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An Observational Drug Utilization Study in Type 2 Diabetes Mellitus with Coexisting Hypertension at a Tertiary Care Hospital in India

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Abstract

Background: Drug utilization studies are powerful exploratory tools to ascertain the role of drugs in society. Aim of this study is to analyze the prescription pattern of type-2 diabetes mellitus 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.

Materials and 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 & 6 months. The data of prescriptions of patients having type-2 diabetes mellitus with co-existing hypertension and patient specific queries on drug information were collected and interpreted using WHO Core drug use prescribing indicators, JNC 8 & American Diabetes Association 2021 guidelines for hypertensive diabetic patients. Suspected Adverse Drug Reactions reporting forms were analyzed by ADR causality & severity assessment scales.

Results: Study population included 160 patients with type-2 diabetes mellitus 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 (41.3%) was 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.

Conclusion:

In this study, monotherapy was more often prescribed than the combination drug therapy. Biguanides (Metformin) and Calcium channel blockers (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 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: Adverse drug reaction, Biguanides, Diabetes mellitus, Hypertension, Drug information queries, polypharmacy

Introduction

Drug utilization studies (DUS) have as their primary goal the evaluation of the elements involved in the prescription, distribution, administration, and consumption of drugs as well as the associated events (either positive or negative). The World Health Organization (WHO) defines DUS as the marketing, distribution, prescription and use of medications in a society while taking into account any potential medical, social, or financial consequences.[1]

Diabetes mellitus (DM) is a chronic condition that is becoming a significant cause of morbidity and mortality. Recent studies of WHO revealed increase in prevalence of Diabetes mellitus 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 diabetes mellitus have co-existing hypertension.[2] Diabetes death rates by age increased by 3% between 2000 and 2019.[3] 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. [4,5]

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% to 60%, as compared to the general population. [6,7] Conversely, patients with hypertension also face a significantly risk developing increased of T2DM.[8]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 irrational prescribing.[9-11] restricting Drug utilization studies, which assess and analyze the medical, social and economic effects of drug therapy, are therefore more important and observe the prescribing behaviour of doctors with the goal of providing drugs rationality and reducing Adverse Drug Reactions(ADRs) due to particular drug by urgent ADR reporting by any health care professional. They also play a crucial role in developing and putting these strategies into action so as to improve quality of healthcare. [12-14]

This was a prospective cross-sectional observational study conducted in patients with type-2 diabetes mellitus having co-existing hypertension attending medicine outpatient department (diabetic clinic & hypertensive clinic) in tertiary care hospital in central India. The study was started after the approval of Institutional Ethics Committee. The study was conducted 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 either sex between the age of 40-70 years with type-2 diabetes mellitus and coexisting hypertension (Essential /Primary) with or without associated chronic complications were included in the study and patients with type-1 diabetes mellitus, secondary hypertension, gestational diabetes mellitus 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 & 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 & ADA 2021 guidelines for hypertensive diabetic patients.

То delineate drug information needs. by accompanying the physician in OPD, the data of patients for whom queries arise was collected in the specific proforma. Patient 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, along with age & sex distribution and the ADR Causality assessment done by Naranjo Algorithm Probability scale.

Materials And Methods

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 case records / prescriptions were collected and analyzed for epidemiologic profile, disease spectrum, drug prescription utilization 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 ischaemic heart disease (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 prescribed 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 our study, among the prescribed oral antidiabetic agents, 82.9% were single drug formulations and only 17.1% combination drug formulations were where Glimepiride(1mg) + Metformin(50mg) was most commonly prescribed as combination.

Among antihypertensive drugs, calcium channel blockers (CCBs) were most common antihypertensives prescribed (41.3%) followed by ACE inhibitors (37.5%) and ARBs (18.8%). Telmisartan (40 mg) + Amlodipine (5mg) 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 & 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 adverse drug reactions indicating underreporting. Most common ADR being hypoglycemia (n=6) (3.75%) caused by insulin & 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 & preventable. Probability of ADR scale (Naranjo-Algorithm) showed that most (10 ADR) fell in the 5-8 Probable scale: 6.25 % patients & (2 ADR) fell in 1-4 Possible scale: 1.25%

Discussion

The present observational drug utilization study aimed to investigate the prescribing patterns and therapeutic approaches in patients with Type 2 (T2DM) Diabetes Mellitus coexisting with hypertension at a tertiary care hospital in India. The high prevalence of T2DM and hypertension, both individually and in combination, represents a significant health burden globally and is particularly pronounced in India. [6,8] 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. [7,15]

Most patients included in the study were among the older age population with slight male prominence. The prevalence of diabetes along with hypertension is mostly observed in the age group of 50-60 years of age with slight male predominance. [16-19] The prevalence of T2DM with coexisting hypertension

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has been steadily rising in India, largely attributed to lifestyle transitions, urbanization and dietary changes. [20,21] These observations found due to increasing sedentary lifestyle, lack of physical activity & obesity necessitating equal need for lifestyle modifications along with medications.

