utilization patterns and restricting irrational prescribing.<sup>9-11</sup> Drug utilization studies, which assess and analyze the medical, social and economic effects of drug therapy, are therefore more important and observe the prescribing behavior of doctors with the goal of providing drugs rationality and reducing ADRs. They also play a crucial role in developing and putting these strategies into action so as to improve quality of healthcare.<sup>12-14</sup>

## METHODS

This was a prospective cross-sectional observational study conducted in patients with T2DM having co-existing hypertension attending medicine outpatient department (OPD: diabetic and hypertensive clinic) in tertiary care hospital in central India. The study was started after the approval of institutional ethics committee during the period of 18 months from January 2020 to June 2021. The

written informed consent was taken from the patients willing to participate after meeting the eligibility criteria.

Patients of middle age either sex between of 40-70 years with T2DM and coexisting hypertension (Essential/primary) with or without associated chronic complications were included in the study and patients with T1DM, secondary hypertension, gestational DM and acute complications like diabetic ketoacidosis and infection were excluded. The study included only one prescription per patient during that hospital OPD visit. Prescription of the eligible patients were collected and details like name of the drug, dosage, route of administration, duration and number of drugs prescribed were noted. Prescription pattern was analyzed using the WHO core drug use indicators and as per recent JNC 8 and ADA 2021 guidelines for hypertensive diabetic patients.

To delineate drug information needs, by accompanying the physician in OPD, the data of patients for whom queries arise was collected in the proforma. Patient specific queries on drug information from physician which would be asked directly (Active) to the investigator or perceived as need by the investigator (Passive) during patient care were collected using study proforma. The classes of drugs for which queries raised, the category of query and the source used for drug information were also noted. Simultaneously, suspected ADRs were observed and analyzed by filling related information in the ADR reporting form. The most common adverse drug reaction reported with pharmacological type, age and sex distribution and ADR Causality assessment done by Naranjo algorithm probability scale.

## Data analysis

Descriptive statistical analysis has been carried out in the present study. Continuous data variables are presented as mean±SD and categorical variables are presented in number/percentage (%). Data presented in terms of ratios, percentages and proportions using Microsoft word and excel used to generate graphs, tables etc.

## RESULTS

In this cross-sectional observational study, total 160 Prescriptions were collected and analyzed for epidemiologic profile, disease spectrum, drug prescription patterns.

The mean age of the study population was 54.99±6.65 years. Most patients included in the study were between 51-60 years of age (43.1%). Slight male prominence was observed (51.3%). Most patients (60%) were from low socio-economic status.

The most common diabetic complication was observed to be diabetic peripheral neuropathy (26.25%) followed by ischemic heart disease (IHD 20%) and diabetic nephropathy (12.5%) (Table 1).

In antidiabetic therapy, 75% patients were prescribed oral antidiabetic drugs and 25% were prescribed insulin. Most common oral antidiabetic drug class prescribed were biguanides (79.4%) followed by sulfonylureas (76.3%) and mostly as single drug formulation (82.9%). Metformin (79.4%) was the only biguanide prescribed most frequently and among sulfonylureas, glibenclamide (30%) was the most common prescribed drug (Table 2). In this study, among the prescribed oral antidiabetic agents, 82.9% were single drug formulations and only 17.1% were combination drug formulations where glimepiride (1 mg) + metformin (50 mg) was most commonly prescribed as combination.

Among antihypertensive drugs, CCBs were most common antihypertensives prescribed (41.3%) followed by ACE inhibitors (37.5%) and ARBs (18.8%). Telmisartan (40 mg) + amlodipine (5 mg) was the most common combination prescribed once a day (Table 3).

Polypharmacy (5 or more than 5 drugs) was seen in 29.4 % of study population. Most drugs were prescribed by generic name 71.9% and 28.1% of the drugs were prescribed by brand name (Figure 1 and 2).

The active queries were 48 (85.7%) and passive were 8 (14.3%). Most queries were for antidiabetic drug class (28.6%), followed by anti-hypertensives (25%). The most common queries were about adverse effects (32.1%) and dosage (19.6%) of the drugs (Table 4).

