

Study on drug utilization pattern in cardiology outpatient department at tertiary care hospitals in South India: A prospective multicenter cross-sectional observational study

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ABSTRACT


Background: Study of prescription patterns is an important to determine rationality of drug therapy and to maximize the utilization of resources. **Objective:** This prospective, multicenter, cross-sectional observational study was conducted at three selected tertiary care hospitals in South India to assess the drug utilization pattern (DUP) of cardiovascular drugs in outpatient department (OPD). **Materials and Methods:** A total of 1026 prescriptions of the patients attending cardiology OPD over a period of 1 year were randomly identified then critically analyzed for World Health Organization (WHO) core prescribing indicators. **Results:** The average number of drugs prescribed was five and medicines prescribed by its generic name were 2.33%, encounters with an injection prescribed (14.52%), medicines prescribed from National List of Essential Medicine (NLEM) were 89.27%, apart from above some other class of drugs also prescribed for patients with different comorbidities. Majority of drugs were prescribed as single drugs (86.78%) whereas 13.21% as fixed-dose combinations (FDCs). The most commonly prescribed single drug was aspirin (59.93%) and FDC were Aspirin + Clopidogrel (40.24%). Most of drugs were prescribed from the recent NLEM of India which indicates the implementation and adoption of national drug policy by the hospitals and cardiologists. **Conclusion:** Antiplatelets dominated the prescribing pattern in the cardiology OPD and expected to overtake anti-cholesterol agents as the sales leader. Updated knowledge about the banned drugs, irrational FDCs, deleted drugs, and recent NLEM are very important to both practitioners and pharmacists, also pharmacists have to encourage the prescribers to prescribe the cardiovascular drugs by its generic name.

KEY WORDS: Cardiovascular Drugs; Drug Utilization Pattern; Fixed Dose Combinations; Antiplatelet Drugs; National List of Essential Medicine

INTRODUCTION

The World Health Organization (WHO) reports an estimated 17.9 million people died from cardiovascular disease (CVDs) in 2016, representing 31% of all global deaths, of these

deaths 85% are due to heart attack and stroke.^[1] The WHO has estimated that the current burden of CVD in India would lose \$237 billion from the loss of productivity and spending on health care over a 10-year period 2005–2015,^[2] by 2025 deaths from CVDs are predicted to rise to almost 50 million in India. According to the WHO, more than 50% of all medicines are prescribed, dispensed or sold inappropriately, on the other side, 50% of patients take them incorrectly and about one-third of the world's population lacks access to essential medicines.^[3] Prescription is a critical issue in the rational treatment.^[4] Study of prescription patterns is an important to determine rationality of drug therapy and

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to maximize the utilization of resources.^[5] The prescribing pattern reflects the physician's knowledge about the disease process and application of pharmacotherapeutics.^[6] Studies on drug utilization pattern (DUP) have become a potential tool to be used in the evaluation of health-care system.^[7] Drug utilization research encourages rational prescribing of drug, contributes to the knowledge of current use of drugs in the society and explore whether a particular intervention affects the drug use in the population by observing the drug use pattern.^[5] Hence, this study was planned to assess the DUPs in cardiology outpatient department (OPD) at different tertiary care hospitals in South India using the WHO prescribing indicators and also to measure the degree of implementation of national drug policy by the practitioners as indicated as prescribing drugs in National List of Essential Medicine (NLEM).

MATERIALS AND METHODS

Study Design

The present prospective, multicenter, and cross-sectional observational study was conducted in three selected tertiary care hospitals from different parts in South India. Prescriptions from the patients attending the cardiology OPD from the beginning of 2016 to 2017 were included in this study.

Ethical Approval

The study was approved by the main Centre's Institutional Ethics Committee (IEC) for Human Research with the approval number SVCP/IEC/JAN/2016/11 dated 27 January 2016. Hence, it is a non-invasive patients' prescription analysis based study it was exempt from obtaining individual informed consent from each patient according to the Helsinki Declaration of 1964 revised in 2000,^[8] but the objective of the present study was explained to all participants.

