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IDENTIFICATION, EVALUATION AND ANALYSIS OF MEDICATION SAFETY ASSOCIATED WITH HIGH ALERT MEDICATIONS IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

A high-alert medication (HAM) is a "medication that bears a heightened risk of causing significant patient harm when used in error." High Alert Medications are frequently associated with harm; the harm they cause is serious. The objectives were to identify and determine the percentage of HAMs in ICU and to calculate the rate of medication error caused by HAMs, and to develop strategies to reduce ME by HAM. A prospective observational study was conducted for a period of six months in ICU patients at SSIMS, Davangere, Karnataka. 175 prescriptions meeting the inclusion criteria were included for the study. The data required for the study was collected from the patient's case sheet. The patients were followed until they were shifted up from ICU. After analyzing prescriptions, the rate of medication error caused by HAMs was calculated. Following the identified HAM specific errors, strategies were developed and distributed in ICU. The study included 175 patients, in that 123 were males and 52 were females. Out of 175 cases, 150 cases were identified with at least 1 HAM and 25 cases were without HAM. A total of 2125 drugs were determined, in that 277 were HAMs. We determined a total of 776 medication errors from 175 cases among that 310 errors were caused by HAMs. The rate of error caused by HAM was found to be 40%. Based on the HAM specific medication errors identified, strategies were formulated and distributed in ICU department.

KEYWORDS: ICU, HAM, Medication errors.

INTRODUCTION

A high-alert medication is a "medication that bears a heightened risk of causing significant patient harm when used in error." This does not imply that errors occur more often with high-alert medications than other medications but rather, when an error does occur, the consequences can be severe and even fatal. In the mid-1990s, the Institute for Safe Medication Practices (ISMP) examined the drugs that were most likely to cause harm to patients. They revealed that medication errors resulting in death or serious harm involved only a small number of medications and this served as the foundation for ISMPs list of HAM.[1]

ME may occur at any part of the medication system and may involve any of the countless medications that are available, including those classified as high-alert medications. Many medication errors may not cause grave harm to patients, some medications are known to carry a higher risk of harm than other medications and errors in the administration of these medications can have catastrophic clinical outcomes. These medications are identified as high-alert medications (HAM) and require special considerations.[2]

Critical care areas present a particular challenge with regards to medication error. They have a dynamic environment with critically ill patients who often require rapid adaptation of ongoing management. ICU can be error prone settings, were even otherwise minor ADR can lead to serious disability. The reason is that ICUs are complex environments in which patients present at different severity levels, are submitted to countless procedures and receive a great variety of drugs, including HAM.[3]

Medication safety is defined as freedom from preventable harm with medication use (ISMP Canada, 2007). Medication safety issues can impact health outcomes, length of stay in a healthcare facility, readmission rates, and overall costs to healthcare system. The first step in improving medication safety is to identify medication errors and develop strategies respectively to improve the quality of health care provided.[4]

Providing strategies to effectively prevent medication errors and adverse drug events in hospitals has gained international recognition. The Institute for Safe Medication and Practices has developed some recommendations to reduce errors by considering the specificities of different scenarios of clinical practice, such as acute care and long-term facilities, and communities' care settings. Being more important in terms of medication errors, High Alert

Medications should have specific and effective strategies to improve patient safety in a health care system.[5]

Medication errors have important implications for patient safety, and their identification is a main target in improving clinical practice errors. Considering all the medication errors High Alert Medications possess a greater risk of causing harm to the patient. So, special care and monitoring is required in High alert medication use to ensure better patient safety. Hence, our study focuses on identification of HAM and calculating the percentage of HAM related errors in ICU. Strategies were developed after assessing the rate of medication errors; these are distributed to the staffs for minimising the occurrence of high alert medication errors.

METHODOLOGY

STUDY SITE

Shamanur Shivashankarapa Institute of Medical Sciences And Research Centre (SSIMS), Davangere Karnataka.

STUDY DURATION

The study was conducted for a period of six months.

STUDY DESIGN

Prospective, Observational study.

PROPOSED SAMPLE SIZE

150.

STUDY CRITERIA

The study was carried out by considering the following inclusion and exclusion criteria.

Inclusion criteria

- All patients admitted to ICU
- Patients above 18 years of age
- Patients of either sex

Exclusion criteria

- Patients with insufficient data in their records and who are not willing to participate in the study.
- Medical staff who are not willing to participate in the questionnaire survey.

SOURCE OF DATA

- Data was collected from case sheets of inpatients who are admitted in the Intensive Care Units.

MATERIALS USED

- Informed consent form
- Data collection form
- Patient case sheet
- ISMP list of HAM
- HAM questionnaire
- Micromedex

ETHICAL APPROVAL

Ethical approval was obtained from The Institutional Ethics Committee of Bapuji Pharmacy College, Davangere, Karnataka.

STUDY PROCEDURE

- A Prospective observational study was conducted in the patients admitted in ICU in SSIMS & RC, Davangere.
- The data required for the study were collected from the patient's case sheet.
- The patients were followed up during their stay in the ICU.
- The demographic details, number of drugs prescribed, dose and frequency during their stay in ICU were recorded in a properly designed data collection form.
- All prescriptions meeting inclusion criteria were analyzed for medication error and the HAM error rate was calculated.