Total number of drugs prescribed were 778 and number of prescriptions were 160. Average number of drugs per prescription was 4.86. Vitamins and miscellaneous drugs like NSAIDs were most common classes of drugs prescribed other than antidiabetic and antihypertensives (41.2% each). In the study population, 47.82% of the prescribed variety of drugs were from EDL and 52.18% of the drugs were not from EDL (Table 5).

Out of the 160 patients, about only 12 (7.5%) patients reported ADRs indicating underreporting. Most common ADR being hypoglycemia (n=6) (3.75%) caused by insulin and sulfonylureas. The ADRs were most reported in geriatric age group above 60 years of age (6.25%). Type A augmented reactions were commonly observed in 8 patients out of 12 ADRs (66%) which are mainly dose dependent and preventable. Probability of ADR scale (Naranjo-Algorithm) showed that most (10 ADR) fell in

the 5-8 probable scale: 6.25% patients and (2 ADR) fell in 1-4 possible scale: 1.25%.

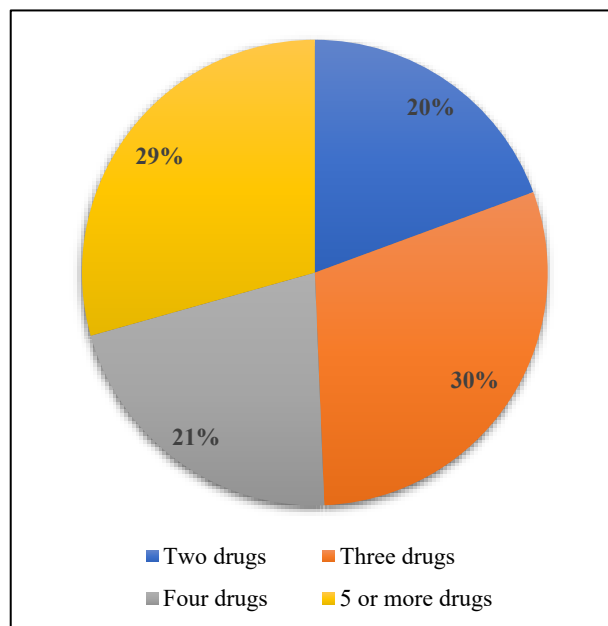


Figure 1: Number of drugs prescribed per encounter.

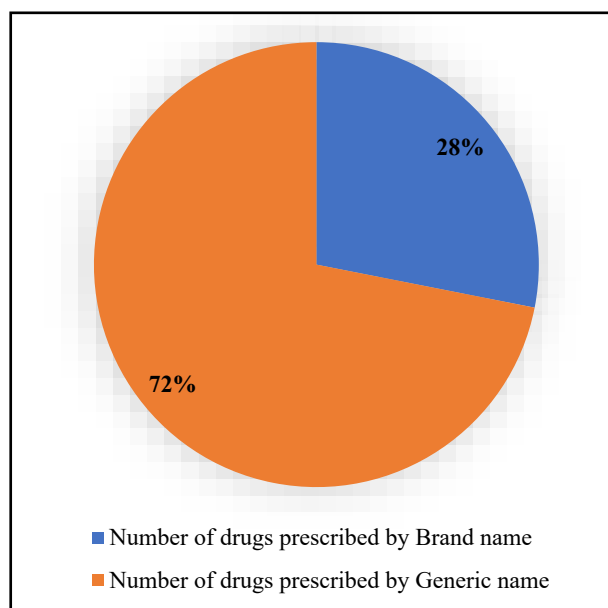


Figure 2: Number of drugs prescribed by brand name and generic name.

Table 1: Clinical and demographic characteristics of study patients, (n=160).

Characteristics	N	Percentage (%)
<b>Age (in years)</b>		
40-45	20	12.5
46-50	34	21.3
51-55	26	16.3
56-60	43	26.8
61-65	33	20.6
66-70	4	2.5

Continued.

