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Research Article

Prescribing Pattern, Drug Utilization and Clinical Pharmacy Services in Acute Coronary Syndrome Patients

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Abstract

Background and Objective: Coronary Artery Disease (CAD) is the major leading cause of death worldwide according to WHO 2011. The aim of drug utilization research in Coronary artery disease was to facilitate the rational use of drugs in a specialized group of populations. The main objective of the study was to analyze the current trend of prescribing patterns of the drugs used in the management of Acute Coronary Syndrome at study site. **Materials and Methods:** The prospective observational study was conducted for a period of 6 months in the Department of Medicine from Shri B. M. Patil Medical College, Hospital and Research Center. A total of 120 patients were selected for the study. Patient case files (including patient's specific information, drug therapy and laboratory investigations) were used to extract the necessary data. The percentages of data were calculated with the help of regular Microsoft excel 2007 sheet and the Sample size was calculated using the formula. Risk factors contributing to the development of Acute Coronary Syndrome were analyzed and various clinical pharmacy services were provided as a part of the study. **Results:** Out of the 120 patients enrolled in the study majority were male (81) and were found in the age group of 60-69 years. Smoking constituted the dominant risk factor followed by hypertension. Drug Related Problems (DRPs) found to be equally prevalent among all the age groups and were equally distributed among both the genders. Cessation of drug 28 (23%) and change in dose 17 (14%) were the interventions most frequently provided. The treatment received by the patients was in partial accordance with the ACC/AHA guidelines which was used as a comparative standard for the study. The study also unveiled the scope for the modification of this partial status to whole with the active participation of clinical pharmacists at the bed side. Drug utilization pattern among ACS patients were examined with the help of WHO prescribing indicators. **Conclusion:** The results were not optimal in accordance with the standard values of WHO prescribing indicators which suggest the necessity of modifying the hospital drug formulary and also to create awareness among physicians about rational drug use. On the whole, this study highlights the need of appropriate and timely interventions by the clinical pharmacist for the improvement of drug use, the patient's quality of life and to minimize DRPs.

Key words: Prescribing pattern, WHO prescribing indicators, DRPs, clinical pharmacist role, therapeutic management, acute coronary syndrome, rational use of drugs

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Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

Coronary Artery Disease (CAD) is the major leading cause of death worldwide according to WHO 2011¹. According to the World Health Organization, around 17 million people die of coronary diseases each year and over 80% of CAD deaths take place in low and middle-income countries (WHO). Conversely, the rate has been decreasing during the last 3 decades as a result of better coronary risk factor reduction and better clinical management¹. Acute Coronary Syndromes (ACS) are a common presentation of coronary artery disease and pharmacists have important role all across the spectrum of managing ACS patients, starting from the Emergency Department (ED) to throughout their hospitalization and till to get discharged.

Acute coronary syndrome is a term that includes all clinical syndromes compatible with acute myocardial ischemia resulting from an imbalance between myocardial oxygen demand and supply².

In contrast to stable angina, an ACS primarily results from diminished myocardial blood flow which is secondary to an occlusive or partially occlusive coronary artery. According to electrocardiographic (ECG) changes, ACSs are classified into ST segment elevation myocardial infarction, non-ST segment elevation myocardial infarction and unstable angina².

Approximately 21% of patients presenting with ACS have STEMI. In NSTEMI ischemia is severe enough to produce myocardial necrosis, resulting in the release of a detectable number of biochemical markers, [troponin I or T, creatine kinase myocardial band (CK MB)] from the necrotized myocytes into the bloodstream². The patient is considered to have experienced unstable angina if no such biomarker can be detected in the bloodstream hours after the initial onset of ischemic chest pain³.

The main cause of ACS is atherosclerosis in the coronary arteries. Atherosclerosis is a complex inflammatory-fibro protective response to the retention of plasma derived atherogenic lipoproteins in the coronary artery⁴. This deposition of lipoproteins in the coronary artery results in the formation of plaque⁵. The plaque progression, disruption and thrombosis further contribute to infarction.

The national practice guidelines from the American College of Cardiology (ACC) and American Heart Association (AHA) promote the use of several medical therapies to reduce recurrence of ischemic events and mortality. These medications include dual antiplatelet agents, β -blockers, Angiotensin Converting Enzymes inhibitors (ACEIs) or Angiotensin Receptor Blockers (ARBs), statins and nitroglycerin¹.

