



Received on 02 April 2026; received in revised form, 02 May 2026; accepted, 08 May 2026; published 01 August 2026

A PROSPECTIVE STUDY TO OBSERVE DRUG UTILIZATION PATTERN USING WHO DRUG PRESCRIBING INDICATORS IN PATIENTS OF ISCHEMIC HEART DISEASE AT TERTIARY CARE TEACHING HOSPITAL

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Keywords:

WHO prescribing indicator, Rational drug use, Essential drug list, Drug utilization pattern

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ABSTRACT: The prescription writing process by prescriber is a very important step, and prescription error can lead to irrational use of medicine. The objective of the research is to describe and evaluate drug utilization patterns using WHO core indicators at the tertiary level. This is prospective observational study which was carried out in indoor IHD patients (IPD). WHO drug prescribing indicators were used to assess the drug utilization pattern. A total of 400 patients with IHD were recruited for the study. The cardiovascular class accounted for 68.02% of all drugs prescribed. 29.82% of FDCs in total drugs were prescribed in this study. The percentage of prescriptions with injections and antibiotics prescribed was 84.25% and 4% respectively. A total of 3743 drugs were prescribed, with an average of 9.36 ± 0.88 drugs per prescription. All drugs (100%) were prescribed with a generic name. 98% drugs were from essential drug list (Rajasthan-2019). The percentage of prescriptions with prescriptions for injections and the average number of drugs per prescription were much higher than the WHO standard, which has to be improved to make drug use rational. Most of the prescribed drugs were from EDL developed by Rajasthan state government; all prescriptions were prescribed with generic names; and the antibiotic is prescribed to only a few patients which is appreciable. Nevertheless, there is a need for strict adherence to WHO prescribing indicators, and there should be frequent training sessions to improve the rationality of treatment.

INTRODUCTION: The World Health Organization (WHO) rational drug use means that patients should be given appropriate medicines for their clinical needs in an appropriate dose for an adequate period of time and at lowest cost that can be afforded by them and community. According to the WHO, more than 50% of medicines are inappropriately prescribed, dispensed or sold globally¹.

The prescription writing process by the prescriber is a very important step, and prescription error can lead to irrational use of medicine. Irrational prescription has numerous drawbacks, including increased treatment cost, increased drug interaction and adverse effects, decreasing adherence and compliance, and increased microbial resistance. While rational prescription is beneficial to the patient by increasing their quality of time, it is beneficial to the nation by cutting down the overall health budget.

The behavior of irrational prescription includes polypharmacy, which means prescribing five or more drugs², the prescription of branded drugs instead of generic, the use of drugs not including in essential drug list, the overuse of antibiotics and

QUICK RESPONSE CODE  DOI link: https://doi.org/10.13040/IJPSR.0975-8232.17(8).2474-81	DOI: 10.13040/IJPSR.0975-8232.17(8).2474-81 This article can be accessed online on www.ijpsr.com
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injections, unnecessary prescription of multivitamins, the prescribing of drugs without taking 'drug interactions' into consideration, and the use of unapproved fixed drug combinations. In India, many factors like illiteracy, poverty, drug advertising and promotion, and the sale of drugs without a prescription are responsible for the irregular pattern of drug use. These factors may lead to an irrational prescription.

To assess the drug use pattern in the health care set-up, WHO developed core prescribing indicators. These indicators include drug prescribing indicators, patient care indicators, and health facility indicators. The purpose of this indicator is to describe the drug use situation in a country, region, or individual health facility. These measures will allow the health planner or health care provider to differentiate between the various situations. These indicators will allow the measurement of impact following the implementation of proper interventions to improve drug usage patterns³.

The purpose of this study is to evaluate drug utilization patterns in IHD patients using the WHO core prescribing indicators and to analyze the current status and the developing trends of drug utilization at the tertiary level. The drug utilization pattern used in IHD varies in different geographical regions and from hospital to hospital. This depends on the type of IHD, age of the patient, the presence or absence of comorbidity, and the availability of cardiovascular drugs. Given the growing global prevalence of IHD, it is a necessary to recognize determinants and patterns of drug prescription and drugs utilization in IHD patients.