Characteristics	N	Percentage (%)
<b>Gender</b>		
Male	82	51.3
Female	78	48.8
<b>Socio-economic status</b>		
Low	96	60
Middle	64	40
High	00	00
<b>Duration of DM</b>		
1-5 years	64	40.0
6-10 years	53	33.3
11-15 years	37	23.1
>15 years	6	3.8
<b>Duration of hypertension</b>		
1-5 years	74	46.3
6-10 years	62	38.8
11-15 years	19	11.9
>15 years	5	3.1
<b>Complications</b>		
Diabetic retinopathy	8	5.0
Diabetic nephropathy	20	12.5
Diabetic peripheral neuropathy	42	26.25
Gastroparesis	4	2.5
Diabetic foot	8	5.0
IHD	32	20
Stroke/ CVA	6	3.75
<b>Without complications</b>	40	25

**Table 2: Drug utilization of antidiabetic drugs in study patients, (n=160).**

Variables	N	Percentage (%)
<b>Patients on oral anti-diabetic therapy</b>	120	75
<b>Patients on insulin therapy</b>	40	25
<b>Class of antidiabetic drugs prescribed</b>		
<b>Biguanides</b>	127	79.4
Sulfonylureas	122	76.3
Insulin	40	25.0
Alpha glucosidase inhibitor	21	13.1
Thiazolidinediones/Glitazones	19	11.9
<b>Antidiabetic drugs</b>		
Metformin	127	79.4
Glimepiride	43	26.9
Gliclazide	19	11.9
Glipizide	12	7.5
Glibenclamide	48	30.0
Insulin	40	25.0
Acarbose	2	1.3
Voglibose	19	11.9
Pioglitazone	19	11.9
<b>Total number of the oral antidiabetic agents prescribed</b>	245	100
<b>Number of oral antidiabetic drugs prescribed as single drug formulation</b>	203	82.9
<b>Number of oral antidiabetic drugs prescribed as combination drug formulation</b>	42	17.1
<b>Patients on short acting insulin</b>	23	14.4
<b>Patients on intermediate acting insulin</b>	17	10.6

**Table 3: Drug utilization of antihypertensive drugs in study patients, (n=160).**

Variables	N	Percentage (%)
<b>Antihypertensive class of drugs</b>		
Alpha blocker	1	0.6
Beta blocker	28	17.5
ACE inhibitors	60	37.5
ARBs	30	18.8
CCBs	66	41.3
Diuretics	9	5.6
<b>Antihypertensive drugs (Individual)</b>		
Prazosin	1	0.6
Atenolol	20	12.5
Metoprolol	9	5.6
Nebivolol	1	0.6
Enalapril	37	23.1
Ramipril	21	13.1
Losartan	17	10.6
Telmisartan	11	6.9
Olmesartan	2	1.3
Nifedipine	1	0.6
Amlodipine	65	40.6
Hydrochlorothiazide	10	6.3
<b>Total number of antihypertensive drugs prescribed</b>	182	100.0
<b>Number of antihypertensive prescribed as single drug formulation</b>	172	94.5
<b>Number of antihypertensives drugs prescribed as combination formulation</b>	10	5.5

**Table 4: Drug information queries among the study patients, (n=56).**

Drug information queries (Type)	N	Percentage (%)
<b>Active queries</b>	48	85.7
<b>Passive queries</b>	8	14.3
<b>Different classes of drugs with drug information queries</b>		
Nootropic	1	1.8
Antidiabetics	16	28.6
Antihypertensives	14	25.0
Hypolipidemic	4	7.1
Antiplatelet	3	5.4
Antibiotics	4	7.1
H2 blockers/PPI	2	3.6
Vitamins (Neutraceuticals)	2	3.6
Miscellaneous	10	17.9
<b>Categories of drug information queries</b>		
Mechanism of action	10	17.9
Actions	2	3.6
Dosage	11	19.6
Adverse effect	18	32.1
Availability of new drugs, preparations	2	3.6
Uses/ Indications	4	7.1
Contra-indications	4	7.1
Advantages	4	7.1
Drug interactions	1	1.8
Pharmacokinetic queries	1	1.8
<b>Drug information sources used</b>		
Primary sources (journals/publications)	10	17.8
Secondary sources (indexing/abstracting)	16	28.5
Tertiary sources (EDL/therapeutic formularies)	30	53.5