The most patients in this study belong to low socioeconomic status showing disease being common in lower socio-economic group. This study is conducted in a tertiary care government set up hence the patients attending the OPD are from low socioeconomic strata. These results were consistent with those from a previous study. [22] The most common diabetic complication was observed to be Diabetic peripheral neuropathy (26.25 %) Similar findings are observed in previous study. [23] followed by IHD & diabetic nephropathy.

In the present study, in 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. [5,17,24] Biguanides class of drugs includes Metformin has been proved to improve insulin sensitivity and bear positive effect on lipid profile reducing the cardiovascular risks as well as have 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 the physicians. The antidiabetic therapy in most patients was prescribed as monotherapy in the present study. On the other previous studies have observed hand, that polytherapy is more common compared to monotherapy. [5,24,25] Since DM is chronic disease the treatment goes on lifelong, and it may be difficult to control the sugar levels with single drug. The severity of the disease may also vary in different population along with the availability of the drugs, thus the variability in prescriptions is found.

In the present study, 25% of the patients were prescribed insulin; short acting insulin prescribed more compared to intermediate acting insulin in the study population. This proportion of patients is higher compared to other studies which ranged between 15-17%. [17,19, 24] This variation may be due to the variation in the percentage of patients with Type I and II DM. It may also vary due to the availability of the drugs in the study area.

Among antihypertensive drugs in the present study, calcium channel blockers (CCBs) were most common antihypertensives prescribed (41.3%) in which Amlodipine (40.6%) was most commonly prescribed. Similar results are observed in other studies. [17,26,27] On the other hand, angiotensin receptor blockers (ARBs) [18] and Angiotensin Convertase Enzyme Inhibitors (ACEI) [1] were also reported as most commonly used drug. Telmisartan (40 mg) + Amlodipine (5mg) was the most common combination prescribed to the patients in this study. Telmisartan, a promising cardiometabollic sartan is the therapy of choice for HTN in diabetic patients observed in study. Prescribing & promoting combined drug formulations, minimize the cost & improve patient compliance. In other studies, different combinations were used like Atenolol+ Amlodipine [1], Losartan + Hydrochlorothiazide [19], ARBs + CCBs [25].

According to JNC 8, the first line of antihypertensives for the Asian population, should consist of a thiazide-type diuretic, calcium channel blocker (CCB) and either angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) in hypertensive diabetics. [28] So the choice of drug or combination to be prescribed depends on the physician, the race, comorbidities, disease control and availability of the drug. There is also need to adhere to recent hypertension and diabetes guidelines to encourage rational prescribing according to which ACEI or ARBs should be considered as first choice while treating them 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/guidelines given by WHO; insufficient availability of cost-effective generic medicines because of patency issues and sometimes patients trust /doctors preference for innovator medicines. [24]. The average number of drugs prescribed per prescription in this study 4.86 was comparable to some studies [24,29] but lower than studies by some other studies. Polypharmacy (5 or more than 5 drugs) was seen in 29.4 % of study population especially geriatric patients. Appropriate

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polypharmacy is the need of hour for which appropriate measures are needed like Good prescribing practices, Medication reconciliation, deprescribing etc. to provide optimized evidence based safe & effective therapies to the patients encouraging vigilant & rational use of drugs through proper communication between Doctor & Patient [30,31]

Variety of drugs prescribed from EDL were 47.82% whereas in other study it was 64.29%. [5] 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 & 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 antihypertensive(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 and measures must be taken to improve that by providing specific training and facilities to prescribers focusing on skills to receive & comprehend enquiries, available resources, literature searching skills. These results closely match with the findings in a study done by George B 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%) [32] 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 & Sulfonylureas.

Even though this study was conducted with sound methodology, there are some limitations to the present study. The sample size of present study was modest, and completed during short term. To obtain more reproducible findings, additional long-term research can be conducted. The study only considered OPD. Future research on the use of antidiabetic medication in admitted patients can be conducted in the inpatients department. Due to the unicentric nature of the study, the utilization patterns of other diabetic treatment centers could not be ascertained.