A drug utilization study can be used to give feedback to the prescriber and health care provider. It may also help to identify potential targets for improvement and suggest modifications in patient care and prescribing practice to make patient care and drug use rational.

METHODS: This is a prospective observational study that was carried out in indoor IHD patients admitted in the cardiology department at SMS Medical College and Hospital, Jaipur after approval from the institutional ethical committee, the research review board and department of

cardiology. Duration of the study was 12 months, from June 2020 to May 2021.

A sample of 400 cases of IHD were required at 95% confidence interval with 10% relative error to verify expected 50% of patient given rationalization- Utilization of drugs (50% in taking to obtain maximum sample size).

Indoor IHD patients of either sex between the age of 20 and 80 years; IHD Patients with or without any of the following comorbidities: diabetes mellitus, obesity and hypertension; all patients, regardless of intervention status at the time of recruitment, were included in our study while indoor patients admitted for diseases other than IHD such as endocarditis, rheumatic heart disease, arrhythmia, cardiac tumors; chronic active infection like tuberculosis, HIV and hepatitis; and pregnant and lactating women were excluded.

After explaining the study procedure to the participants, written informed consent was taken, and patients were recruited randomly according to inclusion and exclusion criteria. IHD patients were diagnosed through a combination of medical history (chest pain, shortness of breath, pain in the jaw, neck or left arm etc.), physical examination and various tests (Electrocardiogram, stress test, 2-D Echo and coronary angiography). The most reliable test for diagnosing IHD is coronary angiography. The patients were categorized into an interventional and non-interventional group. Those patients who did not undergo intervention were included in non-interventional group and those patients who had already undergone intervention were included in interventional group. The prescriptions of these patients were studied at the time of hospitalization and interviews were taken by the investigator. The entire process of data collection strictly adhered to the Indian Council of Medical Research (ICMR) and good clinical practice (GCP) guidelines. The following data were collected from the prescriptions of these patients.

1. Demographic profile: patients were divided into three age groups i.e., 21-40, 41-60 and 61-80 years. The patient's gender was noted
2. The drugs prescribed to each patient in both groups were noted as follows:

- The number of medicinal formulations prescribed to each patient. (Fixed drug combination/s were considered as single medication).
- Name of single prescribed drug (Cardiovascular drugs and non -cardiovascular)
- Name of drugs in a fixed drug combination
- Name of antimicrobial agents prescribed
- Name of injectable drugs prescribed
- Drugs prescribed by generic name
- Drugs prescribed from the essential drug list (Rajasthan-2019)

3. WHO drug prescribing indicators³ were calculated as follows:

Average number of medicines perprescription = (Total number of medicines prescribed for the total prescription) / (Total clinical prescription) × 100

Percentage of drugs prescribed by generic name = (Total number of medicines prescribed in INN format) / (Total number of medicine prescribed) × 100

Percentage of medicines prescribed from EDL = (Total number of medicines prescribed from EDL) / (Total number of medicine prescribed) × 100

Percentage of prescriptions with injections prescribed = (Total number of clinical prescription with prescription of injection (one or more) / (Total clinical prescription) × 100

Percentage of prescriptions with antibiotic prescribed = (Total number of clinical prescription with prescription of antibiotic (one or more) / (Total clinical prescription) × 100

Measuring Daily Defined Dose (DDD): Anatomical Therapeutic Chemical (ATC) and DDD are gold standards for drug utilization monitoring and research. The ATC classification system groups the active medical substances according to the organ or system on which they act and according to their therapeutic, pharmacologic, and chemical properties.

The DDD is a unit of measurement of drug consumption and is linked to the ATC code. WHO defines DDD as the assumed average maintenance dose per day for a drug used for its main indication in adults⁴.

The underlying study assessed drug utilization measures by using WHO core indicators and also observed drug consumption by ATC/ DDD.

