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Original Research Article

Study on the knowledge, attitude, and practice of pharmacovigilance among the post-graduate trainee in a tertiary care hospital, Dibrugarh

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ABSTRACT

Background: Adverse drug reactions (ADR) are a major cause of illness and death worldwide. Pharmacovigilance (PV) helps in improving patient's safety through reporting and assessment of ADR, but underreporting by healthcare professionals remains a major drawback. Therefore, the study was conducted to assess the knowledge, attitude and practice (KAP) regarding PV among the postgraduate trainee of a tertiary care hospital who are often the first line treatment providers.
Methods: The study was cross-sectional, questionnaire based designed to assess KAP among 280 postgraduates. Data were analysed using descriptive statistics, Pearson's correlation, multiple regression analysis, and Chi-square test.
Results: The study highlighted that attitude of the postgraduate medical residents and practical exposure to ADR related activities play a greater role than knowledge alone in improving ADR reporting.
Conclusions: The findings provide evidence for strengthening institutional support and continuing medical education among the healthcare workers on the topic.

Keywords: Pharmacovigilance, Adverse drug reaction, Postgraduate residents, KAP, Healthcare workers

INTRODUCTION

Medicines play an indispensable role in the prevention, diagnosis, and treatment of diseases. Despite their therapeutic benefits, all medicines have the potential to produce adverse drug reactions (ADRs) which are a major cause of morbidity, mortality, prolonged hospital stay and increased healthcare cost.[1,2] A recent meta-analysis reported that ADR accounts for approximately 2.85% hospital admissions and 6.34% of hospitalized patients develop ADRs during hospital stay in India.[3] However, overall ADR reporting rate in India is less than 1%, which is considerably lower than the estimated global reporting rate of 5%.[4]

Pharmacovigilance (PV) the literal meaning of which is "to keep a watch on drug" is defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug effects or any other drug related problems", is an essential component of healthcare systems aimed at ensuring patient safety by detecting known and unknown ADRs to drugs.[5] Keeping in view the importance of it, India in 1997 joined the World Health Organization (WHO) "International Drug Monitoring Program" coordinated by the Uppsala Monitoring Centre in Sweden, and subsequently formed Pharmacovigilance Program of India (PvPI) in July 2010 by Ministry of Health and Family Welfare, Government of India.[6,7]

Under PvPI, spontaneous ADR reporting is a voluntary reporting system in which healthcare professionals as well as consumers report suspected ADRs to PV centers or regulatory authorities for continuous monitoring of drug safety. Several drugs such as encainide, fenfluramine, rofecoxib, cisapride, and terfenadrine were withdrawn from the market due to serious ADRs detected during post-marketing surveillance.[8]

The effectiveness of pharmacovigilance initiatives largely depends on the active participation of healthcare professionals, particularly physicians and post-graduate medical trainees, who are often first to encounter ADRs in clinical practice. However, it also depends on the knowledge, attitude and practice (KAP) of the healthcare workers.[9]

Medical residents have an important role in PV as they are directly involved in patient care. A systematic evaluation of the KAP among PGTs can reveal significant gaps and barriers in ADR reporting and helps identify interventions to enhance PV practices. By understanding these determinants, it becomes possible to develop targeted educational policy initiatives that foster a culture of safety and accountability within healthcare institutions.

Objectives

The objectives were to evaluate KAP and identify determinants of ADR reporting among the PGTs of AMCH, Dibrugarh using the KAP framework.

METHODS

This study was conducted among the postgraduate medical residents of Assam Medical College and Hospital, a tertiary care hospital of Dibrugarh district, Assam, India from September 2024 to November 2024. This was a cross-sectional observational study conducted using a semi-structured and pre-validated KAP questionnaire towards PV and ADRs. The KAP questionnaire consisted of total 22 questions. Pretesting of the questionnaire was conducted on 20 randomly selected participants representing the whole study population to identify the misleading and confusing questions and time taken to complete the task. Questions were modified accordingly.

The questionnaires were distributed among the postgraduate residents in google form via WhatsApp or email. The questionnaire was subsequently evaluated by assigning one point against each correct response, with a highest obtainable score of 21. Based on the obtained scores, the participants were categorized into 3 groups: poor, moderate, and good.

The compiled data were then analyzed by using both descriptive and inferential statistics (Pearsons's correlation (KAP score), univariate and multivariate linear regression (predictors of practice) and Chi-square (demographic association)) with the help of statistical package for the social sciences (SPSS for windows, version 21.0. Chicago: SPSS Inc.) and Microsoft excel 2010.

