

PRESCRIPTION AUDIT AND DRUG INTERACTIONS OF ANTI-DIABETIC DRUGS AT OUTPATIENT DEPARTMENT AT A TERTIARY CARE TEACHING HOSPITAL IN EASTERN NEPAL

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ABSTRACT

Type 2 diabetes mellitus (T2DM) is the third major non-communicable disease in Nepal. Drug utilization studies help in reducing the patient's expenditure, adverse drug reactions and drug-drug interactions. It would help in understanding of consumption of drugs including newer ones. Objective was to analyze the prescribing pattern and drug interactions of anti-diabetic drugs. A prospective cross-sectional study was conducted among patients having T2DM at Birat Medical College and Teaching Hospital (BMCTH), Biratnagar, Nepal from May 2019- August 2019. WHO core drug use indicators were used to analyze the obtained data. Descriptive statistics like mean, standard deviation, frequency and percentage were calculated using Microsoft Excel 2013. Out of 200 patients, 104 (52.0%) were females and 49.5% were from the age group of 41-60 years. Average number of drugs per patient was 5.74. Biguanides (40.7%) were the most common prescribed oral antidiabetic drugs followed by Sulfonylureas (23.3%). The percentage of drugs prescribed by generic name and from WHO essential drug list was 0.6% and 15.4% respectively. A total of 95 (47.5%) patients has potential drug-drug interaction (DDI) and it was most common in the age group of 41-60 years (43.2%). Among 95 DDI, Metformin+Amlodipine ranked in 1st position (16 encounters). Polypharmacy was prevalent in the present study. Metformin was the most commonly prescribed anti-diabetic drug. The percentage of drugs from the WHO essential medicine list and prescribed by generic names was low. Prevalence of potential DDI was high.

KEYWORDS

Drug interaction, polypharmacy, type 2 diabetes, prescribing, audit, anti-diabetic drugs, Nepal

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INTRODUCTION

Diabetes mellitus is a chronic metabolic disease characterized by elevated levels of blood glucose which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves. The global diabetes prevalence was estimated to be 9.3% in 2019 which is expected to rise to 10.2% by 2030 and 10.9% by 2045.¹ About 1 in 11 adults worldwide now have diabetes mellitus, 90% of whom have type 2 diabetes mellitus (T2DM).² Its prevalence is 8.5% in Nepal.³ T2DM is the third major non-communicable disease in Nepal and is approaching pandemic levels due to rapid change in socioeconomic status and life-style of the people.⁴

Drug Utilization Research (DUR) is the marketing, distribution, prescription and use of drugs in the community with special emphasis on the resulting medical, social and economic consequences. It creates a rigorous socio-medical and health economic basis for healthcare decision making. It also helps to determine the role of drugs in society.⁵ It provides valuable evidence to the researchers, policymaker and drug and therapeutics committee members. Its ultimate importance is the rational use of drugs that helps in reducing the patient's expenditure, adverse drug reactions and drug-drug interactions.⁵ The associated complications and comorbidities results in prescription of several drugs that ultimately leads to polypharmacy.⁶

Prescription studies help to expand the importance of rational use of drugs. It would help in understanding of consumption of drugs including newer ones.⁷ Studies on drug utilization in diabetes is scarce in our context where the available resources are limited. Objective of the study was to analyze the prescribing pattern and drug interactions of anti-diabetic drugs at medicine OPD department in tertiary care teaching hospital, Eastern Nepal.

MATERIALS AND METHODS

It was a prospective and quantitative hospital-based study and was conducted in Birat Medical College and Teaching Hospital (BMCTH), Biratnagar, Nepal. The hospital is providing the tertiary level of health services. The data were collected from the patients having T2DM and visiting Medicine Outpatient Department at BMCTH, Biratnagar, Nepal from May 2019-August 2019. Using the formula, $n = Z^2 * P * (1-P) / d^2$, sample size was calculated to be 145 at 95% confidence level and prevalence of 56.4%⁸

and the convenience sampling was used as sampling technique.

