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Research Article

Knowledge, attitude and practice of adverse drug reaction monitoring and reporting among nurses of secondary healthcare

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ABSTRACT

Background: Adverse drug reactions (ADRs) are responsible for significant morbidity and mortality. Nurses will play a vital role in monitoring and reporting of ADRs. Hence this study was conducted to assess the knowledge, attitude and practice of adverse drug reaction monitoring and reporting among secondary healthcare level.

Methods: In this questionnaire based study, 98 nurses working in district hospital Karwar (a secondary level healthcare facility) were grouped according to their working experience. Pre-validated questionnaire was distributed to assess the knowledge, attitude and practice of ADR monitoring and practice in their setting. Responses were converted into scores using predetermined scoring method and assessed for their level of knowledge, attitude and practice. Suitable statistical tests were applied to assess the statistical significance.

Results: It has been found out that, the knowledge score ranged from 30.52±2.89 to 40.5±2.3 with no statistical significance. The attitude and practice score ranged from 43.33±2.13 to 53.85±2.67 and 23.8±4.17 to 45±7.54 respectively, with the statistical significance of 0.03 and 0.02 respectively between the groups. 72.5% participants had observed at least one ADR, while 45% of them had reported the ADR to higher authority. 82.5% of participants opined that there should be frequent awareness programs to update their knowledge on ADRs. Many factors like legal liabilities (14.5%), didn't know where to report (24.45%), did not think reporting ADR was important (5%), non-availability of ADR reporting forms (31%) were some of discouraging factors for non -reporting of ADRs.

Conclusions: We conclude from our study that even though knowledge about ADRs was relatively better despite being a resource limited setting, the attitude and practice of reporting of drug reactions needs to be improved.

Keywords: ADR, Attitude, Knowledge, Practice

INTRODUCTION

Drug intervention is one of the important measures to treat many diseases. The WHO defined adverse drug reaction (ADR) 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 function.[1] Occurrence of adverse drug reactions with the use of drugs is inevitable which leads to significant morbidity and mortality. There are reports that some countries are spending 20% of hospital budget in dealing with the drug related complications.[2,3] One study quotes that 0.7% of hospital admission is due to adverse drug reactions.[4] Around 30 % of these adverse drug reactions are preventable.[5]

Pharmacovigilance is defined as the science and activity relating to detection, assessment, understanding and prevention of adverse effects or any other possible drug - related problems.[1] Rational use of drugs, vigilant pharmacovigilance activity and voluntary reporting of adverse drug reactions will definitely help to reduce many adverse reactions and manage related complications. Monitoring of ADR and voluntary reporting is expected from doctors and other healthcare professionals. Underreporting of ADR is common problem throughout the world.[6-8] There are many factors contributing to this underreporting, the important ones being, feeling of guilt, fear of litigation and lack of awareness about Pharmacovigilance program.[9]

Nursing staff will form a vital cog in providing the health services to patients. Among all the healthcare providers, they are giving quality time for patient care. To expect voluntary reporting from nurses, it is very much essential that they should possess proper knowledge about monitoring and reporting of ADRs, right attitude and appropriate practical knowledge regarding monitoring and reporting. To have a sound robust reporting of ADRs, it is important to impart quality training to these healthcare professionals. There are many studies which have been conducted to assess the knowledge, attitude and practice of ADRs among doctors.[10-13] A few of them have been conducted on healthcare workers (doctors, nurses, pharmacists together) from medical college hospitals and tertiary care hospitals.[14,15]

There is a significant knowledge gap between nurses rendering services in tertiary hospitals and others providing service in like secondary, primary health care due to lack of training and teaching program. To best of our knowledge there is limited study that has been done to assess the awareness of adverse drug reaction monitoring and voluntary reporting from the health settings down the line i. e secondary and primary care level. So our aim is to evaluate the knowledge, attitude and practice regarding adverse drug reaction monitoring and reporting among nurses in a secondary health care level in Coastal Karnataka so that we can understand the problem of underreporting at grass root level about adverse drug reaction monitoring and reporting in secondary healthcare level and take necessary remedial measures.

METHODS

In this observational study, 98 nurses who are working in District Hospital Karwar, a secondary healthcare setup and are willing to participate in the study were distributed a prevalidated questionnaire. We received 80 completed questionnaires. Study subjects were divided into five groups based on their number of years of work experience as follows; group A: less than 2 years, group B: 2 - 5 years, group C: 5-10 years, group D: 10-20 years and group E: more than 20 years

Questionnaire

We obtained the feedback from the participants through structured questionnaire which was validated by peer group of medical educationists. The questionnaire (enclosed) consisted of 14 items comprising questions related to knowledge, attitude and to practice issues related to ADR monitoring and reporting. Questions were constructed taking into consideration the previous similar studies as the reference and modification was made 12, 13 and 14. The test –retest reliability was obtained by giving the questionnaire to group of ten nurses on two different occasions with the interval of six weeks. The Cronbach's α error was 0.65.