RESULTS

Distribution of patients based on gender

A total of 175 prescriptions were analysed during the study period, out of which 60% were males and 30% were females.

Table 1 Distribution of patients based on gender.

N=175

Gender	No. of Patients	Percentage (%)
Male	123	70
Female	52	30

Percentage of HAM prescriptions in ICU

Table. 2 Prevalence of HAM prescriptions in ICU.

N=175

Prescriptions	No. of prescriptions	Percentage (%)
With HAM	150	85.7
Without HAM	25	14.3

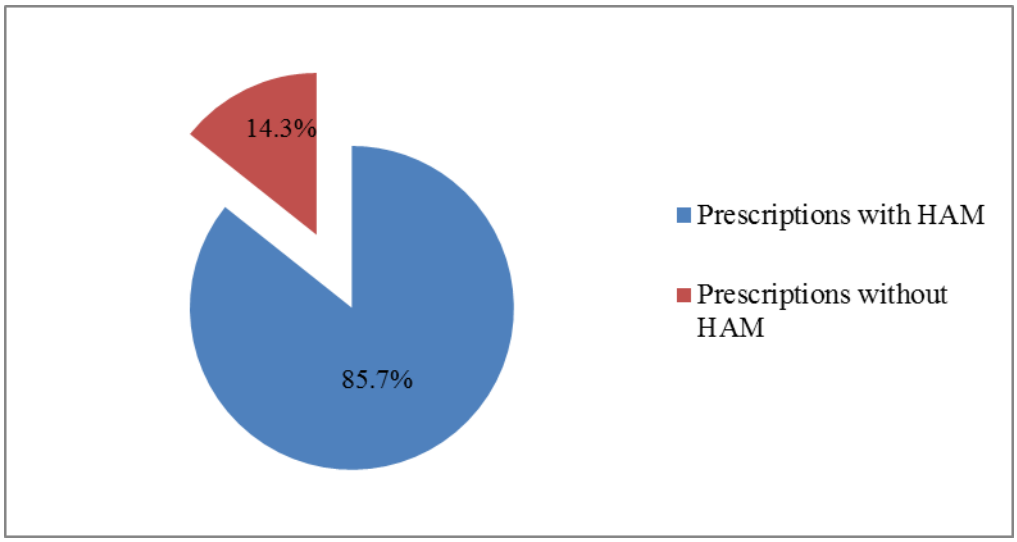

Figure 2.1 Prevalence of HAM prescriptions in ICU.

Distribution of drugs and associated medication errors in ICU

Table 3 shows distribution of drugs prescribed in ICU and associated ME. A total of 2125 drugs were prescribed in 175 cases. Out of which 277 (13%) were identified as HAM and 1848 (87%) were drugs other than HAM and the number of ME caused by them are 310 and 466 respectively.

Table. 3 Distribution of drugs and associated medication errors in ICU.

Drugs prescribed	No. of drugs (n=2125)	No of MEs (n=776)
HAM	277	310
Drugs other than HAM	1848	466

HAMs identified in ICU

Table.4 shows the identified HAMs in ICU. A total of 277 HAMs were identified in which the most frequently prescribed HAM was found to be Insulin (16.6%).

Table. 4: HAMs identified in ICU.

n=277

SL.No	Drugs		Frequency of drugs prescribed	Percentage (%)
1	Adrenergic agonists IV			
	A	Adrenaline	11	4
	B	Noradrenaline	24	8.7
2	Adrenergic antagonists IV			
	A	Metoprolol	3	1
	B	Labetalol	6	2.1
	C	Carvedilol	1	0.4
3	Anti-arrhythmics IV			
	A	Lidocaine	1	0.4
4	Anaesthetic agents IV			
	A	Propofol	2	0.7
5	Anti-coagulants			
	A	Warfarin	1	0.4
	B	LMWH	7	2.5
	C	Heparin	44	15.9
6	Chemotherapeutic agents IV			
	A	Silodosin	1	0.4
7	Dextrose (>20%)		22	7.9
8	Ionotropic agents IV			
	A	Dobutamine	2	0.7
9	Insulin IV		46	16.6
10	Moderate sedation agents IV			
	A	Midazolam	38	13.7
	B	Lorazepam	11	4
11	Opioids (IV/PO)			
	A	Morphine IV	17	6.1
	B	Tramadol PO	10	3.6
12	Neuromuscular blocking agents IV			
	A	Succinylcholine	4	1.4
13	Sodium chloride IV (>0.9%)		10	3.6
14	Sulfonylurea oral		10	3.6
15	Methotrexate PO, Non oncologic use		1	0.4
16	Oxytocin IV		1	0.4
17	Magnesium sulphate IV		1	0.4

Table. 5: Categorization of medication errors.