Inclusion criteria:

1. Patients diagnosed with type 2 diabetes mellitus patients
2. Age >18 years
3. Patients with T2DM on treatment with both oral hypoglycemic agents and insulin therapy

Exclusion Criteria:

1. Gestational diabetic patients
2. Chronically ill patients like HIV/AIDS, tuberculosis and those who need emergency access.
3. Patients who refused to give consent

Ethical approval: This study was ethically approved by the Ethical Review Board of Nepal Health Research Council, Kathmandu, Nepal (138/2019).

Data collection tool: The data was collected utilizing a data collection form designed for this purpose. It consisted of gender, age, races, education status, occupation status, duration of DM, family history of DM, comorbidities and prescribed drugs.

Data collection technique: The study objectives were explained to the patients and written informed consent was taken. The OPD card of the patients were reviewed to collect the relevant data directly into the proforma. Medscape online app was used as drug-drug interaction checker and the pattern of potential DDI were analyzed and identified. Medscape drug-drug interaction checker is an electronic database that contains a separate section on DDI known as Medscape drug reference on entering the list of prescribed medication it enlisted all possible hazardous drug therapy and interactions on the basis of severity and documentation status.⁹ The following WHO core drug use indicators were used to analyze the obtained data:¹⁰

(i). Percentage of drugs prescribed by generic name was calculated to measure the tendency of prescribing by generic name. It will be calculated by dividing the number of drugs prescribed by generic name by total number of drugs prescribed, multiplied by 100.

(ii). Average number of drugs per prescription was calculated by dividing the number of drugs prescribed by total number of patients.

(iii). Percentage of drugs prescribed from an essential drug list (EDL) was calculated to

measure the degree to which practices conform to a national drug policy as indicated in the national drug list of Nepal.¹¹ Percentage was calculated by dividing number of products prescribed which were in essential drug list by the total number of drugs prescribed, multiplied by 100.

(iv). Percentage of fixed-dose combination (FDC) prescribed = $\frac{\text{Number of FDC}}{\text{Total drugs}} \times 100$

Data analysis: The data were entered in Microsoft Excel 2013 and descriptive statistics like mean, standard deviation, frequency and percentage were calculated using SPSS-11.5. The findings were presented as tables and graphs.

RESULTS

A total of 200 patients were enrolled in the study and 104 (52.0%) were males. About one-half of the patients (49.5%) were from the age group of 41-60 years followed by 61-80 years (29.0%). One hundred and eleven patients (55.5%) were found to be illiterate and 126 (62.0%) were unemployed (Table 1).

Table 1: Socio-demographic details of the persons with diabetes (n=200)			
Variables		n	%
Gender	Male	104	52.0
	Female	96	48.0
Age groups (years)	19 – 40	36	18.0
	41 – 60	99	49.5
	61 – 80	58	29.0
	>80	7	3.5
Races	Brahmin	42	21.0
	Chhetri	27	13.5
	Mongolian	36	18.0
	Others	95	47.5
Education status	Primary	60	30.0
	Secondary	23	11.5
	Tertiary	6	3.0
	Illiterate	111	55.5
Occupation status	Unemployment	124	62.0
	Employment	76	38.0
Duration of DM	New cases	64	32.0
	1 – 10 years	117	58.5
	>10 years	19	9.50
Family history of DM	Yes	50	25.0
	No	150	75.0

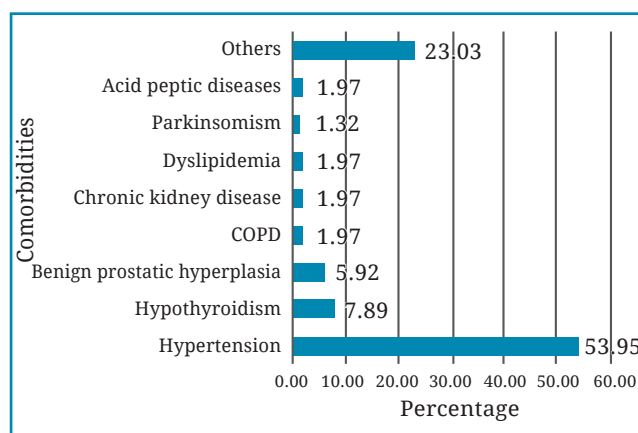


Fig. 1: Comorbidities present in the patients (n=152)

Out of 200, 152 (75.0%) patients had some comorbidities and hypertension (53.9%) was the most common. Other minor comorbidities includes peripheral neuropathy, pneumonia, hepatitis, CVA, psychiatric-disorder, headache, back pain and diarrhea (Fig. 1).