RESULTS

All the 280 participants, nearly show an equal gender distribution among the residents. The majority of the participants were 1st year residents, accounting for 183 (65.36%) of the total study population. Only 63 (22.50%) residents had visited the AMC, whereas a large proportion, 217 (77.50%), had never visited the AMC. Regarding ADR reporting practice, 82 (29.29%) participants had reported an ADR at least once, while 198 (70.71%), had never reported any ADR (Table 1).

Table 1: Demographic characteristics of study participants (n=280).

Variable	Category	Number (n=280)	Percentage (%)
Gender	Female	138	49.29
	Male	142	50.71
Year of residency	1st	183	65.36
	2nd	45	16.07
	3rd	52	18.57
Visited AMC	Yes	63	22.50
	No	217	77.50
ADR reporting	Ever reported	82	29.29
	Never reported	198	70.71

In the knowledge domain, most participants had moderate knowledge (55.71%). Assessment of attitude showed that the majority of residents had a neutral attitude, accounting for 177 (65.21%) participants. And in terms of practice, more than half of the participants, 165 (58.93%), had fair practice scores (Table 2).

The mean knowledge score among the participants was 6.01±1.81, indicating that most residents had moderate to good knowledge levels. The attitude domain also demonstrated a predominantly neutral to positive attitude with a mean score of 4.85±1.10. Whereas, the practice score was comparatively lower i.e. 1.77±1.29, reflecting inadequate translation of knowledge into practice (Table 3).

The participants who had reported ADRs showed significantly higher knowledge scores (6.57±2.21) as compared to those who had never reported ADRs (5.78±1.57). The difference was found to be statistically significant ($U=5912.0$, $p<0.010$).

Similarly, a statistically higher mean attitude and practice score was also seen among residents who had ever reported an ADR ($p<0.001$). Overall, better knowledge, more positive attitude, and improved practice scores were significantly associated with ADR reporting among the study participants (Table 4).

Gender, year of residency, and AMC visit status showed significant associations with ADR reporting among the residents. Male participants (37.3%), first year residents (36.6%), and those who have visited AMC (82.5%) showed better reporting rate (Table 5).

KAP - all the three domains showed statistically significant positive correlations with each other, with the strongest relationship observed between attitude and practice indicating that the participants with a more positive attitude were more likely to demonstrate better practice (Table 6).

Practice score demonstrated the strongest association with ADR reporting. Residents with higher practice scores had markedly increased odds of ADR reporting (OR=1182.12, 95% CI: 119.58–11684.75, p<0.001). Overall, higher knowledge, positive attitude, better practice scores, AMC visits, and 3rd year residents were the significant predictors of ADR reporting among the study participants. However, after adjusting for other variables in the regression model, third- year residents were not found to be a significant predictor of ADR reporting (AOR=1.735, 95% CI: 0.907–3.319, p=0.096).

Knowledge score showed a significant positive association with ADR reporting after adjustment (AOR=1.274, 95% CI: 1.068–1.521, p=0.007). Attitude and practice score remained a strong association with ADR reporting (p<0.001). However, visiting the AMC was found to be the strongest predictor associated with ADR reporting after adjustment for other variables (AOR=23.173, 95% CI: 7.016–76.534, p<0.001). Majority of the participants reported that they do not know how (50%) and where to report (38.8%) as well as fear of legal liability issue, and lack of ADR reporting forms were among the main reasons for not reporting ADRs among the study participants (Table 7 and Figure 1).

Table 2: KAP category distribution (n=280).

Domain	Questions	Category	Number (n=280)	Percentage (%)
Knowledge	Define ADR If ADR and AE same? Who can report an ADR? Define Pharmacovigilance (PV). Regulatory body monitoring ADR. A serious ADR can be reported within? A non-serious ADR can be reported within? Software used for reporting ADR. Rare ADR can be identified in which phase of CT? Most common method for causality assessment.	Poor (0-3)	22	7.86
		Moderate (4-6)	156	55.71
		Good (7-10)	102	36.43
Attitude	PV should be included in core topic. Reporting ADR is necessary. Reporting ADR is a professional obligation. Do you think PV should be taught in details to all HCW? Reporting ADR can improve patient's safety. I believe underreporting of ADR is a serious problem. Reporting ADR makes no contribution to the system.	Negative (0-3)	21	7.50
		Neutral (4-5)	177	65.21
		Positive (6-7)	82	29.29
Practice	Have you ever seen a case of ADR? Have you ever reported an ADR? Have you ever visited an AMC? Have you ever contacted your institute's AMC regarding ADR reporting?	None (0)	37	13.21
		Fair (1-2)	165	58.93
		Good (3-4)	78	27.86

Table 3: KAP mean score distribution (n=280).

