

Awareness of Adverse Drug Reaction Monitoring and Practice among Student Nurses

Sachidananda Adiga MN^{1,*}, Usha Sachidananda Adiga²

¹Associate Professor, Dept. of Pharmacology, ²Associate Professor, Dept. of Biochemistry, Karwar Institute of Medical Sciences, Karwar

***Corresponding Author:**

Email: adigaiscool@yahoo.com

Abstract

Background: Adverse drug reactions (ADRs) accounts for significant morbidity and mortality. Nurses will play a vital role in monitoring and reporting of ADRs. To monitor and voluntarily report the ADR the nursing students should have sound knowledge on monitoring and reporting of ADRs. Hence this study was undertaken to assess the awareness amongst student nurses with regard to knowledge, attitude and practice of adverse drug reaction monitoring and reporting.

Method: In this questionnaire based study, 80 student nurses posted for clinical rotation from two nursing schools of Karwar, in district hospital Karwar (a secondary level healthcare facility) were distributed pre-validated questionnaire. A predetermined scoring method is used to convert the response of these questions. Suitable statistical test was applied to assess the statistical significance.

Results: It has been found out that, the knowledge score was considerably less (32.36±1.01) when compared to attitude and practice scores (.35±1.74 and 41.39±1.67 respectively). There was a very high statistical significance between the three domains ($P<0.0001$). 64% students felt that reporting of ADRs is important to improve the patient safety. Majority of the students also felt that (89%) that awareness program on ADR should be frequently conducted to update the knowledge on ADRs.

Conclusions: We conclude from our study the knowledge on adverse drug reaction is poor among student nurses though they have a good attitude and practice skills of monitoring and reporting ADR.

Keywords: Adverse Drug Reactions, Nursing students, Knowledge, Practice.

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Introduction

Adverse drug reaction (ADR) is defined as any response to a drug that is noxious & unintended & that occurs at doses used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiologic function¹. Science & activity relating to detection, assessment, understanding & prevention of adverse effects or any other possible drug - related problems is called Pharmacovigilance¹. Use of drugs and the occurrence of ADR goes hand in hand. Documented reports estimates that around 1% of hospital admissions are due to adverse drug reactions in India² whereas it is 7% in United Kingdom and 13% in Sweden and New Zealand^{3,4}. Estimated hospital budget to manage the drug related complications is to the tune of 20%^{5,6}. Literature also quotes that about one third of these adverse drug reactions are preventable⁷. In resource limited settings like third world countries, active Pharmacovigilance can greatly reduce the burden on nation in providing effective and meaningful healthcare to the society.

Healthcare professionals have a great responsibility of monitoring and voluntarily reporting the ADRs to Adverse reaction monitoring centres. Despite making the Pharmacovigilance activity of national importance underreporting of ADR is common problem throughout the world^{8,9,10,11,12}. In India the voluntary reporting of adverse drug reaction has to get momentum as it is around 1% as per one study¹³ whereas it five times more in Canada and United States of America¹⁴. The factors responsible for non-reporting or underreporting are of diverse nature and vary from place to place^{15,16}. Many factors contributing to this underreporting, the important ones being, feeling of guilt, fear of litigation and lack of awareness about Pharmacovigilance program⁹.

In the recent years teaching and training of medical graduates and doctors on ADR monitoring and reporting has gained significant boost, while the same has not been focused on nurses as well as student nurses. There are several studies to support the fact that if we impart quality training to student nurses in their formative years and due consideration is given in their curriculum it will be very useful in the future days when they become torchbearers in Pharmacovigilance activity. There are many studies which have been conducted to assess the knowledge, attitude and practice of ADRs among doctors^{17,18,19,20}.

Even though pharmacology subject is a part in the nursing curriculum, they have a limited exposure to Pharmacovigilance in teaching as well as training. To

achieve great success, we need to concentrate not only on the present healthcare workers but also focus on future stakeholders. In this regard we need to identify the level of understanding about pharmacovigilance among student nurses. To best of our knowledge there are few studies that has been done to assess the awareness of adverse drug reaction monitoring and voluntary reporting in student nurses. So our aim is to evaluate the knowledge, attitude and practice regarding adverse drug reaction monitoring and reporting among student nurses in Coastal Karnataka so that we can assess the level of understanding and aim at remedial measures.

