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RESEARCH ARTICLE

Use of Triggers to Detect Adverse Drug Reaction Induced By Cardiovascular Drugs in Outpatient Department in Nasik City

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ABSTRACT:
The use of "triggers", clues to identify adverse drug events (ADEs) is an effective method for measuring the overall level of harm from medications in a health care organization. Cardiovascular drugs have moved to the third place among all drug classes prescribed in the country. The use of multiple medications is a serious problem in current health care system. To detect the ADR in Cardiovascular drugs by using trigger tool methodology was done in the private hospital of Nashik city. Total number of prescriptions was considered and total number of Triggers was calculated in percentage .Total number of positive triggers which had shown ADR was calculated accordingly. Out of 180 sample size total triggers were found to be 21 (11.66%), and ADR reported to be 14 (7.77%) We found 6(3.33%) such triggers which could not detect any ADR. 71% was the success rate in detecting ADR and 29% was failure in detecting ADR. Improving trigger tools and applying them in analyzing the ADR will surely detect the ADR soon and reduce the risk and harms in patients.

KEYWORDS: Cardiovascular system, Adverse drug event, Adverse drug reaction.

INTRODUCTION:
Adverse Drug Reaction (ADR) is defined as any noxious unintended and undesired effect of a drug that occurs at doses used for prevention, diagnosis or treatment.[1] Any unintended effect on the body as a result of the use of therapeutic drugs, drugs of abuse, or the interaction of two or more pharmacologically active agents.[2] ADRs are diverse; any organ can be the principal target or several systems can be involved simultaneously. Knowing this it becomes very difficult to prescribe a medicine safely.[3]

The adverse drug reactions are often not discovered until after the drug has been marketed. Pharmaceutical companies strive to work out the adverse effect profile of a drug before it is marketed, but because the complete range of adverse effects is not known, therefore, most severe drug induced reactions cannot be elucidated before licensing, therefore efficient post marketing surveillance is needed.[3]

Premarketing exposure to the investigational drug is limited usually to 1000 to 3000 subjects. Therefore the probability of identifying adverse reactions with a frequency of less than 1:1000 is remote.[4] The full range of adverse reactions may not be known until a drug has been used in hundreds of thousands of people or in some cases after exposure for prolonged periods or only long after exposure to the drug. Proving that a specific drug is responsible for an adverse event in a patient may be extremely difficult because of multiple drug exposures and underlying illnesses.[5]

Before deciding to prescribe a drug to a patient, a doctor must balance the expected benefits of the drug against its potential risks. In other words he must assess the cost/benefit ratio in that particular situation – where benefits will be measured in terms of the efficacy of the drug and the cost in terms of the side effect liability that use of the drug entails.[6]

The use of **"triggers",** clues to identify adverse drug events (ADEs) is an effective method for measuring the overall level of harm from medications in a health care organization[7]. The use of Trigger Tool for Measuring Adverse Drug Events provides instructions for conducting a retrospective review of patient records using triggers to identify possible ADEs. Each tool includes a limited number of triggers that signal the most common types of adverse events or those that are likely to cause serious harm.[8]

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Adverse drug reactions are classified into six types: dose-related (**Augmented**), non-dose-related (**Bizarre**), dose-related and time-related (**Chronic**), time-related (**Delayed**), withdrawal (**End of use**), and failure of therapy (**Failure**).[9]

Triggers for a potential adverse drug event include orders for antidotes, abnormal laboratory values, abrupt medication stop orders, transfer to a higher level of care and development of a rash.[10]

The highest rate of ADRs was recorded to be induced by Diltiazem (23.5%) and the lowest rate was related to Atenolol (3%).[11]Considering increased use of cardiovascular drugs and limitations in pre-marketing trials for drug safety evaluation, post marketing evaluation of ADRs induced by this class of medicinal products seems necessary.[12]
As a result cardiovascular drugs have moved to the third place among all drug classes prescribed in the country.[12]

Methodology:
A prospective observational study was done in the Tertiary Care hospital of Nashik city for 3 months. The Institutional Ethical Committee approval was received before initiation of study. Patients treated for various C.V.S. problems was selected according to the criteria and written informed consent was obtained before enrolling the patient in study. We enrolled 180 patients with various CVS problems and with different drugs in every prescription. Once the informed consent was obtained, patients' prescription was studied and was followed every 15 days by telephonic conversation and every month in OPD. Prescription was studied and analysed accordingly. Observation of the prescription of the patient using predetermined list of triggers associated with possible ADE was done. ADR assessment was done by WHO Scale, Noronjos Scale After finding specific triggerwe kept record of all finding on ADE report form. Finally we summarized all data on monthly data collection sheet and after analyzing the data possible trigger was confirmed. Total number of ADR and Triggers was calculated. List of drugs in which triggers were found was listed. ADR assessment was done.