Out of these 14 items, six items each testing knowledge (Q 1, 4,10,11,12 and 14) and attitude component (Q2, 3,5,6,13) about adverse drug reaction monitoring and reporting and rest three (Q7, 8 and 9) testing the practice aspect of ADR monitoring and reporting. The responses of these questions were translated to points considering the options given and their important. Knowledge and attitude domain carried a maximum of 15 points each and the practice domain carried 10 points. The scores of each item were converted into percentage for statistical analysis.

Statistical analysis

Knowledge (K), attitude (A) and practice (P) scores were compared separately among these groups and within the groups as well. Kolmogorov Smirnov test was applied to assess the normality of the sample. If the data followed Gaussian distribution, one way ANOVA test was applied followed by a post test (Tukey-Kramer multiple comparison test). Normal distribution was confirmed by Barlet's test. Kruskal Wallis test was applied for skewed data, followed by a post test (Dunn's multiple comparison test). K, A and P scores were compared within the individual groups was carried out by ANOVA for group A and Kruskal Wallis for remaining groups. Descriptive statistics was used to compare the responses of participants about ADR monitoring and reporting, expressed as percentage.

RESULTS

A total of 80 nurses completed the study questionnaire out of 98 (81.63%). The percentage of participants in different study groups were given in Figure 1. We have converted their opinion into scores as mentioned in the methodology. The mean score of knowledge was lowest in group B (30.52±2.89) and maximum in Group D (40.5±2.3) and there was no significant difference in scores between these groups. Attitude score ranged from 43.33±2.13 to 53.85±2.67 while practice score ranged from 23.8±4.17 to 45±7.54 (Table 1 and Figure 2). Attitude and practice scores differed significantly with P value 0.03 and 0.02 respectively between the groups. However post-tests applied for the above two components did not reveal any significant difference. Table 1 shows comparison of scores of knowledge, attitude and practice scores in the five groups.

Within the groups there was extremely significant difference ($P<0.0001$) in knowledge, attitude and practice scores of group A. Tukey-Kramer multiple comparison test showed highest difference between A versus P ($P<0.001$) as compared to K versus A ($P<0.01$) and K versus P ($P<0.05$) (Table 1).

In group B, variation between K, A and P was significant ($P=0.001$). Dunn's multiple comparison test showed greater difference between A versus P ($P<0.01$) as compared to K versus A ($P<0.05$). K versus P was

insignificant (Table 1). In group C, knowledge, attitude and practice differed extremely (P=0.003). Post test showed a significant difference between K versus A (P<0.01), (Table 1). There was no statistically significant difference among K, A and P in groups D and E.

In our study 72.5 % participants had observed at least one ADR, while 45% of them had reported the ADR observed. Out of these, 55.5% have reported to hospital authority, 33.3% to the treating doctors, 5.5% each to the ADR Centre and pharmaceutical company respectively. 72.5% of them were not aware of any ADR reporting centre in Karnataka. Majority of them opined (82.5%) that frequent awareness programs need to be conducted to update their knowledge about ADRs (Table 2).

Table 1: Comparison of KAP scores of different study groups.

Parameter	A (N=13)	B (N=13)	C (N=25)	D (N=17)	E (N=12)
Knowledge	36.9±3.93Ŧ	30.52±2.89•	33.59±2.2	40.5±2.3	36.95±5.1
Attitude *	53.85±2.67 Ŧ Ŧ	44.62±2.29••	50.78±2.39•••	43.33±2.13	45.29±2.77
Practice**	23.8±4.17 Ŧ Ŧ Ŧ	23.85±4.6	42.48±4.65	40.88±6.89	45±7.54

Scores in percent (Mean±SEM); * P=0.033; ** P=0.0245, Comparison between the groups. (Kruskal-Wallis); Ŧ P<0.001, A versus P, Ŧ Ŧ P<0.01, K vsrsus A, Ŧ Ŧ Ŧ P<0.05, K versus P within Group A (One way ANOVA, Tukey-Kramer multiple comparison test; •P<0.01, A versus P, •• P<0.05, K versus A within Group B (Kruskal Wallis test, post hoc Dunn's multiple comparison test; •••P<0.01, K versus A within Group C. (Kruskal Wallis test, post hoc Dunn's multiple comparison test).

Table 2: The opinion of participants regarding ADR Reporting.