It is important to administer the treatment according to the risk category of the patient. Moderate and high-risk patients are admitted to a coronary intensive care unit, depending on the patient's symptoms and recognized level of risk. High-risk patients should undergo early coronary angiography (within 24-48 h) and revascularization (with PCI or CABG) if a significant coronary artery stenosis is established. Moderate-risk patients with positive biochemical markers for infarction typically also undergo angiography and revascularization during hospital admission².

Pharmacist play a key role in addressing many issues that might arise within and during the entire period of therapy². The practice of clinical pharmacy is regarded as an imperative part of a health care team to provide the best quality use of medicines. Potential role of clinical pharmacist in the management of ACS patients includes prevention of drug-related problems, management of cardiovascular risk factors and to implement steps to preserve the rationality of the prescription⁵. This study can be useful to understand how the drugs are being used in a particular patient population in a given period of time. Researchers can also estimate to what extent drugs are being properly utilized⁶. The present study was conducted keeping in mind one of the specific duties of clinical pharmacist to determine rationality of the drug therapy assuring maximum utilization of the resources. Prescription pattern study in turn serves as an important tool to determine rational drug therapy and improves resource utilization using WHO prescription indicators.

MATERIALS AND METHODS

Study design and setting: A prospective and observational study was conducted for a period of 6 months from October, 2015-March, 2016 in the Department of Medicine of a Shri BM Patil Medical College, Hospital and Research Center after obtaining the Institutional Ethical Committee clearance. Hospital provides primary and specialized health care facilities to people in and around Vijaypur district. The patients admitted to the general medicine ward were screened according to inclusion and exclusion criteria and 120 patients were selected for the study.

Inclusion criteria:

- All the patients of either gender with confirmed diagnosis of acute coronary syndrome from the Medicine Department
- Patients with cardiac failure, who have been previously diagnosed with ACS

- All the inpatients from Intensive Care Unit, Cardiac Care Unit and Causality with diagnosis confirmed as ACS

Exclusion criteria:

- Pregnancy patients
- Outpatients
- Patients diagnosed with other CVS disorders except ACS and HF such as endocarditis, rheumatic heart disease, arrhythmias, cardiac tumors etc
- Patients in other departments except in medicine and cardiology

Source of data: Patient case files (including patient’s specific information, drug therapy and laboratory investigations).

Data collection: Data from each patient was collected from respective patient case files and conducting patient interviews. The collected data from each patient was documented and evaluated for the study parameters. The entire enrolled patient who met the criteria was followed on a daily basis from the date of admission to the date of discharge. Past medication and medical history were also reviewed by providing medication history interview forms to the patients/care takers (relatives). The drug prescribed in each prescription was critically analyzed using WHO prescribing indicators to evaluate the rationality of the prescriptions. One of the main objectives was to evaluate whether the inpatients were provided with ACC/AHA guideline recommended cardiac medications during their treatment period. Every change made in the therapy plan of each patient during the treatment period was updated systematically in specially designed data collection form. Medication details of all the patients were reviewed independently to identify DRPs and to explore various clinical pharmacy services in the management of ACS.

Statistical analysis: The number of patients and percentage of data were calculated with the help of regular Microsoft excel 2007 sheet and the sample size was calculated by the Eq. 1⁷ with the help of statistician.

$$n = \frac{Z\alpha^2 \times S^2}{d^2} \quad (1)$$

where, n is sample size, Zα is normal deviate at the level of significance (where Zα is 1.96 for 5% level of significance and 2.58 for 1% level of significance), S is standard deviation and d is accuracy of estimate⁷.

RESULTS

Out of the 120 patients enrolled in the study a majority of 81 were male. The patients between the ages of 60-69 years constituted the higher number (Table 1). A number of 104 patients were brought to the hospital with chest pain as presenting symptom (Table 2). Smoking constituted the dominant risk factor followed by hypertension (Table 3). Greater number of patients was diagnosed with NSTEMI and only a least number of 22 were diagnosed with unstable angina. Maximum number of patients had inferior wall involvement. Patient's conditions were matched with the drug therapy (Table 4). The most common DRP encountered was drug use without indication (Table 5). The most frequent intervention provided by the intervening pharmacist was cessation of drug followed by change in dose (Table 6). The study observed that anticoagulants, anti-platelets and lipid lowering drugs were prescribed to the entire study population. Most of the patients were prescribed with Antihypertensive drugs followed with anti-anginal medications respectively. Comparatively a small fraction of patients was given thrombolytics and inotropic agents. Most frequently administered anticoagulant drugs were LMWH [Enoxaparin and heparin (Table 7). Every patient received anticoagulants, antiplatelet and lipid lowering drugs which is in accordance with ACC/AHA guideline.