**Table 5: Drug prescribing indicators.**

Prescribing indicators	Average/percentage	Standard derived/ ideal
Average number of drugs per encounter	4.86%	1.6-1.8
Percentage of drugs prescribed by generic name	71.9%	100%
Percentage of drugs prescribed from essential drug list	47.82%	100%
Percentage of encounters with injections	26.8%	<20%
Percentage of encounters with antibiotics	18.7%	<30%

## DISCUSSION

The present study aimed to investigate the prescribing patterns and therapeutic approaches in patients with diabetic hypertensives at a tertiary care hospital in India. The high prevalence of both individually and in combination, represents a significant health burden globally particularly pronounced in India.<sup>6,8</sup> The coexistence of these two chronic conditions bears unique challenges for clinicians in terms of managing multiple risk factors and optimizing treatment strategies to achieve optimal therapeutic outcomes.<sup>7,15</sup>

Most patients included in the study were among the older age population with slight male prominence. Prevalence of diabetes and hypertension is mostly observed in the age group of 50-60 years of age with slight male predominance.<sup>16-19</sup> Prevalence of diabetes with hypertension has been steadily rising in India, largely attributed to lifestyle transitions, urbanization and dietary changes.<sup>20,21</sup> These observations found due to increasing sedentary lifestyle, lack of physical activity and obesity necessitating equal need for lifestyle modifications along with medications. Most patients belong to low socioeconomic status as the study is conducted in a tertiary care government set up hence patients attending OPD are from low socioeconomic strata. These results were consistent with those from prev study.<sup>22</sup> The most common diabetic complication observed to be diabetic peripheral neuropathy similar to findings in previous study.<sup>23</sup>

As antidiabetic therapy, 75% patients were prescribed oral antidiabetic drugs. Most common oral antidiabetic drug class prescribed were biguanides (79.4%). Similar findings were found in previous studies.<sup>5,17,24</sup> Biguanides class of drugs includes metformin improves insulin sensitivity and bear positive effect on lipid profile reducing the cardiovascular risks and showing beneficial effects like effective glycaemic control, weight reduction, less risk of hypoglycemia and it is economical. Hence, it is the most preferred oral hypoglycemic drug by physicians. Antidiabetic therapy in most patients was prescribed as monotherapy in the present study. On other hand, previous studies have observed that polytherapy is more common compared to monotherapy.<sup>5,24,25</sup> Since DM is chronic disease treatment goes on lifelong, and it may be difficult to control the sugar levels with single drug. The severity of disease may also vary in different population and availability of drugs, thus variability in prescriptions is found.

In the present study, 25% of the patients were prescribed insulin; this proportion of patients is higher compared to other studies which ranged between 15-17%.<sup>17,19,24</sup> This variation may be due to the variation in the percentage of patients with type I and II DM and availability of the drugs in the study area.

Among antihypertensive drugs in the present study, CCBs were most common antihypertensives prescribed (41.3%) in which Amlodipine (40.6%) was most commonly prescribed. Similar results are observed in other studies.<sup>17,26,27</sup> On the other hand, angiotensin receptor blockers (ARBs) and Angiotensin convertase enzyme inhibitors (ACEI) were also reported as most commonly used drug.<sup>1,18</sup> Telmisartan (40 mg) + Amlodipine (5 mg) was the most common combination prescribed to the patients in this study. Telmisartan, a promising cardiometabolic sartan is the therapy of choice for HTN in diabetic patients observed in study. Prescribing and promoting rational combined drug formulations, minimize the cost and improve patient compliance. In other studies, different combinations were used like atenolol+ amlodipine, losartan + hydrochlorothiazide, ARBs+CCBs.<sup>1,19,25</sup>

According to JNC 8, the first line of antihypertensives for the Asian population, should consist of a thiazide-type diuretic, CCB and either ACEI or ARB in hypertensive diabetics.<sup>28</sup> So, the choice of drug or combination to be prescribed depends on physician, the race, comorbidities, disease control and drug availability. There is also need to adhere to recent hypertension and diabetes standard treatment guidelines to encourage rational prescribing according to which ACEI or ARBs to be considered as first choice to delay the progression to overt diabetes and prevent diabetic nephropathy in coexisting hypertensives.