Conclusion

In this study, it was observed that monotherapy was more often prescribed than the combination drug therapy. Biguanides (Metformin) and Calcium channel blockers (Amlodipine) were the most frequently prescribed agents among oral hypoglycemics and antihypertensives respectively. Rational prescribing using WHO drug use indicators and adhering to recent standard treatment guidelines needs to be followed in hypertensive diabetics. The trends of prescribing the drugs by the generic name found to be increasing. The patients had more queries for the adverse drug reactions and drug dosages. Pharmacovigilance awareness regarding detecting & reporting of ADRs among all the health care professionals as well as patients and their relatives must be brought for better patient safety in diabetic hypertensive patients.

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Characteristics	Number of patients (n=160)	(Percentage)%	
Age in years			
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	
Gender			
Male	82	51.3	
Female	78	48.8	
Socio-economic status			
Low	96	60	
Middle	64	40	
High	00	00	
Duration of DM in Years			

Table 1: Clinical and Demographic Characteristics of study patients

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1-5 years	64	40.0
6-10 years	53	33.3
11-15 years	37	23.1
>15 years	6	3.8
Dur	ation of hypertension in Years	
1-5 years	74	46.3
6-10 years	62	38.8
11-15 years	19	11.9
>15 years	5	3.1
	Complications	
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
Without complications	40	25

Table 2: Drug utilization of antidiabetic drugs in study patients

	Number of patients	0⁄0	
	(n=160)	(Percentage)	
Patients on oral anti- diabetic therapy	120	75%	
Patients on Insulin therapy	40	25%	
Class of Antidiabetic drugs prescribed			
Biguanides	127	79.4	
Sulfonylureas	122	76.3	
Insulin	40	25.0	
Alpha glucosidase inhibitor	21	13.1	
Thiazolidinediones/Glitazones	19	11.9	

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Antidiabetic drugs		
1.Metformin	127	79.4
2.Glimepiride	43	26.9
3.Gliclazide	19	11.9
4.Glipizide	12	7.5
5.Glibenclamide	48	30.0
6.Insulin	40	25.0
7.Acarbose	2	1.3
8.Voglibose	19	11.9
9.Pioglitazone	19	11.9
Total number of oral antidiabetic agents prescribed	245	100.0
Number of oral antidiabetic drugs prescribed as single drug formulation	203	82.9
Number of oral antidiabetic drugs prescribed as combination drug formulation	42	17.1
Patients on Short acting insulin	23	14.4
Patients on intermediate acting insulin	17	10.6

Table 3: Drug utilization of antihypertensive drugs in study patients

	Number of patients	% (Percentage)
	(n=160)	
Antihypertensive class of drugs		
Alpha blocker	1	0.6
Beta blocker	28	17.5

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ACE inhibitors	60	37.5
ARBs	30	18.8
Calcium channel blockers	66	41.3
Diuretics	9	5.6
Antihyp	ertensive drugs (Individu	al)
1.Prazosin	1	0.6
2.Atenolol	20	12.5
3.Metoprolol	9	5.6
4.Nebivolol	1	0.6
5.Enalapril	37	23.1
6.Ramipril	21	13.1
7.Losartan	17	10.6
8.Telmisartan	11	6.9
9.Olmesartan	2	1.3
10.Nifedipine	1	0.6
11.Amlodipine	65	40.6
12.Hydrochlorothlazide	10	6.3
Total number of antihypertensive drugs Prescribed	182	100.0
Number of antihypertensive prescribed as single drug formulation	172	94.5
Number of Antihypertensives drugs prescribed as combination formulation	10	5.5

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Table 4: Drug information queries among the study patients

Drug information queries	Number of patients	Percentage %
(Type)	(n=56)	(35%)

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Active queries	48	85.7
Passive queries	8	14.3
Different cla	asses of Drugs with drug inform	ation queries
1.Nootropic	1	1.8
2.Antidiabetics	16	28.6
3.Antihypertensives	14	25.0
4.Hypolipidimic	4	7.1
5.Antiplatelet	3	5.4
6.Antibiotics	4	7.1
7.H2 blockers/PPI	2	3.6
8. Vitamins (Neutraceuticals)	2	3.6
9.Miscellaneous	10	17.9
Categories of	drug information queries	
1.Mechanism of action	10	17.9
2.Actions	2	3.6
3.Dosage	11	19.6
4.Adverse effect	18	32.1
5. Availability of new drugs,	2	3.6
different preparations		
6.Uses/ Indications	4	7.1
7.Contra-indications	4	7.1
8.Advantages	4	7.1
9.Drug interactions	1	1.8
10.Pharmacokinetic queries	1	1.8
Drug information sources used		
Primary sources	10	17.8

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(journals/publications)		
Secondary sources	16	28.5
(indexing /abstracting)		
Tertiary sources	30	53.5
(EDL/Theurapetic formularies)		

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%

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Table 5: Drug prescribing indicators