A total of 1148 drugs were prescribed to 200 patients and average number of drugs per patient was 5.74. Anti-diabetic drugs (41.5%) were the most common prescribed drugs followed by cardiovascular drugs (21.16%) (Table 2).

Table 2: Therapeutic category of prescribed drug (n=1148)		
Therapeutic classification of drugs	n	%
Anti-diabetic drugs	476	41.46
CVS drugs	243	21.17
GIT drugs	89	7.75
CNS drugs	52	4.53
Antibiotic	38	3.31
Analgesics and anti-inflammatory drugs	40	3.48
Respiratory system drugs	43	3.75
ANS drugs	24	2.09
Antihistamine	19	1.66
Anti-thyroid drugs	12	1.05
Vitamins, minerals and dietary supplements	112	9.76

Biguanides (40.7%) were the most common prescribed oral antidiabetic drugs followed by Sulfonylureas (23.3%) and di-peptidyl peptidase inhibitors (19.9%) (Table 3).

About 99 (48.5%) patients were prescribed three antidiabetic drugs followed by two drugs in 52 (26.0%) patients (Fig. 2).

Table 3: Classification of anti-diabetic drug (n= 476)

Antidiabetic drugs	ATC code	n	%		
Oral antidiabetic drugs	Biguanides	Metformin	A10BA02	194	40.8
		Glibenclamide	A10BB01	8	
	Sulfonylureas	Gliclazide	A10BB09	1	23.3
		Glimepiride	A10BB12	102	
	Thiazolidinediones	Pioglitazone	A10BG03	5	1.0
	Alpha-glucosidase inhibitors	Acarbose	A10BF01	2	3.8
		Voglibose	A10BF03	16	
	Dipeptidyl peptidase-4 inhibitors	Sitagliptin	A10BH01	40	20.0
		Linagliptin	A10BH05	55	
	Insulin	Rapid acting	Insulin lispro	A10AB04	3
Short acting		Regular insulin	A10AB	22	11.1
Intermediate acting		NPH	A10AC	22	
Long acting		Insulin glargine	A10AE04	6	

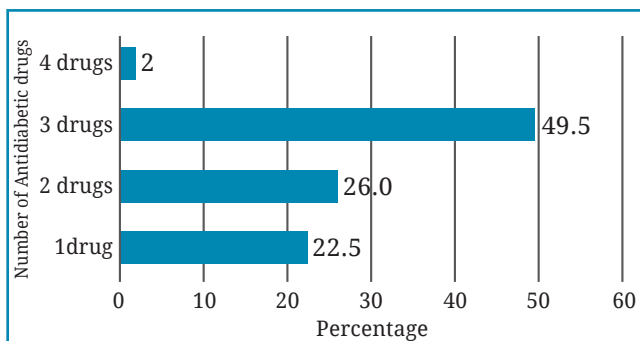


Fig. 2: Numbers of anti-diabetic drugs prescribed to the patients (n=200)

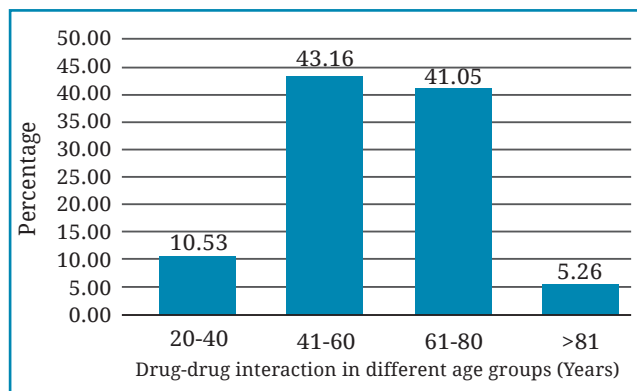


Fig. 3: Drug-drug interaction in different age groups (n=95)

WHO prescribing indicators are shown in Table 4. The percentage of drugs prescribed by generic name was 0.6%. The percentage of encounters with an injection preparation was 4.6%. The percentage of drugs prescribed from WHO essential drug list was 15.4%. The number of fixed dose combination prescribed was 12.2%.