Materials and Method

In this observational study, 80 student of two nursing school who were posted for clinical training in District Hospital Karwar, a secondary healthcare setup and are willing to participate in the study were distributed a prevalidated questionnaire. Study subjects were 4th year Bsc Nursing and General nursing students of 3rd year.

Questionnaire: We obtained the feedback from the participants through structured questionnaire which was validated by peer group of medical education unit of our college. The questionnaire consisted of 15 items comprising questions related to cognitive domain(knowledge), Affective (attitude) and to Psychomotor (practice) domains, related to ADR monitoring and reporting. Questions were constructed taking into consideration the previous similar studies as the reference and modification was made^{19,20}. The questionnaire was distributed to 20 students on two occasions 4 weeks apart to test the test –retest reliability. The Cronbach's alpha error was found to be 0.68.

Out of these 15 items, eight items each testing knowledge and four on attitude component of adverse drug reaction monitoring and reporting and rest three testing the practice aspect of ADR monitoring and reporting(enclosed). The responses of these questions were translated to points considering the options given and their important. Knowledge attitude and practice domain questions carried a maximum of 16 points, 9 points and 10 points respectively. The scores of each

item were converted into percentage for statistical analysis.

Statistical analysis

Statistical analysis was done using Graph pad Instat Software. Kruskal –Wallis test followed by Dunn's multiple comparison test was used to compare the Knowledge, attitude and practice score among the students. Statistical significance was fixed at P<0.05. The responses to various questions on the ADRs were expressed in percentages. Descriptive statistics was used to express the response to the questions.

Results

The mean knowledge, attitude and practice scores were 32.36±1.01, 59.35±1.74 and 41.39±1.67 respectively. We found an extremely significant difference in the above mentioned scores (p<0.0001) among these students. Post-test (Dunn's) was also highly significant (p<0.001) between knowledge, attitude score with that of practice score (**Table 1**).

Table 1: Showing Average scores and percentage scores of three components

Components	Average score	Average percentage score
Knowledge (16)	5.18±0.16	32.3±1.01
Attitude (09)	5.36±0.14	59.35±1.74
Practice (10)	4.51±0.41	41.39±1.67

*P<0.0001, between the groups, Kruskal-Wallis test followed by Dunne multiple comparison test

Knowledge Domain: 58% of students correctly identified the definition of adverse drug reaction whereas only 10% could differentiate adverse drug reaction from side effect. There was very little knowledge regarding the banned drugs in India as evidenced by 7.5% positive response. 6.25% students were aware of adverse drug reporting centre in Karnataka (Table 2). 32% and 29% students felt that doctor and nurses have to report the ADR to ADR monitoring centre respectively (**Fig. 1**). Majority of the students (82.50) received the information on ADR by text books. Most of the students did not knew about the drugs banned India (92.5%) (**Table 2**).

Table 2: The responses to various items of adverse drug reactions

Item	Number Responses	Correct/Yes	Wrong/no
Definition of ADR	80	47(58.75)	33(41.25)
Have you ever observed an ADR?	80	16(20)	64(80)
Whether ADR and Side effect same	80	08(10)	72(90)
Are you aware of any drug banned due to ADR?	80	06(7.50)	74(92.5)
Have you ever reported an ADR?	80	10(12.5)	70(82.5)
Are you aware of any ADR Centre in	80	05(6.25)	75(93.75)

Karnataka?			
Do you have free access to ADR reporting form?	48	9 (18.75)	39(81.25)