Medication errors considered	ME by HAM	ME by other drugs
Drug-drug interaction	140	157
Prescribing errors	61	66
Drug choice problem	48	135
IV incompatibility	43	105
Dosage regimen problem	18	3

$$\text{Rate of medication error caused by HAM} = \frac{\text{No. of ME by HAM}}{\text{Total no. of ME}} \times 100$$

$$= \frac{310}{776} \times 100$$

$$= 40\%$$

Formulation of strategies

According to the HAM errors identified in our study, different strategies were formulated for the safe use of each HAMs and these were distributed in the ICU.

Table. 5: Simple strategies to avoid high alert medication errors.

HIGH ALERT MEDICATIONS	SPECIFIC SAFETY STRATEGIES
Heparin IV	Don't use error prone abbreviations, i.e.'IU' in orders Store vials separately from insulin Limit the concentrations available Double check required upon administration Appropriate monitoring of orders
Insulin (IV/SC)	Double check is required upon administration Avoid the use of error prone abbreviations, i.e. 'U' Standardise the concentration available Specify the dose, route and frequency in the prescription
Sedation agents and Anaesthetic agents IV (midazolam, lorazepam, propofol)	To be administered with clinical monitoring Independent double check Limit interruptions during administration Specify the dose, route and frequency in the prescription
Opioids IV/oral (morphine, tramadol)	Use standard concentrations of morphine, hydromorphone Labelling to show 'high concentration' product to differentiate from standard concentration Independent double check at rate change is required
Adrenergic agonists IV (adrenaline, noradrenaline)	Standard infusion concentrations for all continuous infusion Specify the dose, route and frequency in the prescription To be administered with clinical monitoring
Neuromuscular blocking agents IV (succinylcholine, vecuronium)	Warning: paralyzing agent auxiliary label placed on all storage locations and patient specific doses in all

	locations Segregated storage Confirm intubation status prior to administration
Adrenergic antagonists IV (metoprolol, labetalol)	To be administered with clinical monitoring Specify the dose, route and frequency in the prescription Limit interruptions during administration Double check required upon administration
Ionotropic agents IV (digoxin, dobutamine)SS	High alert auxiliary labels should be placed on all storage locations Limit the concentration available Double check required upon administration To be administered with clinical monitoring
Methotrexate, non-oncologic use	Specify the dose, route and frequency in the prescription Limit interruptions during administration
Oral hypoglycaemic agents (glimepiride)	Appropriate monitoring of orders Administer with clinical monitoring
Concentrated electrolytes IV (potassium chloride, sodium chloride)	High Alert auxiliary label placed on all storage locations High Alert auxiliary label placed on all patient specific vials Storage is segregated Use premixed products when available Double check required upon administration

DISCUSSION

Our study analysed 175 prescriptions from ICU meeting the inclusion criteria. Gender wise distribution showed, males (70%) were more when compared with females (30%). This study revealed male predominance over females as similar to a study conducted by Elizabeth Manias et.al.[6] This may be due to possibility of various risk factors like smoking, alcoholism and road traffic accidents compared to female population.

In our study the percentage of HAM prescriptions in ICU was 85.7%, this was in accordance with the study conducted by Queiroz Soares et al where the prevalence of HAM prescriptions was found to be 92.7%.[7] This relates to a fact that the unit assessed in the study were intensive care units.

The highest number of HAM prescribed was insulin 46 (16.6%) followed by heparin 44 (15.9%) and midazolam 38 (13.7%). The use of these medications is more frequent in ICU due to increased incidence of DM cases and cardiac diseases. Anaesthetics are also predominantly prescribed in ICUs to sedate patients, due to their very clinical condition and due to invasive and painful procedures and exams, which bring discomfort and anxiety in patients. The results in our study were in contrast with the study conducted by Elena Bohomol where, the highest number of HAM prescribed was venous anaesthetics.[3]

The present study identified the high alert medications frequently causing medication errors, which were found to be heparin (98) followed by midazolam (43), insulin (33) and morphine (25). Similar to the present study, a study about HAM conducted by Sanjaya Kumar et al, identified that 45% of these events involved insulin and 21%, heparin and warfarin in equal proportions.[8]

The rate of medication error caused by HAM (40%) in the current study was far higher than the figures reported by another study conducted by Parag Gadhave et al, which found only 5.7% as the rate of medication error caused by HAM. This may be due to increased use of HAMs in ICU.[9]

Due to the seriousness of the medication error caused by HAM it is necessary to follow risk reduction strategies such as

- Double check before administration
- Specific label for high alert medications
- Medicine order review by the clinical pharmacist
- Following the policy of nonverbal order
- Following proper storage practice
- Following guidelines

The strategies were developed according to the specific HAM errors identified in ICU, by considering the specific safety strategies proposed in studies conducted by Barbara Crawford et al.[10], Sachin Raval et al[11] and from the study conducted by Anderson P et al.[12]

CONCLUSION

High Alert Medications are frequently associated with harm, the harm they cause is serious and when they are misused the risk of serious injury or death is high.

In the study, the most frequently used HAM was found to be insulin followed by heparin. The rate of error caused by HAM was found to be 40%. Drug-drug interaction was found to be the most common error and the HAM which caused highest number of error was heparin.

Following the identified HAM specific errors, strategies were developed and distributed in ICU thereby ensuring the medication safety associated with HAM.

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