Table 1: Age wise distribution of ACS

Age groups (years)	No. of patients (n = 120)	Percentage
40-49	20	16.6
50-59	33	27.5
60-69	38	31.6
70-79	22	18.3
80-89	07	5.8

Table 2: Distribution of presenting symptoms

Symptoms	No. of patients (n = 120)	Percentage
Chest pain	104	86.6
Sweating	43	35.8
Breathlessness	41	34.2
Palpitation	19	15.8
Vomiting	44	36.6
Giddiness	22	18.3
Abdominal pain	15	12.5

Table 3: Distribution of selected risk factors

Risk factors	No. of patients (n = 120)	Percentage
Family history	06	05.00
Smoking	70	58.33
Tobacco	35	29.16
Dyslipidemia	06	05.00
Obesity	00	00.00
Diabetes	22	18.30
Hypertension	36	30.00

Table 4: Co-existing illnesses of ACS patients

Co-existing illness	No. of patients (n = 120)	Percentage
Hypertension	30	25.0
Diabetes mellitus (DM)	16	13.3
Old coronary artery disease	12	10.0
Cerebrovascular disease	00	00.0
Hypertension and diabetes	06	05.0
Asthma/COPD	04	03.0
None	53	44.0

Table 5: Drug related problems encountered

Drug related problems	No. of patients (n = 120)	Percentage
Drug use without indication	37	30
Improper drug selection	24	20
Untreated indication	22	18
Class duplication	00	00

Table 6: Interventions of the pharmacist

Interventions	No. of patients (n = 120)	Percentage
Cessation of drug	28	23.0
Addition of drug	14	11.0
Change in ROA	09	7.5
Change in dose	17	14.0
Change in dosage form	09	7.5
Change in duration of therapy	00	00.0
Change in frequency of administration	00	00.0

Table 7: Cardiac drug utilization

Classes of drugs	No. of patients (n = 120)	Percentage
Anticoagulants	120	100.0
Antihypertensive	117	97.5
Antiplatelets	120	100.0
Lipid lowering drugs	120	100.0
Thrombolytic	39	32.5
Positive inotropic agents	11	9.1
Vasodilators	116	96.6

Table 8: Emergency department drug utilization

Classes of drugs	No. of patients (n = 120)	Percentage
Streptokinase	26	21.6
Aspirin	71	59.1
Clopidogrel	60	50.0
SL/IV nitrates	25	20.8
Morphine	65	54.1
IV heparin	22	18.3
LMWH	98	81.6
Statins	117	97.5
B blocker	60	50.0
ACEI	29	24.1
ASA/Clopidogrel	20	16.6
Diuretics	25	20.8

Table 9: Total prescribing indicator of acute coronary syndrome patients

Indicators	WHO deal values	Value (%)
Average No. of drugs per prescription	1.6-1.8	2.80
Prescriptions with an injection	13.4-24.1	7.50
Drugs prescribed by generic name	100	3.03
Prescription with antibiotics	20.0-26.8	5.30
Drugs prescribed from essential drug list	100	61.00

Morphine was found to be extensively prescribed among patients who were brought to the emergency department with the symptom of chest pain. A number of 62.5% were administered with a combination of morphine and oxygen inhalational therapy. The LMWH is preferred over heparin at the emergency ward. Atorvastatin is the most frequently prescribed lipid lowering drug followed by Rosuvastatin. Thrombolysis was mainly treated with streptokinase and the rest were on tenecteplase. Approximately 67.5% received non-thrombolytic therapy (Table 8).

Out of 120 prescriptions analyzed, a total of 1320 drug products were prescribed. The average number of drugs per prescription was 2.8 which were found to be deviated from the standard prescribed. Branded drugs were found dominant in the prescription of about 96% whereas the total number of drugs prescribed by generic name was only 3.03%. The percentage of antibiotics prescribed were 5.3% which were found to be too less in comparison with WHO reference value and percentage of injections prescribed were 7.5%. Only of drugs prescribed were from essential drug list WHO (Table 9).