Study Protocol

A total of 1026 prescriptions of the patients attending cardiology OPD of the selected hospitals over a period of 12 months were randomly identified and included in this study according to the inclusion criteria then critically analyzed using WHO core prescribing indicators, particularly different types of drugs prescribed and their prescribing pattern was determined. Prescriptions of patients with age < 30 and >80, pregnancy, lactation, critically ill patients, patients with lifestyle modification alone, prescriptions of outpatients of other departments, prescriptions of patients diagnosed with non-cardiac diseases, prescriptions of patients those not willing to participate were excluded from this study.

Prescribing Indicators

Prescription were analyzed for WHO Prescribing Indicators such as (i) average number of drugs per encounter, (ii) percentage of encounters with an antibiotic prescribed, (iii) percentage of encounters with an injection prescribed, (iv) percentage of drugs prescribed by generic name, and (v) percentage of drugs prescribed from essential drugs list or formulary,^[9] then all values were compared with the optimal level prescribed by the WHO. Each prescription was also analyzed for the completeness of prescription using other important components such as the presence of demographic data, diagnosis, doses of drugs, route of administration, frequency, duration of treatment, and amount of fixed-dose combinations (FDCs) prescribed.

Statistical Analysis

The collected data were numerically coded and descriptive statistical analysis was performed by using Microsoft Excel™ software and results were expressed as Mean ± standard error of the mean for numerical variables and as percentage (%) for categorical variables. Descriptive statistical analyses were performed.

RESULTS

Age and Gender-Wise Distribution of CVD Patients

Based on the results obtained it is found that male patients 64.61% had high frequency of cardiovascular incidences when compared to female patients 35.38%. Out of 1026 patients, 37.62% of patients (Male 25.14% and Female 12.47%) belong to the age group of 51–60 years which is considered to be highest percentage when compared to all other age groups and 8.10% of patients (Male 5.06% and Female 3.02%) present in the age group of 71–80 years which are considered to be lowest percentage among all age groups, these demographic data reveal the influence of gender and age in disease and prescribing pattern [Table 1].

Estimation of Prescribing Indicators

Average number of drugs prescribed

In our study, the average number of drugs per patient encounter was 5, which was far more when compared with the WHO recommended standard value 1.6–1.8.^[9] This suggesting a trend of polypharmacy in the prescription pattern all the results are shown in Table 2.

This finding was more than other studies conducted in India such as 3.2,^[10] 2.9,^[11] 2.4,^[12] as well as studies conducted in some other countries 3.8^[13] and 3.52.^[14] Polypharmacy leads to many consequences such as adverse drug reactions; drug-drug interactions even though it is found to be unavoidable in certain diseases and cases particularly in hypertensive, type 2 diabetes

Table 1: Age- and gender-wise distribution of CVD patients

Age in years	No. of patients	Percentage	Male	Percentage	Female	Percentage
30–40	116	11.30	083	08.08	033	03.21
41–50	227	22.12	142	13.84	085	08.28
51–60	386	37.62	258	25.14	128	12.47
61–70	214	20.86	128	12.47	086	08.38
71–80	083	08.10	052	05.06	031	03.02
Total	1026	99.99	663	64.61	363	35.38

CVD: Cardiovascular disease

Table 2: WHO core prescribing indicators

Prescribing indicators	Results
Average number of drugs prescribed per patient encounter	5
Percent medicines prescribed by generic name	2.33
Percent encounters with an antibiotic prescribed	3.11
Percent encounters with an injection prescribed	14.52
Percent medicines prescribed from NLEM	89.27

NLEM: National List of Essential Medicines 2015

mellitus and elderly patients characterized by comorbidity. The advantage of using polypharmacy over monotherapy has been proven in many common disease entities.^[15]