Domain	Scale	Mean	SD	Range		Median
				Min	Max	
Knowledge	0–10	6.01	1.81	0	10	6.0
Attitude	0–7	4.85	1.10	2	8	5.0
Practice	0–4	1.77	1.29	0	5	1.0

Table 4: KAP mean scores by ADR reporting status.

Domain	Not reported (n=191), mean±SD	Reported (n=89), mean±SD	U statistic	P value*
Knowledge	5.78±1.57	6.57±2.21	5912.0	<0.001
Attitude	4.58±0.93	5.49±1.20	3925.5	<0.001
Practice	1.08±0.70	3.46±0.69	266.0	<0.001

*Mann-Whitney U test; p is significant at 5% level of significance

Table 5: Association of categorical variables with ADR reporting.

Variable	Category	Not reported, N (%)	Reported, N (%)	Total, N (%)	χ^2 (df)	P value*
Gender	Female	109 (79.0)	29 (21.0)	138 (49.3)	8.219 (1)	0.004
	Male	89 (62.7)	53 (37.3)	142 (50.7)		
Year of residency	1st	116 (63.4)	67 (36.6)	183 (65.4)	18.613 (2)	<0.001
	2nd	43 (95.6)	2 (4.4)	45 (16.1)		
	3rd	39 (75.0)	13 (25.0)	52 (18.6)		
Visited AMC	No	187 (86.2)	30 (13.8)	217 (77.5)	108.028 (1)	<0.001
	Yes	11 (17.5)	52 (82.5)	63 (22.5)		

*Chi-square test/Fisher exact test; p is significant at 5 level of significance

Table 6: Correlations between KAP domains.

Domain 1	Domain 2	R value	P value*	Interpretation
Knowledge	Attitude	0.169	0.005	Weak positive
Knowledge	Practice	0.173	0.004	Weak positive
Attitude	Practice	0.537	<0.001	Strong positive

*Pearson correlation; p value is significant at 5% level of significance

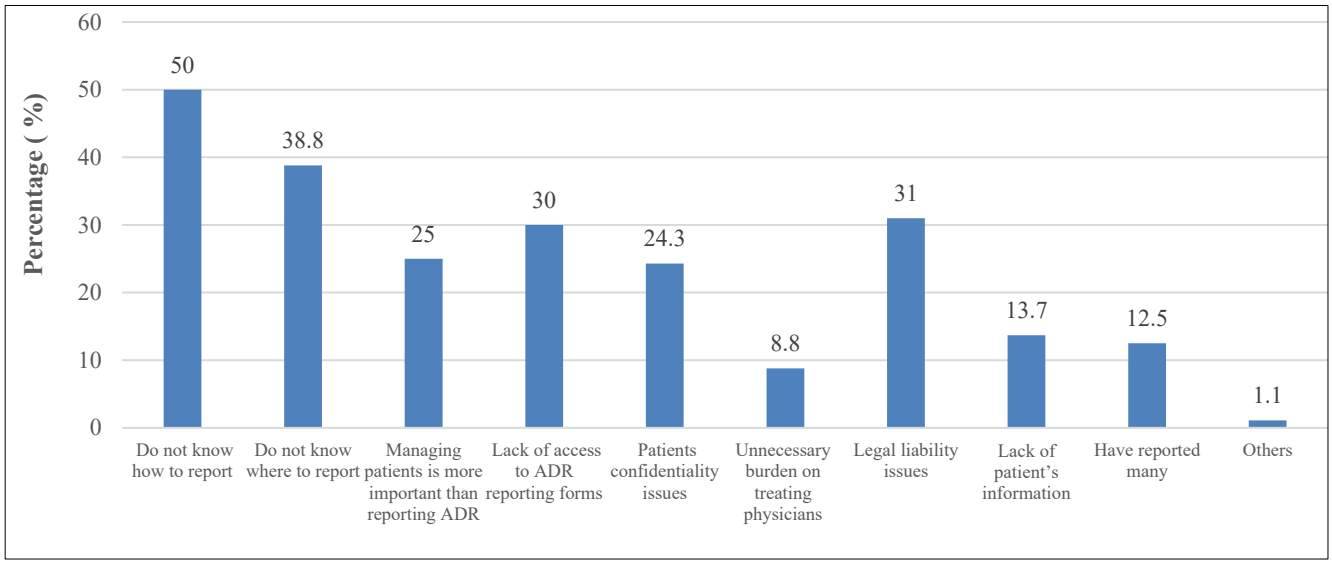

Figure 1: Reasons for under-reporting of ADRs.

