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Expert Opinion Article

Knowledge, attitude and practice of pharmacovigilance among paramedics and non-medical personnel in a newly opened tertiary care center

Dr. PRANJIT NARZAREE[1]*, Dr. Swapnanil Gohain[2], Dr. Hibu Habung[3], Dr. Amit Kumar Muchahary[4]

[1]*Assistant professor, Department of Pharmacology, Kokrajhar Medical College & Hospital, Assam, India, Email i.d: drpranjit504@gmail.com
[2]Associate Professor, Department of Pharmacology, Kokrajhar Medical College & Hospital, Assam, India, E Mail: drswapnanil20@gmail.com
[3]Associate Professor, Department of Medicine, Tomo Riba Institute of Health and Medical Sciences (TRIHMS), Naharlagun, Arunachal Pradesh, India, Email id: hibuhabung20@gmail.com
[4]Assistant Professor, Department of Pathology, Kokrajhar Medical College & Hospital, Assam, India, Email i.d: amitkrmuchahary@gmail.com

Abstract

Background: When a drug is taken a risk is taken. Medicinal products are essentially used for beneficial purposes but it may also carry some anticipated side effects, sometimes it could be undesirable and unexpected. The associated risks are significantly reduced with its judicious use i.e recommended dose in a proper dosage form. However there are instances when optimal dose have caused adverse drug reactions ranging from mild to life threatening conditions bring human sufferings in terms of morbidity and mortality, as well as economic burden to the health care system. Assessment of knowledge attitude and practice regarding pharmacovigilance among the medical personnel and the non medical working staff can possibly give us insight in the understanding of various internal and external factors affecting reporting of ADRs. There is a possibility to figure out the lacunae where necessary intervention may be required to address the related issues, as some studies have suggested that lack of knowledge may lead to non-judicious use of medicines and it is concerning.

Objective: The study was undertaken to assess the knowledge, attitude and practice of pharmacovigilance among paramedics and non-medical personnel in a newly opened tertiary care center.

Methods: A cross-sectional study was designed using a self-administered questionnaire to access the knowledge, attitude and practice of pharmacovigilance among the participants from paramedics and non-medical personnel of Kokrajhar medical college and hospital administration.

Results: A total of 150 participants from paramedics and non medical personnel have completed the questionnaire. 31% of the paramedics and 26 % of the non-medical personnel were aware of the term pharmacovigilance. Purpose of pharmacovigilance was known to only 13 % of paramedics and 3 % for non-medical personnel. 45% paramedics and 69% non-medical participants were not aware of suspected ADR reporting system in India showing very limited knowledge among the participants. A positive attitude has been observed among the participants as over 65% of participants from both the groups have chosen for establishing of ADR monitoring centre in every hospital with approximately 56% from both groups thinks that reporting of adverse drug reaction is necessary. Practice part seems to be the area of concern as active participation is lacking among the participants of both groups. Only 2% of paramedics have ever played a role in reporting of ADR followed by 1% from non-medical personnel group.

Conclusion: Our research study had revealed that paramedics in comparison to non medical personnel have better knowledge, both the groups have considerable attitude towards pharmacovigilance which shows positivity towards future prospects. Practice part seemed to be poor in both groups however participant's willingness to participate in ADR monitoring was appreciable. Sharing the knowledge and uplifting the practice based performance by active self participation could bring promising results in solving problems related to ADR underreporting.

Introduction

WHO defines Pharmacovigilance as the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. It is said that when a drug is taken a risk is taken. Medicinal products are essentially used for beneficial purposes but it may also carry some

anticipated side effects, sometimes it could be undesirable and unexpected. The associated risks are significantly reduced with its judicious use i.e recommended dose in a proper dosage form. Some studies have also suggested that lack of knowledge may lead to non-judicious use of medicines and its concerning.[1]

However there are instances when optimal dose can still cause adverse drug reactions ranging from mild to life threatening conditions in certain individuals. Therefore, it can bring human sufferings in terms of morbidity and mortality as well as economic burden to the health care system.[2]

It has been observed that 0.2-24 percent of hospital admissions are due to ADR related complications.[3,4]

With the growing demand for better treatment modalities many novel pipeline drugs are being tested on humans through various phases of clinical trials emphasizing on patient safety and well being. However the sample size involved in clinical trials are relatively small compared to the overall population with diversified race, ethnicity and presence of concurrent diseases etc. puts us in a bigger challenging situation. Other factors such as poly pharmacy, irrational drug use, difference in the pharmacokinetic and pharmacodynamics parameters for pediatric and geriatric age groups could increase vulnerability to drugs related ADRs.[5]

Thus post marketing drug safety monitoring on long term use in clinical practices can significantly improve the overall outcome.[6]

Hence the need for effective pharmacovigilance system is very crucial at this point of time.

With the introduction of various novel drugs and the complexities of treatment with multidrug therapies many ADRs have surfaced. There are instances when many promising drugs are banned from the market. It was September 2022 when very popular drug ranitidine has been removed by the government of India from National List of Essential Medicine. The drug was banned because of cancer causing concerns. Another very popular drug pantoprazole was reported to cause anaphylactic shock in a patient.[7] Therefore, it is imperative to enhance our understanding of ADRs in order to effectively address these challenges. There is a need to identify the associated risk and to implement strategies to mitigate.

For patient's safety and well being a robust and effective pharmacovigilance system is needed. A part form international regulatory bodies and healthcare providers, a collaborative effort from the patient party as well as general public can collectively play a vital role to meet these challenges.

Pharmacovigilance programme India started decades ago, which played a significant role for identification and analysis of the generated signals or the adverse drug reaction, through various modes of reporting system.[8]

Many marketed drugs have been withdrawn because of their unusual ADRs with the help of spontaneous reporting system.[9] Thus, improving patient's safety and well being.

Pharmacovigilance programme India has led to establishment of various regional ADR monitoring centers and sub- centers facilitating spontaneous reporting of ADRs across India.[10]

However underreporting was considered area of concern. An estimated6-10% of ADRs are being reported.[11]Some of the researchers have concluded lack of awareness and inadequate training as the prime factors.[12,13] Similarly lack of knowledge was concluded by a France survey.[14]

India is a big nation with a diversified race of people. Drug utility pattern and ADRs could be different due to various factors such as socioeconomic, ethnic, nutritional etc. so the factors affecting the reporting of ADRs could be numerous.[15]

Assessment of KAP regarding Pharmacovigilance among the medical personnel and the general population can give us insight in the understanding of various internal and external factors affecting reporting of ADRs in this specific region. More over in India ADR reporting related KAP studies has not yet been studied extensively.[16]

Therefore our study could possibly figure out the lacunae where possible intervention may be required to address the related issues.

AIM-

To study the knowledge, attitude and practice of pharmacovigilance among paramedics and non-medical personnel in a newly opened tertiary care center.

MATERIAL AND METHODS:

STUDY DESIGN:

A survey using a validated self-administered questionnaire was conducted from August to October 2024 among participants belonging from paramedics and non-medical personnel working in Kokrajhar medical college & hospital. Each participant was provided with questionnaire forms, consisting of multiple choice questions and answers, which he/she feels appropriate to answer. For those having difficulty in understanding they were explained verbally and asked to complete the questionnaire anonymously.

SAMPLE SIZE:

The questionnaire was distributed among 150 participants working in various departments of Kokrajhar Medical College& Hospital after obtaining prior written informed consent.

Inclusion criteria
- Willing to participate in the study with written informed consent.

Exclusion criteria
- Refusal to give consent.
- Not available or failed to return questionnaire in spite of the reminder.
- Unable to attempt the questions.

DEVELOPMENT OF QUESTIONNAIRE:
The questionnaire was adapted from previous studies and modified accordingly to suit the conduct of the study. A Questionnaire under heading PART A, PART B, and PART C has been designed in order to access or to obtain data regarding knowledge, attitude and practice towards pharmacovigilance respectively.

DATA ANALYSIS:
The participants were assessed by set of multiple choice questions and single response type question using yes or no and accordingly the percentage calculation was tabulated.

Results –

Table - 1

KNOWLEDGE			
	Correct response	Paramedics	Non-medical personnel
1. Define Pharmacovigilance	The detection, assessment, understanding & prevention of adverse effects	31 %	26 %
2. The important purpose of Pharmacovigilance is?	To identify unrecognized ADR's (Adverse Drug Reactions)	13 %	3 %
3. Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market?	Post Marketing Surveillance (PMS) studies	54 %	6%
4. Pharmacovigilance includes	Drug related problems	44 %	5 %

	Paramedics		Non-medical personnel	
	Yes	No	Yes	No
5. Do you know regarding the existence of PvPI	9 %	66 %	12 %	63 %
6. Are you aware of any drug banned due to ADR	32 %	43 %	7 %	68 %
7. Are you aware of suspected ADR reporting system in India?	30 %	45 %	6 %	69 %

Table -2

PART B : ATTITUDE			
		Paramedics	Non-medical personnel
1. The healthcare professionals responsible for reporting ADR in a hospital is/are?	a) Doctor b) Pharmacist c) Nurses d) All of the above	72 %	54 %

	Paramedics		Non-medical personnel	
	Yes	No	Yes	No
2. Is there a need to include pharmacovigilance in various medical undergraduate curriculums to create awareness?	71 %	4 %	62 %	13 %
3. What is your opinion about establishing ADR monitoring centre in every hospital?	68 %	7 %	65 %	10 %
4. Do you think reporting of adverse drug reaction is necessary?	56 %	19 %	57 %	18 %
5. Do you think ADR reporting benefits both patients and doctors?	70 %	5 %	58 %	17 %
6. Do you think that ADR reporting is a part of professional obligation to health care?	52 %	23 %	10 %	65 %
7. Do you think that medical students could play a role in ADR monitoring?	64 %	11 %	60 %	15 %
8. Do you think that there is a need of information on drugs causing ADRs and their management strategies?	71 %	4 %	61 %	14 %

Table -3

PART: C **PRACTICE**				
	Paramedics		Non-medical personnel	
	Yes	No	Yes	No
1. Have you ever experienced ADR in your patient during your professional practice?	7 %	68 %	0	75 %
2. Have you ever been trained on how to report Adverse Drug Reaction (ADR)?	7 %	68 %	2 %	73 %
3. Have you ever seen the ADR reporting form?	14 %	61 %	3 %	72 %
4. Have you ever reported adverse drug reaction (ADR) to the Pharmacovigilance center?	2 %	73 %	0	75 %
5. Do you keep records of ADR?	7 %	68 %	0	75 %
6. Are you willing for ADR reporting?	59 %	16 %	56 %	19 %
7. Have you seen an adverse drug reporting form by CDSCO	8 %	67 %	4 %	71 %
8. Is there any routine discussion on ADRs during your ward posting	7 %	68 %	9 %	66 %
9. Have you ever played any role in reporting ADR from your institution	2 %	73 %	1 %	74 %
10. Have you anytime read any article on prevention of ADRs	12 %	63 %	17 %	58 %
11. Have you ever visited any ADR monitoring centre	2 %	73 %	0	75 %

A total of 150 participants from paramedics and non medical personnel have participated in this study.Percentage calculation for Part A of the questionnaire, to determine the knowledge of pharmacovigilance among paramedics and non-medical personnel is shown in table-1. Our study revealed that only 31% of the paramedics and 26 % of the non-medical personnel were aware of the term pharmacovigilance. The purpose for pharmacovigilance was known to very less percentage of participants from both the groups which were 13 % for paramedics and 3 % for non-medical personnel. This shows that the participants whether belonging to paramedical or other backgrounds have very limited knowledge towards existence of pharmacovigilance and its purpose. Knowledge of Post Marketing Surveillance studies or monitoring of new drugs in the market for any adverse drug reactions was 54% and 6% for paramedics and non-medical personnel respectively. Only 44% paramedics and 5% non-medical personnel have considered pharmacovigilance as drug related problem. Existence of PvPI (Pharmacovigilance programme India) was known to only 9% of paramedics and 12% of non-medical personnel which is significantly less. Our data also revealed that only 32% paramedics and 7% non- medical participants were aware of drug banned due to ADRs, besides these 45% paramedics and 69% non-medical participants were not aware of suspected ADR reporting system in India.

Data related to Part B of the questionnaire (Table-2) which represents the attitude,revealed that 72% paramedics and 54% non-medical personnel have considered that all the healthcare professionals whether doctor, pharmacist and nurses should report ADRs in a hospital. It was also seen that 71% paramedics and 62% non-medical personnel have opted for inclusion of pharmacovigilance in various medical undergraduate curriculums to create awareness. Over 65% of participants from both the groups have chosen for establishing of ADR monitoring centre in every hospital with approximately 56% from both groups thinks that reporting of adverse drug reaction is necessary. 70% of paramedics and 58% of non-medical participants think that ADR reporting benefits both patients and doctors with 52% paramedics considering ADR reporting as a part of professional obligation to health care system. On the other hand 65% non-medical participants considered ADR reporting non obligatory. 64% of paramedics and 60% non-medical personnel also believe that medical students can play a vital role in ADR monitoring. 71% of paramedics have opted for need of information on drugs causing ADRs and their management strategies followed by 61% of non-medical staff with the same opinion.

Data concerning Part C of the questionnaire (table-3) comprising of practice related questions revealed that only 7% of the paramedics have experienced ADR in their patients. Only 7% of paramedics and very negligible 2% non-medical personnel have everbeen trained on reporting of ADR. 61% paramedics and 72% non-medical personnel have never seen ADR reporting form and only 2% of paramedics have ever reported adverse drug reaction. Record keeping of ADRs was maintained by only 7% participants from paramedical group. However both paramedical and non- medical personnel participants are willing for ADR reporting which constitutes 59% and 56% respectively. Data have also shown that there is no routine discussion on ADRs in ward posting as opted by 68% paramedics and 66% non-medical personnel. Only 2% of paramedics have ever played a role in reporting of ADR from their institution followed by 1% from non-medical personnel group. 63% paramedics and 58% non-medical personnel haven't came across any article on prevention of ADRs and only 2% of paramedics have ever visited ADR monitoring centre.

Discussion -

Medicinal products are essentially used for patient's wellbeing, but may carry some anticipated side effects, generallyavoided by its judicious use. But adverse drug reactions could be noxious and unintended even at the optimal dose and dosage form, causing humanitarian concern in terms of morbidity and mortality[2]. ADRs are expensive too, itcan significantly affect the cost of treatment and hospital stay.[3,4] In many research studies lack of awareness and inadequate training has been regarded as the prime factor related to underreporting of ADRs.[12,13] Based on the outcome of our comparative study many aspects related to pharmacovigilance have become evident. Knowledge based questions have revealed that very limited number of participants from both groups were aware of pharmacovigilance and the purpose associated with it. However participants from paramedical group were aware that pharmacovigilance includes drug related problems and necessary post marketing surveillance studies are employed to monitor ADRs. Pharmacovigilance programme India seems to be unfamiliar among majority of participants from both groups perhaps due to some kind of communication gap. Participants were unaware of suspected ADR reporting system in India as well as unaware of those drugs that are banned due to ADRs. Based on participant's attitude data, both groups believe that all the healthcare professionals should responsibly report ADRs in the hospitals. Perhaps establishment of ADR monitoring centre in every hospital and inclusion of pharmacovigilance study in various medical undergraduate curriculums could be a great initiative in creating awareness among all. Most of the participants from both groups believe that reporting of ADR is necessary as it benefits both patients and doctors considering it as professional obligation to health care system and also medical students could play a significant role in this regard. It was also observed that participants emphasized on the need of ADRs related informations on drugs and subsequent management strategies. Practice related questions revealed that very few participants from paramedical group have experienced ADR in their patients. Training for reporting of ADR seems to be very less among the participants of both groups, with majority of them had never seen ADR reporting form. All though paramedics have reported ADR but the participation was seen to be very less and lack of record keeping was another concern among majority of participants. Routine discussion on ADRs in the ward posting needs to be encouraged as limited number of participants has played a role in reporting of ADRs. Information sharing via leaflets, banners, and screen display could be useful as participants from both groups had hardly come across any article on prevention of ADRs and they haven't visited ADR monitoring centre as well. However the positive part is majority of the participants from both groups were willing for ADR reporting which is quite encouraging for future endeavor in this regard. In our research study it was observed that paramedics in comparison to non-medical personnel comparatively have better knowledge, show similar attitude towards pharmacovigilance which shows optimism, but practice part seems to be the area of concern which showed poor result and needs to be addressed. Lack of knowledge and active participation probable could be the prime cause of underreporting of ADRs which is coherent with other study results. [17-18]

Therefore, decreasing communication gap, providing adequate training by conducting CMEs, workshops, spreading awareness and encouraging active participation among all and inclusion of AI(artificial intelligence) driven platforms could perhaps significantly improve the outcome.[19]

Conclusion-

Our research study had revealed that paramedics in comparison to non medical personnel have better knowledge, both the groups have considerable attitude towards pharmacovigilance which shows positivity towards future prospects. Practice part seemed to be poor in both groups however participant's willingness to participate in ADR monitoring was appreciable. Sharing the knowledge and uplifting the practice based performance by active self participation could bring promising results in solving problems related to ADR underreporting.

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