Medicines prescribed by generic name

Medicines prescribed by its generic names were only 2.33%, which are very less when compared to the WHO standard optimal value 100%.^[9] It was more than findings from the others studies such as 1.5%^[12] and 0.05%^[16] but very less when compared to findings from other studies such as 68%^[11] 46.2%^[10] and other international studies.^[17,18] This indicates that prescribing habits are directly influenced by some medical representatives of the drug companies, impressive, and continuous communication with prescribers made prescribers more likely to prescribe proprietary products than generic products. In general generic prescribing reduces the chances of dispensing errors and also reduces the economic burden to the patient because generic drugs are available for lesser prices compared to various branded drugs.^[19]

Encounters with an antibiotic prescribed

This study was carried out in cardiology OPD and its based on CVS drugs only hence measuring this objective is not applicable even though it is measured in our study the percentage of encounters with antibiotics prescribed was 3.11% only, prescribed in few elderly patients to treat their other ailments. This is not falls within the WHO prescribed optimal values 20–26.8%.^[9] In general, proper and less use of antibiotics will prevent the development of drug resistance and also reduces the cost of drug therapy.^[19]

Encounters with injections prescribed

Percentage of encounters with injections prescribed in our study was 14.52% which is within the WHO prescribed

standard values 13.4–24.1%.^[9] This was clearly more comparable to others findings such as 8%^[11] but it was less when compared to findings from other countries such as South Ethiopia 38.1%^[17] and Uganda 48%.^[20] The lower rate of use of injections would reduce the cost of the treatment and economic burden to the patient and also reduces the non-compliance of the patient to the treatment.

NLEM

The percentage of drugs prescribed from the NLEM in our study was 89.27% which was found to be fare when compared to the WHO prescribed ideal value 100%.^[9] This finding was more than other studies conducted in India such as 45.71%^[10] and almost similar to finding from study conducted by other country Nepal 88%^[13] at the same time, it is found to be less when compared to the other countries such as South Ethiopia 99.6%^[17] The percentage of drugs prescribing from NLEM is higher in South India compared to North India but lower when compared to other countries.

Estimation of associated risk factors in CVD patients

During this study, different adjustable risk factors associated with CVDs were also observed in the patients particularly 3.50% of inadequate diet, 5.16% of physical inactivity, 18.90% of tobacco consumption, 21.05% of alcoholics, and 29.04% of obesity, as shown in Figure 1.

Prescribing pattern of different cardiovascular drugs in cardiology OPD

The results indicates that most commonly prescribed class of drugs were found to be antiplatelets (67.73%), lipid-lowering (62.57%), beta-blockers (49.51%), angiotensin-converting enzyme (ACE) inhibitors (40.93%), angiotensin receptor blockers (ARB) (30.40%), calcium channel blockers (CCB) (30.11%), and diuretics (20.56) then all other class of cardiovascular drugs were prescribed within (0.87%–25.34%), it is also found that apart from cardiovascular drugs most frequently prescribed non-cardiovascular class of drugs in CVD patients was anti-ulcers (69.10%), rest of the other drugs present within (<5.0%) are given in Table 3.

In our study, it is observed that patient's aged ≥ 60 years had more number of prescriptions of both cardiovascular

Table 3: List of commonly prescribed drugs for patients with different CVDs

Class of drugs	Name of the drugs	Number of prescriptions	Percentage
Anti-platelets	Aspirin	695	67.73
	Clopidogrel		
	Ticagrelor		
Lipid-lowering	Atorvastatin	642	62.57
	Simvastatin		
	Rosuvastatin		
Beta blockers	Atenolol	508	49.51
	Metoprolol		
	Carvedilol		
	Propranolol		
ACE-inhibitors	Ramipril	420	40.93
	Enalapril		
	Lisinopril		
	Captopril		
Angiotensin receptor blockers	Telmisartan	312	30.40
	Olmesartan		
	Candesartan		
	Losartan		
Calcium channel blockers	Amlodipine	309	30.11
	Verapamil		
Anti-anginal (Nitrates)	Isosorbide dinitrate	260	25.34
	Isosorbide mononitrate		
	Nitro glycerine		
	Nicorandil		
Diuretics	Furosemide	211	20.56
	Hydrochlorothiazide		
	Amiloride		
Anti-coagulants	Enoxaparin	208	20.27
	Dalteparin		
	Tinzaparin		
Vasodilators	Hydralazine	102	9.94
Antiarrhythmics	Amiodarone	49	4.77
	Verapamil		
Centrally-acting antihypertensives	Clonidine	21	2.04
	Methyldopa		
HCN channel blockers	Ivabradine	16	1.55
Cardiac glycosides	Digoxin	09	0.87
Anti-ulcers	Pantoprazole	709	69.10
	Esomeprazole		
	Rabeprazole		
	Ranitidine		
Opioid analgesics	Tramadol	42	4.09
	Fentanyl		
Antacids	Aluminum hydroxide dried gel	39	3.80
	Magnesium hydroxide		
	Simethicone		
Anti-emetics and pro-kinetics	Ondansetron	19	1.85
	Domperidone		