Triggers : -
T1 Diphenhydramine
T2 Vitamin k
T3 Flumazenil
T4 Anti emetics
T5 Naloxone .
T6 Antidiarrheals
T7 Sodium polystyrene
T8 Sodium glucose < 50
T9 C.difficile positive
T10 PTT > 100
T11 INR>6
T12 WBC<3000
T13 PLATELET COUNT
T14 Digixinlevel>2
T15 Rising Sr. Creat
T16 Over sedation
T17 Rash
T18 Abrupt sessation of medication
T19 Transferred to higherlevel of care
T20 Atropine
T21 Bilirubin >2x normal
T22 Potassium <3.5 mmol
T23 Lip swelling and angio oedema
T24 Seizures/ dizziness *
T25 Decreased level of consciousness
T26New arrhythmia
T27 New onset of jaundice
T28 New hypotension
T29 Bronchospasm
T30 Parenteral / tropical corticosteroids
T31 Dyspnea
T32 Cough
T33 Chest pain
T34 weakness
T35 Vertigo
T36 Gastritis

RESULT:

Out of 180 sample size total triggers were found to be 21 (11.66%), and ADR reported to be 14 (7.77%)
We found 6(3.33%) such triggers which could not detect any ADR (Table-1 to 3 and Graph-1 and 2).
1 ADR was reported without finding any triggers.

Table No 1:- List of ADRs

Sr. No.	DRUGS	ADR	No. of ADR
1.	Atenolol	Hypotension	4
2.	Amlodepine	Hypertension	2
3.	Nifedapine	Vertigo	2
4.	Ramipril	Cough	4
5.	Losartan	Bipedal oedema	1
6.	Hydrochlorthiazide	Hypokalaemia	1
7.	Digoxin	Palpitaion	1
8.	Digoxin	CCF	1

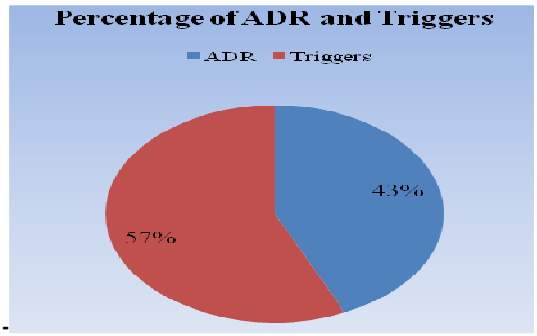
Table No 2: Drugs, Triggerand ADR

Sr. No.	List of Drug	Triggers	No. of Triggers	ADRs	No. of ADR
1.	Atenolol	Headache	(4)	Hypotension	4
2.	Amlodepine	headache	1	Hypertension	2
3.	Nifedepine	Generalized Weakness	2	Vertigo	2
4.	Ramipril	Cough	4	Cough	4
5.	Losartan	Swelling over ankle	2	Bipedal oedema	1
6.	Hydrochlorthiazide	Muscle cramp	3	Hypokalemia	1
7.	Digoxin	Restless	2	Palpitation	1
8.	Digoxin	Restless	2	CCF	1
9.	Warfarin	PT INR >6	1	-	-

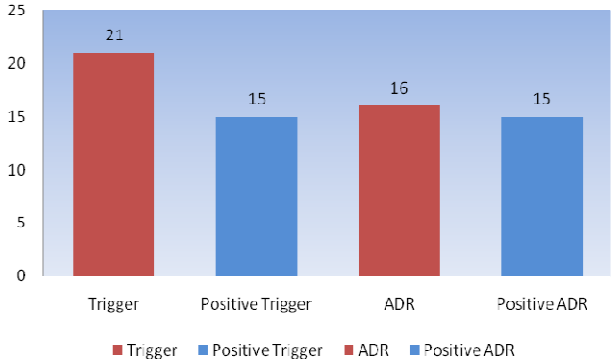
Table No 3: - List of positive Triggers and ADR

Sr. No	Triggers(No.)	Positive Triggers	ADR(No.)
1.	Headache (4)	4	Hypotension(4)
2.	Headache (2)	2	Hypertension(1)
3.	Generalized weakness(2)	2	Vertigo (2)
4.	Cough (4)	4	Cough (4)
5.	Swelling over Ankle (2)	1	Bipedal oedema
6	Muscle Cramp(3)	1	Hypokalemia
7.	Restless (4)	2	1-palpitation and 1-CCF

GRAPH 1



GRAPH 2



71% we found success in detecting ADR and 29% we could not found any ADR.