Most drugs were prescribed by generic name (71.9%) similar to other study which indicates increasing trend of prescribing drugs with generic name. Slight inclination towards brand name prescribing was mainly due to limited awareness among prescribers about prescribing indicators; insufficient availability of cost-effective generic medicines because of patency issues and sometimes patients trust or doctors preference for innovator medicines.<sup>24</sup> The average number of drugs prescribed per prescription in this study 4.86 was comparable to some studies but lower than studies by some other studies.<sup>24,29</sup> Polypharmacy (5 or more drugs) was seen in 29.4% of

study population especially geriatric patients as seen in some studies.<sup>30,31</sup>

Variety of drugs prescribed from EDL were 47.82% whereas in other study it was 64.29%.<sup>5</sup> Vitamins and Miscellaneous drugs like NSAIDs were most common classes of drugs prescribed other than antidiabetic and antihypertensives (41.2% each). Overuse of vitamins (41.2%) was also observed in our study as compared to other similar studies which needs to be decreased to reduce polypharmacy and cost of treatment and increase compliance. Lipid lowering drugs (statins) were prescribed to 38.9% of the study population suggesting pleiotropic effects in reducing CVS events in diabetic patients independent of lipid levels. Antiplatelets were prescribed to 25.6% of the study subjects presuming high risk of CVS complications like IHD.

Most drug information queries were for antidiabetic drugs (28.6%) followed by antihypertensives (25%) drugs and common queries on adverse effects (32.1%) and drug dosages (19.6%) indicating physicians concern and need of drug information services during patient care. These results closely match with the findings in a study done by George which showed that maximum queries were on drug dosage and administration (27%) followed by ADR (24%). In this study, the most commonly used drug information source were tertiary sources (53.5%).<sup>32</sup> Out of the 160 patients, about only 12 (7.5%) patients reported adverse drug reactions indicating underreporting. Most common ADR being hypoglycemia (n=6) (3.75%) caused by insulin and sulfonylureas.

### Limitations

Even though this study was conducted with sound methodology, there are some limitations to the present study which includes modest sample size and shorter duration. To obtain more reproducible findings, additional long-term research can be conducted. The study is uncentric on outpatient basis. Future research on the use of antidiabetic medication in admitted patients can be conducted in the inpatients department.

### CONCLUSION

In this study, it was observed that monotherapy was more often prescribed than the combination drug therapy. Biguanides (Metformin) and CCBs (Amlodipine) were the most frequently prescribed agents among oral hypoglycemics and antihypertensives respectively. Prescribing practices reflects polypharmacy, increasing generic drug use and decreasing use of EDL drugs. Rational prescribing using WHO drug use indicators and adhering to recent standard treatment guidelines needs to be followed in hypertensive diabetics. This study addresses drug information needs of the physician and gives feedback to the prescribers to improve quality of healthcare. Pharmacovigilance awareness among all the

health care professionals as well as patients and relatives are must for better patient safety.

### Recommendations

Good prescription practices, advocating appropriate polypharmacy, medication reconciliation, deprescribing etc. to provide optimized evidence based safe and effective therapies to the patients encouraging vigilant and rational use of drugs through proper doctor and patient communication. Measures must be taken to increase reporting of ADRs and improve drug information services by providing specific training and facilities to prescribers focusing on skills to receive and comprehend enquiries, available resources, literature searching.

### ACKNOWLEDGEMENTS

Authors would like to thank to department of medicine IGGMC, Nagpur.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee IEC, IGGMC, Nagpur.*

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**Cite this article as:** Nakhate VA, Badar VA. Assessment of prescribing pattern, adverse drug reactions and drug information sources in middle aged diabetic hypertensives at a tertiary care hospital in central India: a prospective observational study. *Int J Basic Clin Pharmacol* 2026;15:339-46.