DISCUSSION

Total 120 patients were enrolled in the study out of which 81 (67.5%) were male and 39 (32.5%) were female and the ACS incidence rate were found to be more in between the age group of 60-69 (31.6%). Most of the ACS cases were of male dominant constituting about 81 (67.5%) of total ACS cases, suggesting that it is predominately a disease of men which correlates to the study conducted by Singh *et al*.⁸ In the present study, most of the cases showed inferior wall MI as common site of illness, this result was found to be correlated to a study conducted by Deshpandey and Dixit⁹ in which anterior wall MI was the common site affected. The study showed that the predominant symptom of the ACS was chest pain contributing to 104 (86.6%) of total cases and the other presented symptoms like abdominal pain, giddiness, loss of consciousness were mostly seen in elderly patient group as observed by Holay *et al*.¹⁰ Male prevalence and smoking were the most important contributed risk factor which is similar to the study conducted by Singh *et al*.⁸, followed by hypertension. Diabetes was found to be the risk factor in 13% of cases and hypertension in case of 25%. Diabetes mellitus is well found to have an adverse influence on the prognosis of patients with ACS as noted by Hasdai *et al*.¹¹

Drugs Related Problems (DRPs) were found among the cases of all age groups and evenly distributed among both male and females. Majority of the patients received 5-8 drugs i.e., poly pharmacy even if there are no co-morbidities present and it was predicted to be the reason for increased DRPs. The most common DRP observed was drug use without indication i.e., 30% (n = 37) which was followed by improper drug selection [20% (n = 24)] and these results were similar to a study conducted by Kumar *et al.*¹² but contrary to the study conducted by Parthasarathi *et al.*¹³ in which inappropriate dosing was the highest DRP observed (31%) followed by improper drug selection (17%). The drug mostly given without proper indication included alprazolam, zolpidem, rabeprazole and ranitidine. Although anti secretory agents like PPI and H2 receptor blockers often used for prevention of acidity and gastric irritation were prescribed especially in patients with previous peptic ulcer disease history, without proper indication also the agents were prescribed. The second most common DRP found was improper drug selection (20%), the cause of improper drug selection would be lack of standard treatment protocol and poor medical history review. Untreated indication was found to be 18% (n = 22) of the total DRPs. Few of the untreated conditions included were vomiting, anemia, cough, giddiness etc. for which appropriate drugs were recommended to be added.

Arriving to the clinical pharmacist interventions, cessation of drug 28 (23%) and change in dose 17 (14%) were the interventions most frequently provided. This finding differs from observation made in an Indian study where in change in drug dose was reported as the most common suggestion made and correlates with another study by Alagiriswami *et al.*¹⁴, where stopping of drug was the most suggested intervention. Drugs were suggested to be included in the prescriptions of patients who had discomforts which left unnoticed and untreated. In case of anti-hyper lipidemic medications like statins, a change in the drug dose was suggested. In this study, the major reasons for the cessation of drug were due to drug use without indication and improper drug selection, similar to another Indian study¹⁴. In which some examples of cessation of drug were the use of beta blockers in diabetic and in patients with left ventricular dysfunction, amlodipine in unstable angina patients, irrational prescribing of sedatives etc.

Drug utilization research assesses rational drug usage in a better way. For most patients with ACS, ACC/AHA guidelines recommend a combination of dual antiplatelet agents, a β -blocker, an ACEI or ARB and a statin unless any of these is contraindicated. For all patients enrolled in the study, it was

found that an antiplatelet (aspirin, clopidogrel), statin and anticoagulant therapies were given during different stages of their hospital stay. Antihypertensive medications beta-blockers and ACEI (or angiotensin 2 receptor blockers) were given to 69 and 59%, of patients respectively. This is contradictory to a study conducted by Ghosh *et al.*¹⁵, where under-utilization of these antihypertensive were observed. The use of other adjunctive pharmacotherapy, specifically aspirin, clopidogrel and lipid-lowering therapy (Statin) (67.5, 58.3 and 100%, respectively) were also found to be optimal and in concordance with the recommended guidelines followed, similar to the study conducted by George *et al.*¹⁶. Atorvastatin was most commonly used hypolipidemic agent being prescribed in 110 (92%) which is much higher than the value reported by CREATE investigators. Out of 120 total subjects 98 (82%) received LMWH (enoxaparin) and 22 (18%) received IV heparin. This is in contrast to the study conducted by George *et al.*¹⁶ who used IV heparin in maximum patients. Out of 39 patients who received thrombolytic, 26 (66.6%) were on thrombolytic therapy (with Streptokinase) and the remaining 13 (33%) were on Tenecteplase. Only 60% of eligible patients were received guideline recommended treatment. The WHO core prescribing measures the performance of health care providers in several key proportions related to the proper use of drugs. Average number of drugs per prescription is an important index of the standard of prescribing. In the present study, average number of drugs per prescription was 2.8 which is a little higher than the WHO recommended value of 1.6-1.8. Similarly, this value is higher than the results of studies conducted by Demeke *et al.*¹⁷ (2.61) and much lesser than the results of Singh *et al.*¹⁸ (3.11) and Upadhyay *et al.*¹⁹ (3.76), respectively. The differences occurred may be because of variations that are present within the health care providing system or variations due to the rate of incidence of a disease and mortality characteristics of the population.

In several prescriptions, the tendency to prescribe as many as 5-8 drugs were observed. The prescription of many drugs per prescription tends to have major drawbacks like high risk of drug interactions, reduced patient's compliance with the treatment and high incidence of drug toxicities. The deviation of this study results from the recommended WHO values might be due to any factors. This can be due to setting therapeutic expectations by the health care practitioners which are impractical, to obtain speedy recovery of patients, by practicing ongoing common methods of irrational drug combinations, needless use of vitamins etc¹⁷.

The percentage of drugs prescribed by generic name in this study was only 3.03%, which is too less compared with the standard used (100%). This outcome is similar to the studies conducted by Chandelkar and Rataboli²⁰ in which the ratio was 0.05%. The generic drug use helps in reducing the cost of drugs and thereby the overall treatment and provides more options for drug purchases¹⁷. Possible cause for reduced prescription of drugs by generic names may be the result of continuous and impressive communication of pharmaceutical companies with the doctors which may have influenced the doctors more likely to use non-generic (brand) names than generic drugs²⁰.

Percentage of antibiotics prescribed was 5.3% that is less than the standard (20-26.8) derived to be ideal. This is in contradiction to the study conducted by Summoro *et al.*²¹ (66.5) and Lalan *et al.*²² (46.17) in which the value was much higher than the ideal value recommended by WHO. This study ruled out the antibiotic misuse in ACS patients which is prevalent in many other health care sectors.

Over use of Parenteral products like injections may leads to increase in economic cost and also health issues like hepatitis, HIV/AIDS and other blood borne diseases can occur as non-sterile injections can contribute to the transmission of the virus and other pathogens. The percentage of injections prescribed was 7.5% which is less compared to the standard (13.4-14.1) and is contrary to the result of studies conducted by Kumar *et al.*¹² (42.06) and Summoro *et al.*²¹ (37.7) in which the results were found to be higher than that of standard.

Rational drug use can be measured by evaluating whether drugs are prescribed from an Essential drug list or national drug formulary, which serves as one of the indicators to measure rational drug use. In the study, it was observed that only 61% of prescribed drugs were from WHO essential drug list. On the other hand, studies conducted by, Lalan *et al.*²² (48.26%), Chandana *et al.*²³ (54.1%) and Ghosh *et al.*¹⁵ (40.8%) secured lesser ratio compared to present study. The result of the study conducted by Demeke *et al.*¹⁷ is contrary, in that entire drugs (100%) were prescribed from essential drug list.

CONCLUSION

Patient satisfaction can be achieved only if the patient receives rational treatment for his disease or illness. The study reveals that drug therapy is not consistent with the prescribed guidelines followed and observes the scope and importance of having a clinical pharmacist to monitor the drug therapy. Present study showed that drug utilization pattern was not optimal in accordance with the standard

values of WHO prescribing indicators and also suggests the necessity of improvement in light of the WHO prescribing indicators. The study also brought to light the need of appropriate and timely interventions by the clinical pharmacist to improve the drug usage and prescribing patterns.

SIGNIFICANCE STATEMENTS

Drug utilization research provides the improved prescribing habits in health care setting, therefore current study enabled to make the necessary modifications in the existing drug prescribing system thus improving the quality of treatment provided to the ACS patients by increasing therapeutic benefits and decreasing adverse effects.

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