Question	Yes (%)	No (%)
Have you ever observed an ADR?	58 (72.5)	22 (27.5)
Have you ever reported an ADR?	36 (45)	44 (55)
Are you aware of any ADR reporting centre in Karnataka?	22 (27.5)	58 (72.5)
Do you think frequent awareness programme is needed to update yourself regarding ADRs?	66 (82.5)	14 (17.5)

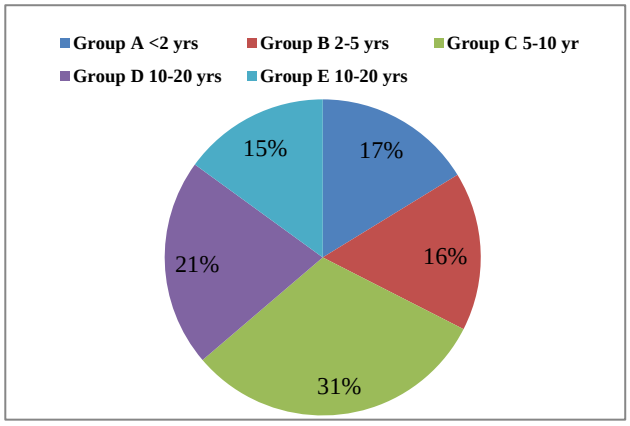

Figure 1: Pie chart of the percentage of participants in various study groups.

There are many factors discouraging non -reporting of ADRs among healthcare workers. 27% of our study participants did not know how to report to appropriate authority. Around 5% did not think reporting ADR was important. 31% of participants claimed non-availability of ADR reporting form was the reason for non- reporting. As mentioned in the Table 3, legal liabilities (14.5%), didn't know where to report (24.45%), patient confidentiality reason (10.9%), professional liability (18%). Majority of them opined treating patient was more important than reporting (Table 3).

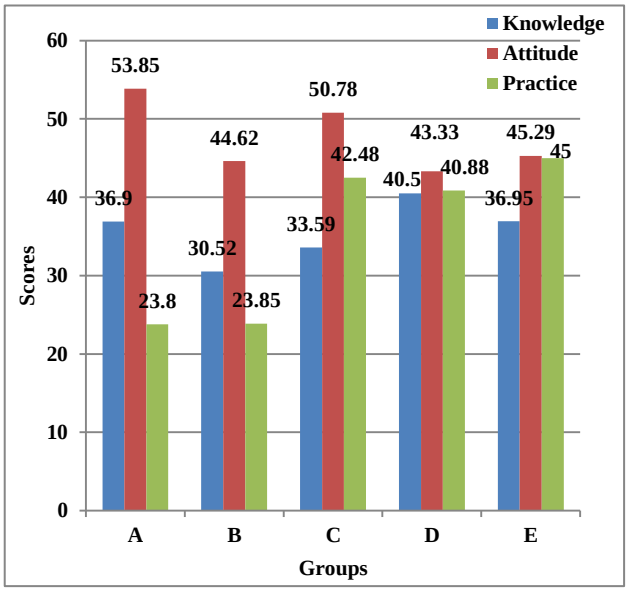

Figure 2: Bar chart for comparison of KAP scores within groups.

Table 3: The factors affecting the non-reporting of ADR.

Factor affecting the reporting of ADR	Number of responses N=80 (%)
Did not know how to report	15 (27.27%)
Did not think is important to report	3 (5.45)
Lack of access/availability of ADR forms	17 (30.9)
Legal liability reason	8 (14.5)
Did not know where to report	14 (25.45)
Managing patient is more important than reporting	35 (63.63)
Patient confidentiality reason	6 (10.9)
Concern about professional liability	10 (18.18)
Non responders	25 (31.25)

DISCUSSION

The present study was a questionnaire based study conducted on nurses in a secondary care hospital which is on the verge of becoming teaching hospital. There are many published data analysing the knowledge, attitude and practice of ADR monitoring and reporting among healthcare worker though a few had solely done on nurses. 38.2% was the mean knowledge score in Chetna et al study conducted on doctor population.[14] In our study, the mean knowledge score was in the same range (30.52±2.89 to 40.5±2.3). Compared to the above study, our participants had considerable better knowledge about the ADRs. To best of our knowledge no study was available to compare the attitude and practice scores.

We have compared our findings with four similar studies, Someyah et al (Iran), Ekman et al (Sweden) Fisun et al (Turkey), Joseph et al (Nigeria) and Sivanandy P et al (Coimbatore) in which study was conducted on nurses.[15-19] As for as observation of ADR was concerned, our study (72.5%) showed similar results as Joseph et al (73.3%). The information of similar data was lacking as other studies have not highlighted this observation.

Reporting of ADR is very important because it shows their attitude and commitment to report ADR voluntarily. Several studies have come out with varied outcome. In our study reporting of ADR was 45% similar to Sivanandy et al (45%) while it was 8% in Fisun et al, 9% in Sameyah et al, 14% in Ekman et al and as high as 75% in Joseph et al.[15-19] This clearly shows the disparity in practice component which tells the need to understand the intricacies associated with reporting of ADR.