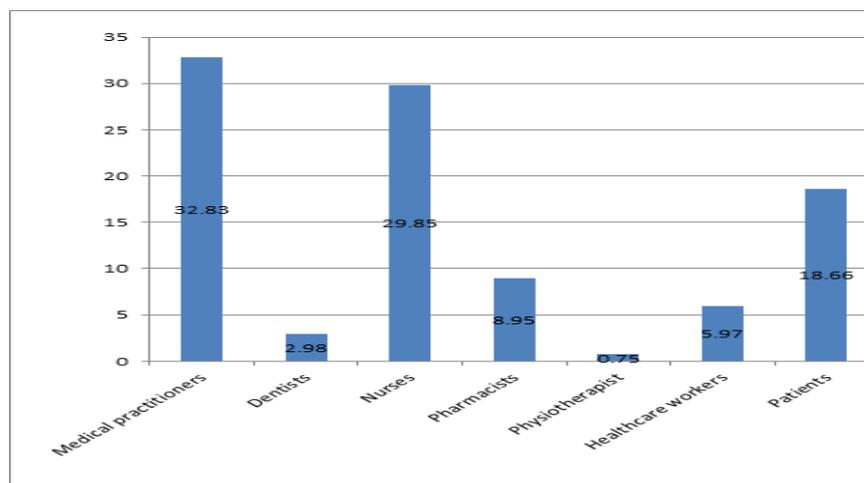


Fig. 1: Students' opinion - who can report ADR?

Attitude component: It was evident from the responses from the students that only 20% of them have observed an ADR (Table 2). 64% students felt that ADRs have to be reported to improve patient safety. Rest of the students equally felt that reporting must be done to identify and grade the ADRS, estimate the frequency of occurrence of ADR and to share the knowledge on ADR (Table 3). Majority of the students (88%) were of the opinion that frequent awareness programs are needed to update their knowledge on ADRs. 91% of students are of the opinion that they prefer to send the ADR information by personally (Table 3).

Practice component: 12.5% students have reported the ADR (2 out of 16 students) which is considerably less (Table 2). Students opined unexpected, unusual (35%) and serious adverse drug reactions (22%) are the two important types of reactions reporting (Fig. 2). Managing patient is more important (28%), did not know how to report (22%) and did not know where to report (19%) were the three main discouraging factors for reporting the ADRs (Fig. 3).

Table 3: The responses to various questions on adverse drug reactions

Item	Response	Number
Why it is important to report an ADR?	To identify and grade new ADR	12(11.01)
	To share the information on ADR	13(11.92)
	To improve patient safety	70(64.22)
	To measure the frequency of ADR	14(12.84)
From which source do you get information on ADR?	Text book	66(82.5%)
	journal	09(11.25)
	Medical representatives	05(6.25)
Which method do you prefer to send the information on ADR?	Personally	73(91.25)
	By post	02(2.5)
	Telephone	05(6.25)
Do you think frequent awareness program on ADR is needed to update yourself?	Yes	71(88.75)
	No	07(8.75)
	Not Sure	02(2.5)