TABLE 1: ATC CLASSIFICATION OF THE PRESCRIBED DRUGS

Sr. no.	Drug name	ATC code
1.	Lactulose	A06AD11
2.	Low Molecular Weight Heparin	B01AB05
3.	Clopidogrel	B01AC04
4.	Aspirin	B01AC06
5.	Streptokinase	B01AD01
6.	Isosorbide Dinitrate (ISDN)	C01DA08
7.	Metoprolol	C07AB02
8.	Ramipril	C09BX03
9.	Atorvastatin	C10AA05
10.	Alprazolam	N05BA12

Drug Utilization:

Utilization in DDD = (Number of packages used × Number of DDD in a package)

DDD/Package = Drug Strength × Package Size / DDD

DDD is expressed as:

DDD/ 100 Bed-days = (Utilization in DDDs) / (Number of occupied bed days) × 100

DDD/ patient = (Utilization in DDDs) / (Number of patients)

The data was entered into an MS Excel spreadsheet and analyzed using the Statistical Package for Social Sciences (SPSS) version 20.0 software. Data are presented as average, frequency, percentage, and standard deviation of the mean.

RESULTS: The data of 400 patients with IHD (325 in the non-interventional group and 75 in the interventional group) were analyzed. Among these patients, 305 (76.25%) were men and 95 (23.75%) were women in both groups.

A total of 2546 drugs from the cardiovascular class (non-interventional group = 2090 and interventional group = 456) were prescribed to 400 patients. Among all cardiovascular drugs, antiplatelets (16.94%) were most commonly prescribed, and fibrinolytics (0.47%) were least prescribed which was only prescribed to patients of interventional group. Among these cardiovascular drugs, two medications (aspirin + clopidogrel, and aspirin + ticagrelor) are fixed drug combinations. Thus, among cardiovascular drugs, 27.66% (294+75+335) were from FDC category.

Two drugs (LMWH and streptokinase) are injections. Among cardiovascular drugs, injectable drugs accounts for 13.24% (325+12) **Table 1**.

A total of 1197 drugs from non-cardiovascular class (non-interventional group = 972 and interventional group = 225) were prescribed to 400 patients. Among all non- cardiovascular drugs, laxative and Proton Pump Inhibitors (33.08%) was most commonly prescribed drug. Antimicrobial agents (1.34%) were the least prescribed and were only prescribed to patients of non-interventional group. Among these non-cardiovascular drugs, two medications (pantoprazole+domperidone, and amoxicillin+ clavulanic acid) were fixed drug combinations. Thus, among non-cardiovascular drugs, 34.42% drugs (396+16) were from the FDC category. One medication (Amoxicillin+ Clavulanic acid) was an injection and among non-cardiovascular drugs, injectable drugs accounts for 1.34% (16) are **Table 2**. 68.02% of cardiovascular drugs were prescribed among all 3743 drugs.

Among all 3743 drugs, 1116 FDCs were prescribed [29.82% (704 from cardiovascular drugs and 412 from non-cardiovascular drugs)] **Table 1 & 2**. More than half of the patients (173, 53.23%) in the non-interventional group were prescribed ten drugs in each prescription, while the maximum number of patients (59, 78.67%) in the interventional group were prescribed nine drugs in each prescription. Overall, 184 (46%) patients received ten drugs per prescription while 145 (36.25%) patients received nine drugs per prescription **Table 3**.

The percentage of prescriptions with injections and antibiotics prescribed was 84.25% and 4% respectively. A total of 3743 drugs were prescribed with an average of 9.36 ± 0.88 drugs per prescription. All drugs (100%) were prescribed with a generic name. 98% drugs were from essential drug list (Rajasthan-2019). The remaining 2% of drugs were a fixed drug combination (aspirin + ticagrelor) which was not included in EDL **Table 4**.