Table 4: WHO prescribing indicators

n	Parameter	%	WHO standard
1	Percentage of drugs prescribed by generic name	0.6	100.0%
2	Percentage of encounters with an injection preparation prescribed	4.6	13.4-24.1%
3	Percentage of drugs prescribed from WHO essential drug list	15.4	100.0%
4	Percentage of FDC	12.2	--

A total of 95 (47.5%) patients has potential drug-drug interaction (DDI) and it was most common in the age group of 41-60 years (43.2%) (Fig. 3).

In this present study, metformin (29.5%) was the most common drug associated with potential DDI followed by glimepiride (24.0%) (Table 5).

Among 95 DDI, metformin+amlodipine ranked in 1st position (16 encounters) followed by

Table 5: Top 5 drug with a high probability of causing drug-drug interactions

Rank	Drug	Encounters (n)	%
1	Metformin	59	29.5
2	Glimepiride	48	24.0
3	Insulin NPH	37	18.5
4	Insulin regular human	37	18.5
5	Linagliptin	25	12.5

Table 6: Top drug pairs with potential to cause drug-drug interaction

Rank	Drug Combination	Encounters	Severity	Potential hazard effect	Mechanism
1.	Metformin + Amlodipine	16	Monitor closely	Increase hypoglycemia	Pharmacodynamic antagonism
2.	Glimepiride + Linagliptin	10	Monitor closely	Increase hypoglycemia	Unknown mechanism
3.	Metformin + Regular Insulin	9	Monitor closely	Increase the effect	Pharmacodynamic synergism
4.	Glimepiride + Aspirin	8	Minor	Increase hypoglycemia	Unknown mechanism
	Metformin + Amitriptyline	6	Minor	Unknown	Pharmacodynamic synergism
	Metformin + Levothyroxine	6	Monitor closely	hypoglycemia	Pharmacodynamic antagonism
5.	Metformin + Hydrochlorothiazide	6	Minor	Increase metformin effect	Basic cationic drug competition
	Linagliptin + Regular Insulin	6	Monitor closely	Synergistic effect	Pharmaco-dynamic synergism
	Telmisartan + Regular Insulin	6	Monitor closely	Changes in blood glucose level	Unspecified/ specified mechanism
	Aspirin + Regular Insulin	5	Monitor closely	Increase effect of insulin	Pharmacodynamic synergism
6.	Glimepiride + Regular Insulin	5	Monitor closely	Either increase effect	Pharmacodynamic synergism
7.	Glimepiride + Amitriptyline	4	Minor	Increase effect of glimepiride	Pharmacodynamic synergism

glimepiride+linagliptin (10 encounters) and metformin+regular insulin (9 encounters) (Table 6).

DISCUSSIONS

The present study revealed that half of the patients (49.5%) with DM were in the middle-aged group (41-60 years) and this was similar to an Indian study (48.57%).¹² It might be due to the unhealthy lifestyle and a high stress level in this age group. These age groups have a high chance of developing diabetes in their productive age because of their lifestyle modification, physical changes and stress. Most of the patients were female in the present study and this was in consistent with other study.¹³ Majority of the patients were illiterate and unemployed in the present study and similar findings were also reported by other reports.^{14,15} These findings suggest that individuals with unemployment and less education are two to four times more likely to develop diabetes mellitus and more likely to be affected by the diabetes complications.¹⁶