ADR Assessment

ADRs	WHO Scale	Naronjos Scale
Hypotension	Possible	4
Hypertension	Possible	3
Vertigo	Possible	4
Cough	Possible	3
Bipedal oedema	Possible	4
Hypokalamia	Probable	5
Palpitation	Probable	5
CCF	Possible	4

Statistical Analysis:-

Total number of prescriptions was considered and total0020number of Triggers was calculated in percentage .Total number of positive triggers which had shown ADR was calculated accordingly.

DISCUSSION:

Our findings shows that the Triggers found were 21 in sample size of 180. Using the trigger tool methodology, ADR findings were 14. The total percentage of Triggers was 11.77% and ADR was %. There was 6 such triggers which has not confirmed with presentation of an ADR. 1 case presented with ADR but without Trigger.

Using the trigger tool methodology, several organizations have reduced their ADEs by more than 60% in 6 months. Our efforts were directed towards creating a tool for investigating clinical events associated with harm that could be more widely applied in clinical practice.

The current use of the trigger tool is to establish a baseline level of harm in an organization and then, using statistical process control rules, collect data points over time to determine improvement. This is not surprising that pharmacological intervention is so widespread, individual are often receiving several different drugs and the system in place to facilitate therapeutics is varied and often complex. The evolution of the trigger tool into more general method for investigating practice patterns provides a powerful new conceptual framework to understand, quantify and track harmful events.

CONCLUSION:

The study result demonstrates that 71.42% we get success in finding ADR after detecting triggers. We found 28.57% failure in reporting ADR. Improving trigger tools and applying them in analyzing the ADR will surely detect the ADR soon and reduce the risk and harms in patients.

REFERENCES:

1. Shaheen Shah, Huma Shah, Meharun-NissaKhaskheli, JunaidAkhtar Adverse Drug Reactions: Clinical Assessment Of Drug Induced Disease 2005.
2. Shashindran and B.Gitanjali, Adverse Drug ReactionMonitering Health Administrator Vol: XIX Number 1: 20-21, (NCCMERP)
3. Joseph C. Segen McGraw-Hill Concise Dictionary of Modern Medicine. 2002 by The McGraw-Hill Companies, Inc.
4. Naranjo CA, Busto U, Sellers EM et al. A method for estimating the probability of adverse drug reactions. ClinPharmacolTher 1981; 30: 239- 45.
5. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW (2003) the incidence and severity of adverse events affecting patients after discharge from the hospital. Ann Intern Med 138:161–167 2003.
6. Moore N, Lecointre D, Noblet C, Mabille M. Frequency and cost of serious adverse drug reactions in a department of general medicine. Brit. Jour. ClinPharmacol. 1998; 45:301–308.
7. Resar RK, Rozich JD, Simmonds T, Haraden CR. A trigger tool to identify adverse events in the intensive care unit. *JtComm J Qual Patient Saf.* 2006 Oct; 32(10):585–59
8. Hutchinson TA, Flegel KM, Kramer MS, Leduc DG, Kong HH. Frequency, severity and risk factors for adverse drug reactions in adult out-patients: a prospective study. J Chronic Dis. 1986;39:533-542.
9. Douglas McCarthy and David Blumenthal Case Study Using a Trigger Tool to Measure Adverse Events, Quality health Care Institute September 30, 2008.
10. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. *Lancet.* 2000 Oct 7;356(9237):1255–1259.
11. Rosen AK, Nebeker JR, Shimada S, et al. AHRQ; 2007. Development and Use of Ambulatory Adverse Event Trigger Tools. 2007.
12. Gholami K, Ziaie S, Shalviri G. Adverse drug reactions induced by cardiovascular drugs in outpatients. Pharmacy Practice 2008 Jan-Mar;6(1):51-55.