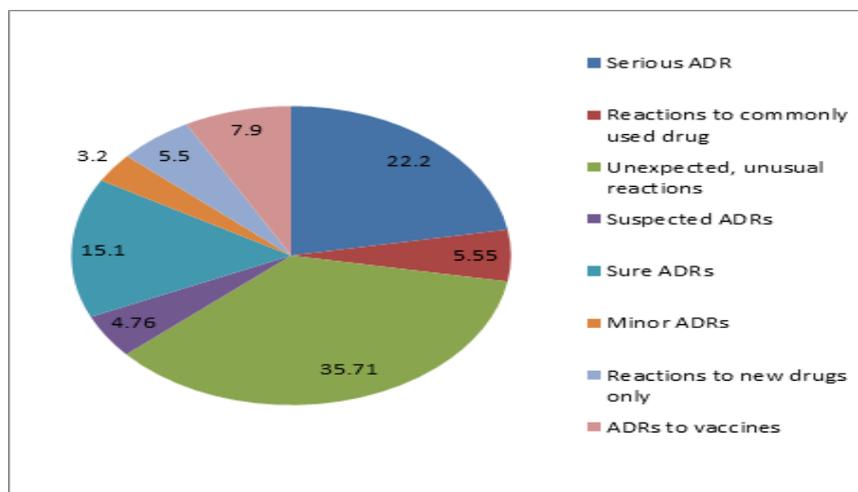


Fig. 2: Pie chart showing what type of ADRs to be reported the of responses

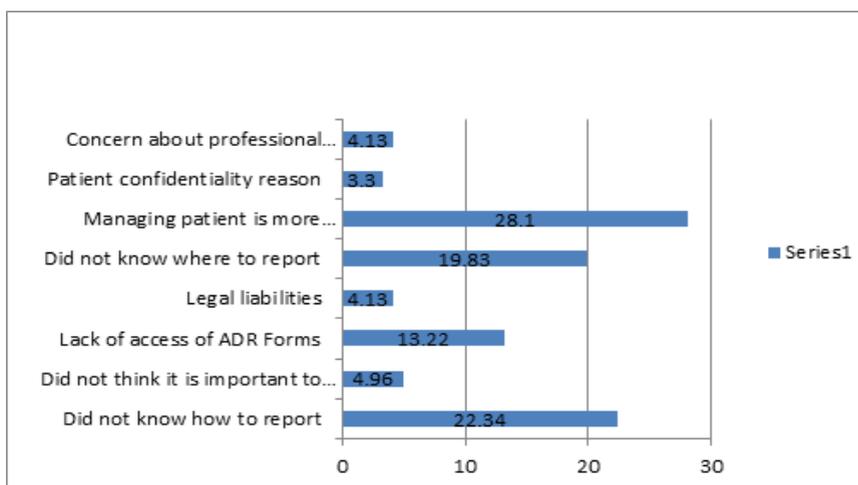


Fig. 3: Showing factors affecting non-reporting of ADRs

Discussions

This study was an observational questionnaire based study conducted on students of bachelor and general nursing in a secondary healthcare setup. Literature search showed only two studies, Sivadasan et al done on Malaysian student nurses and Amarnath et al conducted on student nurses of Puducherry India^{21,22}. The method of assessment was slightly different in both studies compared to our study.

The average knowledge score was less (32.36 ± 1.01) when compared to attitude and practice score 59.35 ± 1.74 and 41.39 ± 1.67 respectively in our study. There was statistically significant difference between the three scores ($P < 0.0001$). This showed that our participants have comparatively good attitude and practical application about adverse drug reactions. The study done by Sivadasan et al quotes a very high knowledge score (75%) which is very high compared to our study. This shows that either our nursing curriculum does not have a structured teaching module for student nurses or ineffective training of students on ADRs when compared to Malaysian counterparts. The

average percentage score of attitude practice score were not assessed in the two comparative studies (Sivadasan et al and Amarnath et al).

Knowledge Component: Knowledge on any subject, tests the cognitive domain of a person as per Blooms Taxonomy. The various questions in our questionnaire assessed the overall knowledge of student nurses on Pharmacovigilance. As per our study, the knowledge on ADRs is poor as explained by the percentage score (32.36 ± 1.01). Our study results were comparable to Hinafi et al²³ and Hajabi et al²⁴. Detailed account on knowledge components revealed that, the correct definition on ADR was given by 58.75%, difference between ADR and side effect was stated correctly by 10%, Aware of ADR centre in the region (6.25%) by our participants. The overall knowledge on ADRs was high (75%) in Sivadasan et al study though these questions were differently framed²¹. As per Amarnath et al study students had knowledge in the range of 33-47% as they considered consolidated scoring system²².

Attitude and practice components: Only 20% of participants have observed the adverse drug reactions and out of which only 12.5% have reported. Ekman et al study showed that 50% students were aware of reporting and but only few had actively took part in reporting.²⁵ This means that there must be some compelling reason for not showing interest in reporting. On detailed enquiry on non-reporting of adverse drug reactions, 28% felt that patient management is more important than reporting, 22% felt that they did not know how to report the ADR and 19% stated they did not know where to report. Sivadasan et al study revealed a different reason for non-reporting that, 60% felt reporting of ADR will not contribute to overall reporting system of their country²¹. Amarnath et al study showed only 40% of students had good reporting skill and 16% had good documentation skill²².

There are ample evidence to suggest that awareness program helps to update the knowledge on ADR^{26,27}. Our study showed similar results i.e. 88% students opined that frequent awareness programs have to be conducted to update their knowledge on ADR which was similar to the study of Ekman²⁵.

Conclusions

We conclude from our study that knowledge aspect of ADR monitoring and reporting was less in our study participants. We suggest structured teaching of basic concepts of Pharmacovigilance and proper hands on training on reporting ADRs.

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Ethical Approval: Not required

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