CVD: Cardiovascular disease

and non-cardiovascular drugs. Prescription containing cardiovascular drugs was significantly higher in male patients aged ≥ 60 years than in male patients aged between 30 and 59 years, on the other hand, female patients aged ≥ 60 years were prescribed with more non-cardiovascular drugs than those aged between 30 and 59 years. This may be due to the greater number of comorbidities and associated conditions, such as renal dysfunctions and GIT disorders, and respiratory disorders, in elderly patients.

DISCUSSION

Cardiovascular Drugs

Most frequently prescribed drugs in our study were antiplatelet agents (67.73%) such as aspirin and clopidogrel, which is comparable as in other studies.^[21] Ticagrelor is preferred only for the patients those clopidogrel is not successive. Atorvastatin was the highly preferred anti-hyperlipidemic drug in our study as similar to another study.^[22] Beta-blockers such as atenolol and metoprolol were highly prescribed than carvedilol and propranolol, in few prescriptions we observed the drug ivabradine a safe alternative to beta-blockers. ACE inhibitors such as ramipril and lisinopril are frequently prescribed than enalapril and captopril. In ARBs, telmisartan leads the lineup. Amlodipine is found in many prescriptions of CVDs patients and consider as successive CCB. Sublingual tablets isosorbide dinitrate and nitroglycerin are vastly prescribed for emergency purposes. Hydrochlorothiazide diuretic represents one of the most commonly used agents in combination with other drugs to maintain the normal blood pressure and also to decrease the requirements for renal support particularly in elderly patients. Enoxaparin was found to be highly prescribed anticoagulant; in this study, it is also found that anti-coagulants are the only drugs always prescribed as parenteral dosage for the out patients during their regular follow-up after percutaneous coronary intervention. Hydralazine is mostly preferred vasodilators

by most of practitioners. Digoxin is prescribed for patients having an exacerbation of heart failure as symptoms.

Non-cardiovascular Drugs

It is observed in our study, the drug is highly prescribed in CVDs patients surprisingly a non-cardiac drug that is pantoprazole a proton pump inhibitor (PPI). PPIs are widely used in modern medicine particularly for drug induced ulcers,^[23,24] Antacids which contains Aluminum hydroxide dried gel, magnesium hydroxide, and simethicone are prescribed for some patients those have heartburn as one of the symptom. Opioids such as tramadol and fentanyl are prescribed in 4.09% of CVDs patients to treat their pains in different areas due to comorbidities.^[25]

Prescribing Pattern of drugs as FDCs in Patients

In our study, a total of 678 (13.21%) of prescribed drugs were found to be FDCs, rest of the drugs 4452 (86.78%) were prescribed as single dose, as shown in Figure 2.

About 4580 (89.27%) of drugs were prescribed from NLEM-2015 and 5010 (97.66%) drugs are prescribed by their proprietary names. It is found that most of practitioners prefer FDCs, only in certain circumstances and is purely case dependent. FDCs are found to have some advantages such as increasing patient compliance by bring about synergistic action which can reduce the dose of the individual component and adverse effects. On the other hand, rationality of FDCs has become one of the most controversial and debatable issues in general practice.^[26] However, FDCs prescribed here were less when compared to findings 22.55%,^[6] 70.50% of patients were prescribed with two drugs combination while 27.58% and 1.91% of patients were found to be prescribed with three and four drugs combinations, respectively, as shown in Figure 3.