The pattern of reporting was also different in different studies. In our study, majority of the nurses reported ADRs to hospital authority (55.55), treating physician (33.33), ADR centre (5.5) and pharmaceutical company (5.5). 74 % nurses reported ADR to hospital ADR centre as per Someyah et al.[16] It was evenly reported to Pharmacovigilance centre (35%), 25% to quality management unit and 30% to treating physician in Fisun's study.[18] The above finding from our study clearly shows the confusion over where ADR has to be reported, stressing the need for training sessions on proper reporting protocols.

Many studies have analysed the factors hindering the reporting of ADR which varies from country to country. Many factors contributed for this non-reporting, important being lack of awareness about monitoring and reporting (what to report, how to report) and need to understand the importance of reporting ADR.

In our study a total of 51% nurses did not knew how and where to report, while it was 74% in Joseph et al study.[19] 35.7% in Fisun's study didn't know how to report though the study has no data on awareness about where to report.[18] Needless to say again that there is a is wide variation in these grey area of ADR reporting

The attitude of the nurses about reporting of ADRs differs significant in different settings. Financial incentives, fear of litigation, complacency, diffidence, indifference, ignorance, lethargy were the reasons pointed out by Inman et al Financial award, complacency. As it was documented.[20] Similar thoughts were aired by our study participants too. In our study 5% of nurses felt that reporting ADRs don't have an impact on healthcare while 32% nurses answered they did not report as physician thought ADRs are not significant.

Repeated awareness programs or training program will keep the nurses in knowledgeable state so that voluntary reporting of ADRs from nurses may be improved. Most of the study findings were in concurrence with this fact.[21,22] In our study 82.5% nurses felt awareness programs should be conducted on yearly basis so that they can update their knowledge, while it was almost same in Ekman study (88%). This again shows that awareness program for nurses are most sought method to update their knowledge.

CONCLUSION

We conclude from our study that despite reasonable knowledge about adverse drug reaction among nurses, there a still a lot of afforts required overcoming the proper monitoring and reporting of ADR to appropriate authority is required. Training sessions like awareness program are the most sought method to update.

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Questionnaire regarding knowledge, attitude and practice of adverse drug reactions
(Tick the appropriate option)

1. Age:

2. Sex: F/ M

3. Qualification: GNM/B.Sci Nursing /M.Sci Nursing

4. Experience in the field of Nursing after the qualification a) Less than 2 years b) 2-5 years c) 5-10 years d) 10-20 years e) >20 years.

Q1**. What do mean by an adverse drug reaction (ADR)?**

a. Untoward reaction seen due to administration of drug in normal dose
b. Untoward reaction seen due to administration of drug in high dose
c. Untoward reaction seen only due to administration of new drug

Q2. Have you ever observed an ADR?
a. Yes b. No c. seen but not sure

Q3. **If so how frequently you come across ADRs per week on average?**
a) less than 1 b) 1-2 c) 3-5 d) more than 5

Q4. List of drugs that commonly cause ADRs

	Medicine	ADR
a.		
b.		
c.		

Q5. How important do you think an ADR to be reported?
a) Very important b) important c) Not so important

Q6. Why it is important to report an ADR according to you? (can tick multiple option)
a. To identify and grade new ADR c. To share information on ADR with colleagues
b. To improve patient safety d. To measure the frequency of ADR

Q7. Have you ever reported an ADR?
a. Yes b. No
If yes how many till today ----------? And where
a. ADR Monitoring centre b. The concerned pharmaceutical company c. others:

Q8.What type of ADRs do you think need to be reported?(can tick multiple option)
a. Serious of ADR d. Suspected ADR e. Sure ADR f. Minor ADR
b. Reactions to commonly used drugs g. Reactions to new drugs only
c. Unexpected ,unusual reactions h. ADRs to vaccines

Q9. Which are the factors that discourages you reporting an ADR?(Can tick multiple option)
a. Did not know how to report e. Did not know where to report
b. Did not think is important to report f. Managing patient is more important than reporting
c. Lack of access/availability of ADR forms g. Patient confidentiality reason
d. Legal liability reason h. Concern about professional liability

Q10. Are you aware of any ADR reporting centre in Karnataka?
a. Yes b. No

Q11. From which source do you get information?
a. Text book b. Journal c. Medical representatives d. Seminars e. Any other:

Q12. Do you have free access to ADR reporting Form?
a. YES B. No

Q**13. Which method do you prefer to send the information on ADR/**
a. Direct contact b. by post. C. Telephone d. Other…….. Specify

Q14. In your opinion who are qualified to report an ADR? (can tick Multiple option)
a. Medical Practitioners b. Dentists c. Nurses d. Pharmacists
e. Physiotherapist f. Health care workers g. Patients

Remarks/suggestions: