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Research Paper

Observational study to monitoring and assessment of Cardiovascular Drugs polypharmacy leading to detect and intercept adverse drug reaction and medication errors

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Abstract
Objective: *The main objective of the study study was to monitoring and assessment of Cardiovascular Drugs polypharmacy leading to detect and intercept adverse drug reaction and medication errors.*
Materials and Methods: *This was a retrospective observational study carried out in a selected departments of a tertiary care hospital. This study was included hospital in and outdoor patients who were treated for cardiovascular disease. Inclusion criteria of the study was either gender who were hospitalized and prescribed with at least one cardiovascular drug.*
Results: *A total 530 patients were enrolled in the current study. 3.4% was found to be he overall incidence of ADR. A higher number of ADRs (n=123) were observed in older patients (≥ 60 years) in contrast with other age groups. male preponderance over female (25% vs. 22%) was observed but the difference was not statistically significant (p = 0.281). 90.9% patients among overall populations were on more that 6 drugs. Only 3.8% patients were on less than 6 drugs. Beta- blockers (14.68%), on evaluation of drug class implicated in ADRs followed by Renin-Aldosterone-Angiotensen-Receptors (RAAS) blockers and anti—coagulants. In the study, management of ADRs showed that out of total ADRs, 56% ADRs were managed by withdrawing suspected drug, 28% ADRs were managed by adding a supplement, 22% ADRs were managed by replacing a drug, 4% ADRs were managed by altering the dose while no change was made in 4% ADRs. 72% were the possible causality parameters while 53% were having mild severity with 85% were not preventable.*
Conclusion: *In preventing polypharmacy and medication related problems like ADR, building awareness for spontaneous reporting of adverse drug reaction to healthcare professionals and following the evidence based medicine (EBM). To prevent further recurrence, high incidence of ADRs insists for vigilant monitoring. The reporting and monitoring aspects of ADRs might improved by intervention by clinical pharmacists.*
Keywords: *Adverse drug reaction, Cardiovascular drugs, Poly pharmacy, Assessment, Monitoring and Outcomes.*

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I. Introduction:

Adverse reactions to drugs increases significantly by poly-pharmacy along with medication error or risk of hospitalization related to drugs. Is depend on the patient related factors, the disease and the number of drugs. Increased risk of mortality is associated with severe adverse drug reactions (ADRs) caused by polypharmacy [1]. Adverse drug ration, drug interaction, increased risk of side effects, poor compliance and increased costs are few negative connotations carries by poly-pharmacy [2]. Adverse drug reaction (ADR) defines by the World Health Organization (WHO) as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of a disease, or for the modification of physiological function". Type-A (Augmen-ted) and Type-B (Bizzare) reactions are major two traditional classification of ADR's [3]. in recent time's clinical interventions one of the most common is poly-pharmacy and concomitant use of

multiple drugs than are clinically indicated could enhance adverse drug reactions and drug interactions [4]. In both hospitalized and ambulatory patients, adverse drug reactions is an important cause of morbidity and mortality and recognized hazards of drug therapy [5]. Ahead of acquired immune deficiency syndrome (AIDS), diabetes and pulmonary diseases ADR'S are the fourth leading cause of death globally [6-8]. Number of drugs prescribed, drug interactions, age, disease severity and multiple drug therapy are among few factors influence ADR susceptibility [9]. If not monitored properly, cardiovascular drugs are not devoid of adverse effects but could lead to adverse consequences. Drug related problems such as drug-drug Interactions (DDIs) etc are the major tendency to cause drug related problems with increased number of medicines for cardiac patients.

Economic burden on national health budget is significantly impacted by ADR's. It may delay in treatment, mimic disease leading to unnecessary investigations and may raises costs of patient care [10]. Therefore, to reduce the risk, to encourage healthcare professionals in reporting ADRs, to create consciousness about it among patients, there is a need to study ADRs seriously [11]. 9% of medication related visits to clinics have been reported to account for cardiovascular drugs [12]. cardiac patients is known to experience ADR one in every five and 17.9% of those are preventable, which further insist for intensive monitoring and reporting [13]. The main objective of the study study was to monitoring and assessment of Cardiovascular Drugs polypharmacy leading to detect and intercept adverse drug reaction and medication errors.

II. Materials and Methods:

This was a retrospective observational study carried out in a selected departments of a tertiary care hospital. This study was included hospital in and outdoor patients who were treated for cardiovascular disease. Inclusion criteria of the study was either gender who were hospitalized and prescribed with at least one cardiovascular drug. Pregnant and lactating women, mentally retarded patients and patients on drugs other than cardiovascular medications were excluded from the study.

A pre designed pro forma were prepared to capture patients data, doctors review comments, word round feedback, electronic medical records and by reviewing patients' medical records from the day of admission till the day of discharge for the occurrence of ADRs due to cardiovascular drugs. For various clinical parameters such as type of ADRs, demographics, drug class impacted on ADR's, suspected adverse drug reaction, drug class implicated, adverse drug reactions were evaluated. Using standard assessment scales, reported ADRs were also analyzed for preventability [14], severity [15] and causality [16]. By using Naranjo's algorithm scale, causality assessment of reported ADR'S was carried out. Statistical softwere SPSS version-18.0 were used to analyse the data.

III. Results:

A total 530 patients were enrolled in the current study. Demographic characteristics age and gender wise were depicted in table 1. 3.4% was found to be he overall incidence of ADR. A higher number of ADRs (n=123) were observed in older patients (≥ 60 years) in contrast with other age groups. male preponderance over female (25% vs. 22%) was observed but the difference was not statistically significant (p = 0.281).

Table 1: Demographic characteristics age and gender wise

Parameters	TotalNo.of patients	No. of patients with ADRs	No. of ADRs	Incidence (%)
Age group (Years)				
< 40	36	2	2	6%
40 - 49	65	16	23	25%
50 - 59	113	31	40	27%
≥ 60	316	75	123	24%
Gender				
Male	308	76	107	25%
Female	222	48	81	22%

Category of polypharmacy depicted in table 2. 90.9% patients among overall populations were on more that 6 drugs. Only 3.8% patients were on less than 6 drugs.

Table 2: Categorisation ofpolypharmacy

Sl No	No of Drugs	Number of Prescription	Percentage
1	Less than 6	20	3.8%

2	Equal to 6	28	5.3%
3	More than 6	482	90.9%
Total		530	100%

Different drug class impact on overall ADRs were depicted in figure 1. Beta- blockers (14.68%), on evaluation of drug class implicated in ADRs followed by Renin-Aldosterone-Angiotensen-Receptors (RAAS) blockers and anti—coagulants.

Figure 1: Drug class implicated in ADRs.

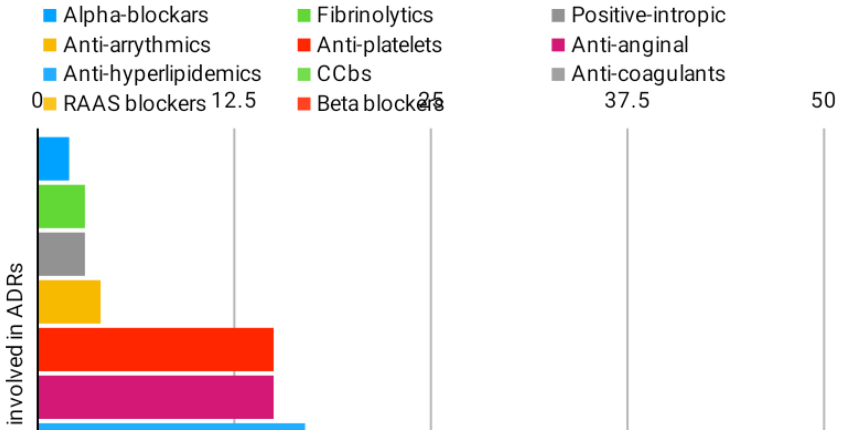
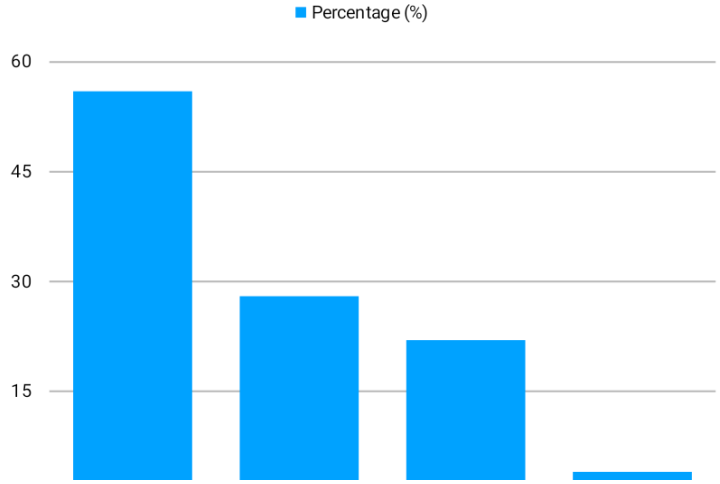


Table 3: Suspected adverse drug reactions.

Suspected ADR	No. (%) of ADRs
Bradycardia	19
Hypotension	15
Elevated serum creatinine	15
Electrolyte imbalance	14
Constipation	14
Raised INR	9
Abdominal discomfort	9
Vomiting	9
Tachycardia	8
Dry Cough	8
Elevated liver enzymes	8
Headache	4
Gastrointestinal haemorrhage	4
Pedal oedema	4

In the study, management of ADRs showed that out of total ADRs, 56% ADRs were managed by withdrawing suspected drug, 28% ADRs were managed by adding a supplement, 22% ADRs were managed by replacing a drug, 4% ADRs were managed by altering the dose while no change was made in 4% ADRs.

Figure 2: Management of Adverse Drug Reactions.



Causality, severity and preventability assessment of ADRs were depicted in table 4. 72% were the possible causality parameters while 53% were having mild severity with 85% were not preventable.

Table 4: Causality, severity and preventability assessment of ADRs

Parameters	**No. (%) of ADRs**
Causality parameters	
Certain	11 (6%)
Probable	34 (18%)
Possible	136 (72%)
Unlikely	7 (4%)
Severity assessment of ADRs	
Mild	100 (53%)
Moderate	71 (38%)
Severe	17 (9%)
Preventability parameters	
Definitely preventable	16 (8%)
Probably preventable	13 (7%)
Not preventable	159 (85%)

IV. Discussion:

One of the major public health concern are considered as adverse drug reactions (ADRs) which may contribute for increase healthcare burden. The present study was conducted with a view to estimate the incidence of ADRs. In Indian population polypharmacy was a frequent condition and mainly depends on the malnutrition, economic status, hereditary, co-morbid conditions and on the type of the diseases. 23.4% was found to be he overall incidence which is in compliance with the pilot study conducted earlier [17]. Even in previously conducted studiers 24.2% is the prevalence of the incidence [18]. Moreover, in contrast with the present findings there are also reports stating a higher incidence of ADRs [19-21]. In the present study, male preponderance over female (25% vs. 22%) was observed but the difference was not statistically significant (p = 0.281). Previously, majority of ADRs were reported in men as documented by Rohit et al [22]. On the contrary, 57% and 27.9% respectively the higher incidence of ADRs in female was observed in studies conducted by Rodenburg et al. [23] and Kaur et al [24]. Due to variation in the disease pattern and different healthcare settings discrepancy in the present study observed.

A higher number of ADRs (n=123) were observed in older patients (≥ 60 years) in contrast with other age groups. A study conducted in United Kingdom by Kongkaew et al., this observation is comparable which showed higher incidence of ADRs (10.7%) in elderly than other age groups [19].

Between the occurrence of ADRs and the number of drugs (polypharmacy) having a positive correlation

which was found to be statistically significant ($p< 0.01$). In line with the early studies present study confirms that polypharmacy was the only predictor for ADRs [25-27].

Beta- blockers (14.68%), on evaluation of drug class implicated in ADRs followed by Renin-Aldosterone-Angiotensen-Receptors (RAAS) blockers and anti—coagulants. Similar to the findings, Haile et al. [28] and Chan et al. [29], confirms the samepreviously.

Continious followup and retrospective nature are the major limitation of the present study. Hence in current study due to maintenance treatment information pertaining to occurrence of ADRs is lacking. However for healthcare professionals, the findings of these study could be helpful based on its intensive approach towards monitoring and reporting of ADRs.

V. Conclusion:

In preventing polypharmacy and medication related problems like ADR, building awareness for spontaneous reporting of adverse drug reaction to healthcare professionals and following the evidence based medicine (EBM). To prevent further recurrence, high incidence of ADRs insists for vigilant monitoring. The reporting and monitoring aspects of ADRs might improved by intervention by clinicalpharmacists.

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