TABLE 2: NUMBER OF VARIOUS CARDIOVASCULAR DRUGS PRESCRIBED IN BOTH GROUPS

Category	Drug	Non-interventional Group (n=2090) Frequency (%)	Interventional group (n=456) Frequency (%)	Total (n=2546) Frequency (%)
β-Blocker	Metoprolol-XL	237 (11.34)	74(16.23)	311(12.22)
ACE Inhibitor	Ramipril	262(12.54)	72(15.78)	334(13.12)
Nitrates	ISDN	323(15.45)	75(16.45)	398(15.63)
Antiplatelet	Aspirin	31(1.48)	0	31(1.22)
	Clopidogrel	31(1.48)	0	31(1.22)
	Aspirin+ Clopidogrel (FDC)	294(14.07)	0	294(11.55)
	Aspirin + Ticagrelor (FDC)	0	75(16.45)	75(2.95)
Diuretics	Torsemide + Spironolactone (FDC)	262(12.54)	73(16)	335(13.16)
Anticoagulant	LMWH (Injection)	325(15.55)	0	325(12.77)
Lipid lowering agent	Atorvastatin	325(15.55)	75(16.45)	400(15.71)
Fibrinolytics	Streptokinase (Injection)	0	12(2.63)	12(0.47)
Total cardiovascular drugs prescribed		2090	456	2546

FDC- Fixed Dose Combination

TABLE 3: NUMBER OF VARIOUS NON-CARDIOVASCULAR DRUGS PRESCRIBED IN BOTH GROUPS

Drug	Non-interventional Group (n=972) Frequency (%)	Interventional group (n=225) Frequency (%)	Total (n=1197) Frequency (%)
Sedative	Alprazolam	75(33.33)	389(32.5)
Laxative	Lactulose	75(33.33)	396(33.08)
PPI	Pantoprazole+ Domperidone (FDC)	75(33.33)	396(33.08)
Antimicrobial agents	Amoxicillin+ Clavulanic acid	0	16(1.34)
	(Injection) (FDC)		
Total non-cardiovascular drugs		972	225

FDC- Fixed Dose Combination

TABLE 4: NUMBER OF DRUGS PER PRESCRIPTION IN BOTH GROUPS

Number of drugs per prescription	Non-interventional Group (n=325)		Interventional group (n=75)		Total (n=400)	
6	3	0.92%	0	0%	3	0.75%
7	12	3.69%	0	0%	12	3%
8	35	10.78%	5	6.66%	40	10%
9	86	26.46%	59	78.67%	145	36.25%
10	173	53.23%	11	14.67%	184	46%
11	16	4.92%	0	0%	16	4%
Mean drugs per prescription $\pm$ S.D.	9.42 $\pm$ 0.94		9.08 $\pm$ 0.46		9.36 $\pm$ 0.88	

S.D.- Standard deviation

TABLE 5: WHO CORE PRESCRIBING INDICATOR IN BOTH GROUPS

WHO Core Prescription indicators	Non-interventional Group (n=3062) Frequency (%)	Interventional Group (n=681) Frequency (%)	Total (n=3743) Frequency (%)	As Per WHO standard ³
Average number of drugs prescribed per prescription	9.42	9.08	9.36	1.6-1.8
Percentage of drugs prescribed by generic name	3062 (100)	681 (100)	3743 (100)	100%
Percentage of medicines prescribed from EDL	3062 (100) n=325	606 (88.99) n=75	3668 (98) n=400	100%
Percentage of prescriptions with injection prescribed	325 (100)	12(16)	337 (84.25)	<25%
Percentage of prescriptions with an antibiotic prescribed	16 (4.92)	0 (0)	16 (4)	<30%

WHO- World Health Organization, EDL-Essential drug list-Rajasthan 2019, n=3062 (total 3062 drugs were prescribed in non-interventional group), n=681 (total 681 drugs were prescribed in interventional group), n=3743 (total 3743 drugs

were prescribed in both groups). n=325 (total 325 prescriptions in non-interventional group), n=75 (total 75 prescriptions in interventional group), n=400 (total 400 prescriptions in both group)

