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Original Research Article

Individual case safety reports by nursing staff: a retrospective pharmacovigilance analysis

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ABSTRACT

Background: The burden of adverse drug reactions is high and accounts for considerable morbidity which can be prevented if healthcare professionals have proper knowledge. Early and spontaneous reporting of ADRs is the mainstay of pharmacovigilance program. Since staff nurses are closely involved in direct patient care, they can easily identify ADRs in the early stage. This study was done to assess the extent of participation of nurses in pharmacovigilance program in our institution.

Methods: Retrospective observational study was conducted by analyzing the 210 Individual Case Safety Reports (ICSR) of 2years duration. Causality assessment in the ICSR was analyzed. Severity of the reactions was categorized into mild, moderate and severe according to Modified Hartwig and Siegel scale. Descriptive statistics were used.

Results: There were 177 cases reported by faculties and 33 were by the staff nurses.19 nurses reported 33 adverse effects (1:1.7) whereas 41 faculties 177 events (1:4). On analyzing the severity of reactions, 188 cases were categorized as moderate (89.5%), 20 mild (9.5%) and 2 severe (1%). In moderate category of 188 reports, 82 % reporting was by faculties and 18% by staff nurses. All the 33 reports by nurses were of moderate category (100%). In the mild and severe category, 100% reporting was by faculties. Causality analysis showed that 194 were classified as probable (92%), 14 as Possible (7%) and 2as certain (1%). In probable category 85% of reporting was by faculties and 15% by nurses, in possible group 71 % by faculties and 29% by nurses and 100% by faculties in severe category.

Conclusions: Training and dedicated participation of nurses can improve reporting of ICSR.

Keywords: Causality, Individual case safety reports, Nursing staffs, Pharmacovigilance

INTRODUCTION

Patient safety is one of the basic principles while providing medical care to patients. But it is the greatest challenge for health professionals to deliver safer care and to prevent adverse drug reactions and events. The burden of adverse drug reactions (ADRs) in the global scenario is high and accounts for considerable morbidity, mortality, and extra-cost to the patients.[1] The incidence of ADRs varies from as low as 0.15% to as high as 30% in various studies. If health care professionals have the knowledge and ability to identify adverse reactions due to certain drugs, lot of morbidity and mortality related to ADR can easily be prevented. Failure to recognize ADR in an early phase leads to an increased burden on economic aspects of the patient, causes undue mental agony to patient life and sometimes may cost the life of the patient by being fatal. Though safe administration of drugs is a priority in healthcare, shortcomings in the monitoring and handling Adverse Drug Reactions (ADRs) cause an undue increase in hospital stay and admissions, increase in financial burdens for patients and society as a whole, poor patient compliance, morbidity, and mortality.[2]

Promoting safe use of medicines is a priority of Indian Pharmacopoeia Commission that functions as the National Coordination Centre (NCC) for Pharmacovigilance Program of India (PvPI).[1] Early, spontaneous and prompt reporting of ADRs due to drugs is the mainstay of pharmacovigilance which can help health professional in the provision of safe and quality healthcare to the community. Pharmacovigilance network, if executed properly, will certainly lead to a reduction of unprecedented fatal reactions due to the particular drug after being marketed. It would be useful to detect adverse reactions unrecognized during drug trials, to identify new drug interactions and risk factors predisposing to drug toxicity.

The worrisome issue in pharmacovigilance is the problem of under-reporting of ADRs. The heavy workload and time constraint of healthcare professionals prevent them to report a greater number of cases pertaining to adverse reactions. Inability or lack of knowledge to identify ADRs, fear of being questioned and uncomfortable reporting methods are the other reasons for under-reporting of ADRs cited in various studies.

Though doctors prescribe, and pharmacists dispense medicine, mostly nurses are the important health persons who administer medicines or observe them being administered. Since staff nurses are the persons who are closely involved in direct patient care, who spend most of their duty time with patients and their relatives and the ones to whom patients talk freely about their illnesses and well-being, they are in the best position to identify adverse drug reactions in the early stage of drug administration. So, Staff Nurses do have an important role in ADR reporting and constitute a potentially valuable source for spontaneous ADR reports in hospitals.

Staff nurses can be considered to be the central anchors in pharmacovigilance program, particularly in identifying ADRs since this aspect still remains outside the reach of other health care providers with special regards to the more vulnerable patients, such as bedridden, critically ill, children and the elderly.[3]

Nursing staff could play a more responsible and indelible role in pharmacovigilance activities because they are not only close to the patients but also have good knowledge of health problems, disease symptoms, drugs and their side effects. Due to their advantage of involvement in direct drug administration and notifying side effects, nurses can even play a prime role in executing the pharmacovigilance program with more vigil. At many times they are helpful in alerting the physicians about the ADRs. There is thus a logical reason to involve nurses and encourage them to contribute to ADR reporting system.[4]

Based on these observations this study was done to assess the extent of participation of nurses in pharmacovigilance program in the author's institution.

METHODS

This retrospective observational study was conducted by analysing the Individual Case Safety Reports (ICSR) collected for a duration of 2 years from March 2015 to December 2017 in Government Thoothukudi Medical College, Thoothukudi. Drug safety information/Individual Case Safety Reports (ICSRs) were collected in predesigned suspected ADR reporting form as per PvPI. A total of 210 ICSR forms with patient details from both outpatient and inpatient departments which were sent to NCC, Pharmacovigilance program of India (PvPI) through Department of Pharmacology were evaluated.

An ideal ICSR form must contain four important elements which are, an identifiable patient, an identifiable reporter, a suspect drug, and an adverse event to make it as a valid tool of ADR collection. After applying these criteria to the collected forms, all 210 reports were taken up for the study.

Information on all the patients regarding age, sex, date of reaction, description of reaction, name of drug, remedial measures and identification of reporting person were recorded from the Individual case reports. Causality assessment done by using WHO criteria and documented in the ICSR were retrieved for our analysis. The severity of the reactions mentioned in the reports was categorized into mild, moderate and severe according to Modified Hartwig and Siegel scale.[5] Descriptive statistics was used to interpret the analysis done.

RESULTS

Out of the 210 total Individual case safety reports taken for our study, 177 (84%) cases were reported by faculties and the remaining 33 (16%) were by the staff nurses (Figure 1). On comparing the number of reports submitted by faculties with those by staff nurses, we found that 19 staff nurses reported 33 adverse effects (ratio is 1:1.73) whereas 41 faculties reported 177 events (ratio is 1:4).
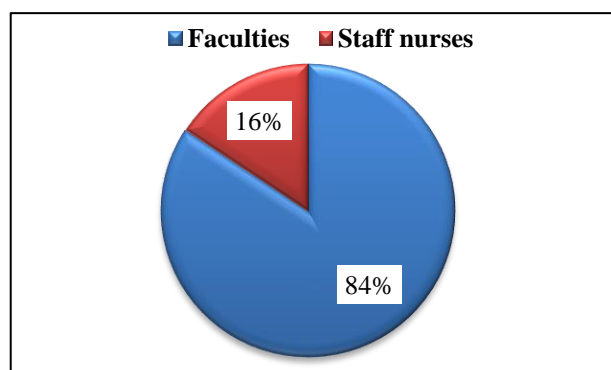

Figure 1: Comparison of reporting by faculties and staff nurses.

On analysing the severity of reactions in all reports by Hartwig-Siegel scale, 188 cases were categorized as

moderate (89.5%), 20 cases as mild (9.5%) and 2 cases as severe (1%). Considering the ICSR by faculties, 155 reports were categorized as moderate (87.5%), 20 as mild (11.3%) and 2 as severe (1.2%). All the 33 reports given by staff nurses came under the moderate category (100%). On considering the pattern of reporting in the overall moderate category of 188 reports, 82 % reporting was done by faculties and the remaining 18% by staff nurses. In the mild and severe category, 100% reporting was done by faculties only (Table 1).

Table 1: Comparison of reports categorized under Hartwig Siegel criteria.

	Faculties	Staff nurses
Mild	20 (100%)	0
Moderate	155 (82%)	33 (18%)
Severe	2 (100%)	0

According to causality analysis by WHO scale, of all the reports 194 were classified as probable (92%), 14 as possible (7%) and 2 as certain 1%) (Figure 2). Comparison of reporting of faculties with staff nurses showed that in probable category 85 % of reporting was done by faculties and 15% by nurses, in possible group 71% by faculties and 29% by nurses and 100% by faculties in severe category (Figure 3).
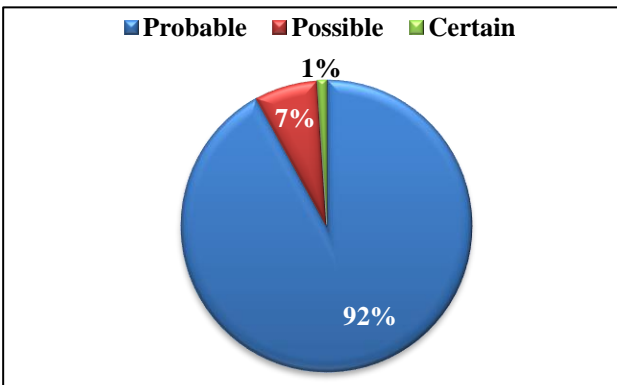

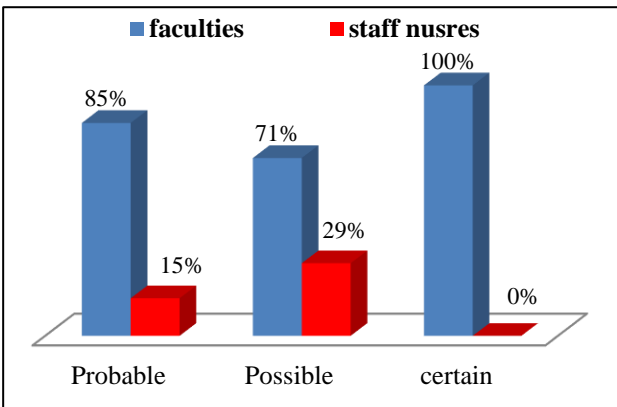**Figure 2: Causality analysis.**

Figure 3: Comparison of causality among faculties and staffs.

Among all the 33 reports by Nurses, analysis of causative drugs revealed that 18 ADRs were caused by antibiotics,4 by Iron preparations, 2 by antiepileptics,2 by antiplatelet drugs, 2 by Intra venous fluids, 2 by Anti Snake Venom, 1 by NSAID and 2 by others (Table 2). Among the systems involved, skin reactions were found in 17 reports, GIT conditions in 7reports, GUT related reactions in 2 reports and musculoskeletal symptoms in 7 cases (Table 3).

Table 2: Analysis of drugs related to ADR reported by the nurses.

Drug class	No. of ADRs reported
Antibiotic	18
Iron	4
Antiepileptic	2
Antiplatelet	2
IV fluids	2
Antisnake venom	2
NSAID	1
Others	2

Table 3: System wise distribution of ADR reports by nurses.

System involved	No. of reports
Skin	17
GIT	7
GUT	2
Musculoskeletal	7

DISCUSSION

Pharmacovigilance is an inherent part of the health system which deals with recording and analysing the effects of drugs, with a focus on determining and maintaining the quality and safety of medicines to patients. As every year a notable number of people die due to adverse drug reactions, it is the responsibility of health professional to monitor and to report any adverse drug reaction in order to render effective and safe pharmacotherapy to the population in the future. Though all the personnel of health care system are involved in reporting adverse drug reactions, nursing staffs deserve an important seat in pharmacovigilance, as they are in a position to closely monitor every activity related to patient care.

In this study, the analysis revealed that nurses have reported 16% of total ADRs which is appreciable but not sufficient for effective pharmacovigilance. Hence, the lower percentage of reporting by nursing staff encountered in our study can certainly be increased if the frequent orientation is provided to them.

The severity analysis showed that all the reports given by staff nurses were of moderate category and no severe reaction has been reported by them. All the severe reactions were reported by the faculty only. This fact is in contrast to the report from Central Portugal Regional

Pharmacovigilance Unit, Portugal, where 46 nurses were able to identify a considerable number of 21 serious ADRs.[6] An original report from Italian pharmacovigilance database also reveals that nurses were able to identify an appreciable number of serious drug reactions (22.9%).[7] The ability of nursing staff to report serious ADRs seems to be less which may be attributed to lack of knowledge, awareness and proper training.

Causality assessment in pharmacovigilance helps to assess the strength of the relationship between the offending drug and its adverse reaction. As per the WHO-UMC scale the category certain; is found to be more significant as it provides the highest degree of association and attributes to the side effect to the particular drug with almost certainty. The categories probable and possible provide lesser strengths of association. On causality analysis of the 33 cases reported by nursing staff in our study, we found that 29 were of probable and 4 were of possible category. In accordance with this, nurses reported a higher number of probable ADRs in the Italian study.[7] This notable difference provides room for more strategies to train nurses to create more awareness among them.

Among all the reports by nurses, 17 were found to be related to skin reactions which go in accordance with the Italian study.[7] Also, skin reactions dominated among the nurses' ADR reports in a study done by Johanna Ulfvarson et al, in Sweden.[8]

Analysis of the group of drugs which caused the reactions in the reports given by the nurses of our study revealed that antibiotics caught the foremost place among al, (54.5%). This matches the reports from a south Korean study by In Young Joung et al, and a Greece study by Toska A et al, where antibiotics were identified as the leading cause of ADRs. In the Greece study more, number of antibiotics induced reactions had been reported by nurses than the faculties.[9,10]

Even though the total number of ADR reports by nurses was small, this analysis indicates that instructed and interested nurses could play an important role in detecting and reporting suspected ADRs. The reporting tendency of ADRs mostly relies upon the attitude of the person who notifies and also personal and professional factors. Nurses, in their position as drug administrators who record signs and symptoms of the patients, play an increasingly important role for detection of suspected ADRs and are now contributing to a significant amount of the ADR reporting in Sweden.[8] So Nursing staff must be motivated to render their highest involvement and cooperation in order to detect a good number of reactions to earn better outcome in PvPI. This study signals the healthcare authorities to conduct a greater number of awareness programs to increase knowledge level on drug reactions especially serious adverse effects, reporting of which was none in our study.[11,12] If staff nurses are oriented properly to ADR reporting according to WHO guidelines, the percentage of certain category can be increased to a higher level which is negligible at present. Such strategies offer opportunities to nurses to place themselves at the centre of the pharmacovigilance program and to bridge the gap between patients and their prescribers.

Training sessions and hands-on workshops can be organized on a regular basis, directing them towards the nurses and budding nursing students. More attention should be paid towards nursing staff while imparting such educational interventions rather than focusing only on the physicians since nurses also play a remarkable role in pharmacovigilance. This could establish a healthy and productive culture of providing higher and significant number of ADRs.

CONCLUSION

In reporting the ADR, the role of nursing staff is vital. If properly trained they can even assume a central role and assure the high success of pharmacovigilance program. The dedicated participation of nursing professionals with this task makes it possible to improve patient safety and to reduce ADR costs.

ACKNOWLEDGEMENTS

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