Over one-half of the patients (58.5%) had DM for 1-10 years. Besides, a family history of diabetes was observed in 25.0% of diabetic patients and was similar to an Indian study (83.4%).¹⁷ A family history of DM was observed in one-fourth of the patients in our study and was lower than a study conducted in India (32.0%).¹⁷ In our study, majority (76.0%) of the patients had one or more co-morbidities and hypertension was the commonest comorbidity. These findings were in consistent with other studies.^{18,19} Person with diabetes having more comorbidities are prescribed more drugs that can lead to polypharmacy and harmful drug-drug interactions.²⁰

Within prescribed drugs, the percentage of anti-diabetic drugs was found to be 41.4% in our study. In contrast to this, Jimoh *et al.* reported that 53.9% drugs were antidiabetics prescribed to the study participants.²¹ Vitamins, minerals and dietary supplements were prescribed to about 10.0% of the patients in our study and similar findings was also reported by Eze Uchenna *et al.*¹⁴ These findings indicated that there might be an influence of pharmaceutical

industries to promote vitamins and other nutrition supplements among doctors.

In our study, metformin (40.7%) was commonly prescribed drug and this finding aligned with other studies.²²⁻²⁴ About half of patients (48.5%) were prescribed three antidiabetic drugs in the present study and it was not consistent with Sharma *et al*²² in which majority (50.6%) patients were prescribed two antidiabetic drugs. The study findings supported trend of combined antidiabetic therapy to achieve better glycemic control and to prevent progression of disease.²⁵ In our study, average number of drugs per prescription was 5.7 that was higher than study by Eze Uchenna *et al*¹⁴ (4.7) and Sharma *et al*²² (4.2) and these findings unfortunately deviate from the WHO standard (1.6-1.8).^{26,27} It might be due to fact that the diabetic patients might have multiple comorbidities along with the various complications that lead to polypharmacy.

Considering, the prescribing indicators the percentage of drugs prescribed by generic names was 0.7% which is too low compared with the WHO standard.²⁷ Abidi *et al*²⁸ found 4.5% of drugs were written in a generic name and Ramachandran *et al*²⁹ found 25.3% of generic drugs was prescribed. It is obvious that the trends of prescribing in the brand name imply to the promotion of the propriety products by pharmaceutical companies and pressure from the medical representatives of the branded products to prescribe their brand.

We found that 3.2% injectable drugs were prescribed that does not fall in the recommended range given by WHO.²⁷ These findings closely matched to Acharya *et al*³⁰ (4.3%). Patients who have diabetes along with hypertension are mostly managed with oral hypoglycemic agents. This could be the reason behind the findings which does not meet the standard value.

In the current study, only 15.4% the drugs prescribed were from the National List of Essential Medicines, Nepal and this was lower than that found in western Nepal (88.0%) and India (90.6%).^{19,31} This could be the lack of advocacy on the importance of essential drugs list in our settings. Enforcement of rules to instruct the prescribers to prescribe from the essential drug lists to patients in private and public hospitals should be advocated.

Nearly half of the patients (47.5%) were exposed to drug-drug interaction (DDI). Similar result was also reported by Londhe *et al*³² (63.3%). The most common drug pair with DDI was metformin-amlodipine. In contrast to this, insulin-metformin was the most common drug pair with DDI in a study by Londhe *et*

al.³² Furthermore, Upadhaya *et al*³³ found metformin-enalapril as the most common interacting drug pair. These variations might be due to varied prescription in other hospitals. Diabetes Mellitus is associated with multiple comorbidities and multiple drug therapy leading to increased risk of DDIs. Hence, to prevent these DDIs health care providers should have adequate information about DDIs not only via drug information center which can provide evidence-based information to healthcare professionals but also through encouraging the empowerment of clinical pharmacists that can provide the evidence-based approach to drugs and thereby prevent drug therapy problems. The present study had some limitations. Sample size of our study was small. The duration of the study was brief. Being a single center study, the findings cannot be generalized.

The present study revealed that polypharmacy was prevalent among persons with diabetes. The percentage of drugs from the WHO essential medicine list and prescribed by generic names was low. Metformin was the most commonly prescribed anti-diabetic drug followed by fixed dose combination of metformin with sitagliptin. Prevalence of potential DDI was high and the topmost drug-drug interaction pair was metformin-amlodipine. Further research on a larger population is needed to sustain our study findings.

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