TABLE 6: DDD RESULTS

Sr. no.	Drug Name	DDD by WHO	Observed DDD/100 bed days
1	Lactulose	6.7 g O	22.1265
2	Low Molecular Weight Heparin	2 TU P	4.875
3	Clopidogrel	75 mg O	7.25
4	Aspirin	1 tab O	7.238
5	Streptokinase	1.5 U P	3
6	Isosorbide Dinitrate (ISDN)	20 mg SL	24.875
7	Metoprolol	0.15 g O	12.984
8	Ramipril	2.5 mg O	8.35
9	Atorvastatin	20 mg O	200
10	Alprazolam	1 mg O	24.3125

DISCUSSION: WHO core prescribing indicators investigates the drug use and pattern in health care setting. It measures the health-care provider's performance regarding rationale use of medicines, and it is used to identify the issues related to medicine use.

In our study, the average number of drugs per prescription was 9.36, which is 5-6 times higher than the WHO recommended value (1.6-1.8). The polypharmacy found in our study is consistent with studies done by Nightingale *et al* ⁵, Nagabushan *et*

al ⁶, and Sawant *et al* ⁷ in which polypharmacy was found at 9.93, 7.8, and 7.7 respectively. The WHO defines polypharmacy as “the administration of many drugs at the same time or the administration of an excessive number of drugs”. Polypharmacy means that the number of drugs per prescription consists of five or more drugs ².

In our study, we analyzed the patients with IHD, and mostly elderly people suffer from cardiovascular disease. There are many risk factors that may contribute to other comorbid conditions.

So, polypharmacy is common in elderly patients due to the simultaneous treatment of multiple diseases with their advanced age⁸.

It is common trend of prescribing the inappropriate drugs in geriatric population in developing countries⁹. If there are more medicines in a single prescription, there are more chances of side effects and drug-drug interactions. It can decrease the patient's medication adherence and drug compliance. It can also put a burden on health care costs.

There is a process of deprescription by which we can minimize polypharmacy. Drug deprescription not only reduces multiple drug prescriptions but also improves the patient's outcomes¹⁰.

In our study, 98% of the drugs prescribed, were from essential drug list (EDL) of Rajasthan-2019, whereas in other studies by Nagabushan *et al*⁶, and Sawant *et al*⁷, percentage of prescribed drugs from EML was 69.43%, 75.1%, and 60.32%, respectively. Only 2% of drugs were not from the EDL in our study. The medication/FDC, aspirin + ticagrelor, is not included in EDL, which was prescribed to all 75 patients in interventional group. The antiplatelet drug of choice in this group was a combination of aspirin and ticagrelor. Ticagrelor has a quicker onset of action than clopidogrel and is more potent in comparison to clopidogrel¹². The concept of EML use is built on the premise that the use of a limited number of well-known and cost-effective medicines can lead to better health care management. EML is a list of medicines that satisfy the priority health care needs of the majority of the population and are easily available¹³.

Prescriptions from EDL are always beneficial to patients, and it also decrease the burden on patients as well as on the government as most of the drugs in EDL are generic drugs that are much cheaper than branded drugs. Recently, in India, latest EDL (National List of Essential Medicines-NLEM) was launched in September 2022 and contains 384 medicines¹⁴.

As per the WHO standard, all drugs should be prescribed by their generic name. The aim of this indicator is to measure the inclination of the prescriber to prescribe the drugs using the international non-proprietary name (INN)¹².

All drugs in our study were prescribed by their generic name, or INN, which is consistent with WHO standard. Mukhyamantri Nishulk Dawa Yojna (MNDY) is a scheme in Rajasthan Government hospitals that provides free medicines to all patients. Following the implementation of free drugs scheme under MNDY in Rajasthan state, the government has made it mandatory for prescribers to prescribe drugs by their generic name at all government-controlled health care facilities. Prescribing drugs by their generic name reduces the cost of therapy significantly. According to a study that compared data from 17 developing countries, purchasing equivalent generic drugs than branded medicines save an average of 60% (with the maximum savings in Colombia at 89% and minimum savings in Kuwait at 9%)¹⁵.