Aspirin + Clopidogrel combination is found to be highly prescribed FDC (40.24%) among all, next to that Telmisartan

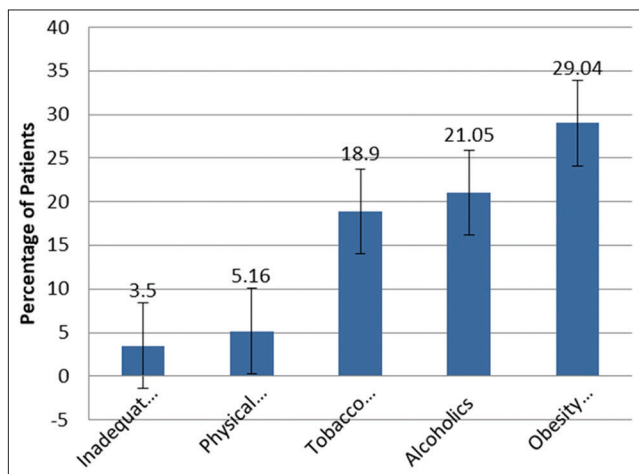


Figure 1: Distribution of selected risk factors in cardiovascular disease patients

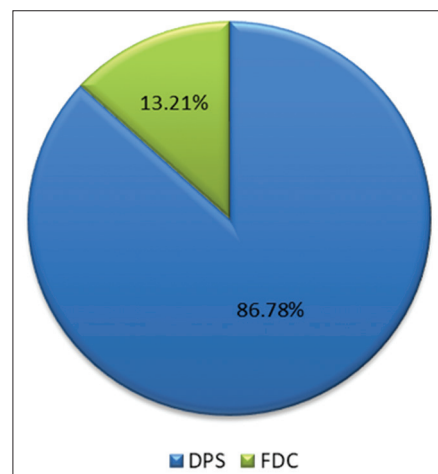


Figure 2: Percentages of drug utilization pattern in cardiovascular disease patients

Table 4: Commonly prescribed fixed dose combinations in cardiovascular disease patients

Class	Fixed dose combinations	Strength (mg)	Percentage
Antiplatelet drugs	Aspirin+Clopidogrel	75+75	40.24
ARB/Diuretic	Telmisartan + Hydrochlorothiazide	40+12.5	14.22
CCB/BB	Amlodipine+Atenolol	5+50	12.62
ACEI/Diuretic	Ramipril+Hydrochlorothiazide	2.5+12.5	5.84
ARB/BB	Telmisartan+Metoprolol	40+50	3.52
ARB/Diuretic	Losartan+Hydrochlorothiazide	50+12.5	3.24
CCB/ARB	Amlodipine+Losartan	40+5	2.48
ARB/CCB/Diuretic	Losartan+Amlodipine+Hydrochlorothiazide	50+5+12.5	2.24

ACEI: Angiotensin converting enzyme inhibitors, ARB: Angiotensin receptor blocker, BB: Beta blocker, CCB: Calcium channel blocker, LM: Lipid-modifying

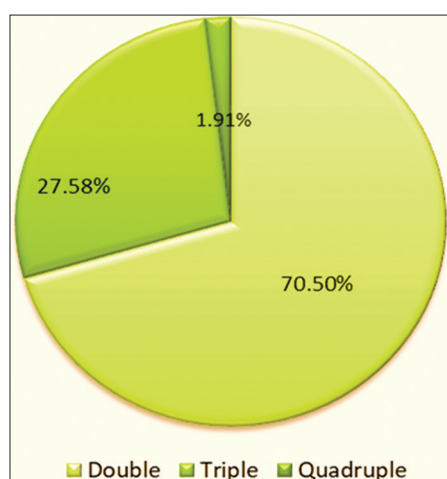


Figure 3: Percentages of different fixed dose combinations prescribed in cardiovascular disease patients

+ Hydrochlorothiazide (14.22%) and Amlodipine + Atenolol (12.62%) were highly prescribed, rest of the FDCs are prescribed within (2–6%) only [Table 4].