The prescriber should be encouraged to prescribe the medicine by its generic name. Secondly, the name of the medicine should be written legibly and in capital letters so that the pharmacist can dispense the medicine correctly. Pharmacists also have an important role in promoting generic medicines. They can dispense the cheaper alternative, which is direct cost cutting, reducing the economic burden on the patients.

In our study, 84.25% patients (100% patients of the non-interventional group and 16% of the interventional group) received injections (but only one). This is much more than the WHO standard. The drug, LMW Heparin, was injected subcutaneously into all patients in non-interventional group because it is not available in oral dosage form. In a study done by Galappaththy *et al*¹¹, total no. of prescription found with injection prescribed was 30.1%. In this study, a total of 353 (9.43%) drugs were prescribed in the form of injections. However, 27.86% injections were prescribed in a study done by Sawant *et al*.⁷

In our study, only 4% of total prescriptions (patients) received antibiotics as per the WHO standard and all patients who received antibiotics belonged to the non-interventional group. This finding is much lower as compared to other similar studies like Nagabushan *et al*⁶, Sawant *et al*⁷ and Christain *et al*¹⁶ where the percentage of prescriptions with antibiotic prescription was found to be 40.2%, 22.06%, and 37.9%, respectively.

Anxiolytics *i.e.*, Alprazolam, Laxatives *i.e.*, Lactulose were prescribed to most of patients to decrease the anxiety. PPI with Antiemetic drugs *ex.* Domperidone was prescribed to almost all patients in both non-interventional and interventional group, because it reduces gastric acid suppression due to IHD induced stress and nausea, vomiting due to medications. In our study, a total of five medications (3 in cardiovascular class and 2 in non-cardiovascular class) were used as fixed drug combinations. All five FDCs used in our study are approved by the central drugs standard control organization (CDSCO)¹⁷. Only one of these FDC combinations, Amoxycillin + clavulanic acid is included in NLEM. However, according to EDL-Rajasthan-2019, four of the five FDCs (except aspirin+ ticagrelor) are included in this list. FDC accounted for 29.82% (1116) in our study. Most of them are antiplatelet drugs. FDC should be rational, as irrational combination will not only increase the drug cost but also expose the patient to avoidable adverse drug effects. Irrational FDCs also contribute to drug-drug interactions, which can be harmful to patients.

While calculating DDD/100-bed days, it was found that Atorvastatin (200) and ISDN (24.875) were highly consumed cardiovascular drugs. Among Non-Cardiovascular drugs Alprazolam (24.3), Lactulose (22.12) were highly consumed.

This study was duration-bound with a restricted sample size. Also, we could not take into account patient care indicators and health facility indicators which can provide strength to the study. DDD could not be calculated for the various fixed dose combinations prescribed in this study as they were not classified under ATC classification of WHO.

CONCLUSION: The percentage of prescriptions with prescription of injections and the average number of drugs per prescription were significantly higher than the WHO standard, which must be improved in order to rationalize drug use, better patient care, and be in the best interests of the patient. In Rajasthan state, the government developed its own essential drug list for the hospital under government control. Most of the drugs were from this EDL except the combination of aspirin and ticagrelor; all prescriptions were prescribed with generic names, and the antibiotic is

prescribed to only a few patients, which is appreciable. Nevertheless, there is a need for strict adherence to WHO prescribing indicators and there should be frequent training sessions to improve the rationality in treatment. Further studies are needed to evaluate the prescription pattern and understand the behavior of the prescriber.

ACKNOWLEDGEMENT: The authors wish to express their thanks to faculty members of the departments of pharmacology and cardiology for their kind support and cooperation.

Funding: No funding source

CONFLICT OF INTEREST: None

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How to cite this article:

Singh A and Mahawar DK: A prospective study to observe drug utilization pattern using who drug prescribing indicators in patients of ischemic heart disease at tertiary care teaching hospital. *Int J Pharm Sci & Res* 2026; 17(8): 2474-81. doi: 10.13040/IJPSR.0975-8232.17(8).2474-81.

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