Most of cardiac FDCs are two drug combinations particularly antihypertensives. FDCs of different categories of drugs also found in some prescriptions, particularly Metformin SR + Atorvastatin (750 + 20 mg) were prescribed in few cardio diabetic patients (2.08%), Aspirin + Atorvastatin (75 + 10 mg) like some other FDCs for comorbidities are prescribed <1% only. There are unfortunately no worldwide acceptable criteria to define irrational FDCs and no uniform principles or international standards for their development and regulatory assessment.^[27]

WHO and Central Drugs Standard Control Organization (CDSCO)

The WHO included 414 medicines in their 19th list of essential medicines in that 27 are FDCs, after due deliberations in national consultations with scientific justifications government of India included 376 entities in that 24 are FDCs in their NLEM 2015. Some state drug authorities had issued manufacturing licenses for many FDCs without prior clearance from the CDSCO therefore

in March 2016 the Ministry of health and family welfare of Government of India has banned a total of 344 FDCs through a gazette notification^[28] for manufacturing and marketing.

The recent NLEM 2015 does not have losartan potassium in their list which is an Angiotensin-II receptor antagonist and is removed from the Section 12-Cardiovascular medicines and alprazolam which is a drug used to treat anxiety and panic disorder sometimes used as an antidepressant also deleted from Section 27-Psychotherapeutics of NLEM-2011, but we found few prescriptions (< 4%) with FDCs of Losartan + Hydrochlorothiazide, Amlodipine + Losartan and Losartan + Amlodipine + Hydrochlorothiazide, some patients prescribed with alprazolam to treat their insomnia based on their request. However, as per the Rule 122E of Drugs and Cosmetics Act 1940, the FDCs are considered as new drugs and CDSCO after due examination of data on rationality, safety, and efficacy issues approval, on the basis of the report State Licensing Authority (SLA) gives the manufacturing and marketing permission. This “disconnect” between the CDSCO and SLAs has precipitated a roadblock in the action against irrational FDCs.^[26]

Limitations

There are few limitations in our study as it is a time bound study with a limited sample size it cannot detect seasonal variations in drug use pattern and health facility indicator is not assessed which would have been able to explain the unfortunate prescription of drugs from NLEM and availability of key drugs in the dispensing pharmacy. The differences between individual prescribers have also not been assessed.

CONCLUSION

It is found that majority of drugs were prescribed from the recent NLEM of India by the most of practitioners which indicates the implementation and adoption of national drug policy by the hospitals and cardiologists but adherence to the generic prescription was found to be partially

deviated from the standards recommended by the WHO. The most commonly prescribed single drug was Aspirin (59.93%) and FDC was Aspirin + Clopidogrel (40.24%). Prescription containing non-cardiovascular drugs was also significantly higher in cardiac patients aged ≥ 60 years due to comorbidities. The important finding of this study is the anti-thrombotic market particularly antiplatelet drugs expected to overtake anti-cholesterol agents as the sales leader. It is also found that effect of FDCs of two different classes of antihypertensives like Telmisartan + Hydrochlorothiazide is higher compared to doubling the dose of a single drug but FDCs are not always safe and usually prescribed by their proprietary name and this may be another important reason responsible for the low percentage of drugs prescribed by its generic name. FDCs prescriber and user should have complete knowledge about all aspects of the approved FDCs also important. Therefore, updated knowledge about the banned drugs, irrational FDCs, deleted drugs, and recent NLEM are very important to both practitioners and pharmacists. The increase in prescriptions with generics from NLEM will increase the compliance of patient to the treatment due to reduced cost therefore cardiologists have to be encouraged by the pharmacists to prescribe the cardiovascular drugs by its generic name. Campaign, intervention, and periodic audit may update all about the prescription standards prescribed by the WHO.

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