Table 7: Reasons for under-reporting of ADRs.

Reasons	Percentage (%)
Do not know how to report	140 (50)
Do not know where to report	108 (38.8)
Managing patients is more important than reporting ADR	70 (25)
Lack of access to ADR reporting forms	84 (30)
Patients confidentiality issues	68 (24.3)
Unnecessary burden on treating physicians	24 (8.8)
Legal liability issues	86 (31)
Lack of patient's information	38 (13.7)
Have reported many	35 (12.5)
Others	3 (1.1)

DISCUSSION

The increasing burden of ADRs and their clinical, social, and economic consequences highlight the importance of strengthening pharmacovigilance activities among healthcare personals. PvPI plays an important role in ensuring drug safety through "detection, assessment, understanding, and reporting of adverse effects or other drug related problems". "Spontaneous ADR reporting" which is the most essential component of PvPI contributes significantly to the identification of previously unknown adverse effects and thus ensures patients safety.[6] Therefore, adequate knowledge, a positive attitude, and good reporting practices among healthcare professionals are crucial for the effective functioning of the pharmacovigilance programme.

The present study evaluated the knowledge, attitude, and practice regarding pharmacovigilance and ADR reporting among postgraduate medical residents and determined the strongest predictor of ADR reporting.

The findings indicated that most of the participants had a moderate knowledge regarding PV, with a mean score of 6.01±1.81. more than half of the participants (55.71%) belonged to the moderate knowledge category, while only one third (36.43%) demonstrated good knowledge scores. Although the participants demonstrated awareness of the basic principles and significance of ADR reporting, there remains a need for ongoing educational initiatives and training programs to further strengthen their knowledge and promote greater engagement with the PV system.

Assessment of attitude demonstrated that most participants had a neutral attitude (63.21%) towards pharmaco-vigilance, while a smaller proportion exhibited a clearly positive attitude (29.29%). This implies that although the residents recognised the importance of ADR reporting, hesitation and lack of motivation refrain them from reporting activities. Positive attitude among healthcare workers is out most important because it directly influences reporting behaviour. However, lack of knowledge regarding how to report, where to report, unavailability of ADR reporting form, lack of time, legal liability issues were among the common barriers contributing to underreporting of ADRs in our institution.

The practice component showed comparatively lower score than the knowledge and attitude domains. The mean practice score was 1.77±1.29 and more than half (58.93%) of the participants demonstrated only moderate practice related to ADR reporting. These findings reflect the gap between theoretical knowledge and actual practical implementation of pharmacovigilance activities.

Our findings were similar with the findings of Gupta et al (2015) who found out that only 22.8% of healthcare professionals reported ADRs, despite having proper knowledge and positive attitudes towards PV and ADR reporting. The major barriers were lack of time, no remuneration, difficulty in deciding whether ADR has occurred or not, unawareness regarding ADR reporting form, and procedures of reporting.[10] Similar findings were also obtained from studies by Upadhyaya et al, Pimpalkhute et al, Khan et al, and Srinivasan et al.[1,11-13]

The present study also demonstrated that participants who had previously reported ADRs possessed higher knowledge, attitude, and practice score compared to non-reporters which implies that improved awareness and positive perceptions towards PV are associated with increased participation in ADR reporting activities.

Correlation analysis revealed statistically significant positive correlations among all KAP domains, with the strongest relationship observed between attitude and practice ($p<0.001$). Knowledge showed only weak positive correlations with both attitude and practice. This suggest that knowledge alone may not be sufficient to improve reporting behaviour unless accompanied by appropriate motivation and institutional support.

The univariate logistic regression analysis identified higher knowledge scores, positive attitude, better practice score, third year residency and AMC visits as significant predictors of ADR reporting. Practice score demonstrated the strongest association, indicating that residents who were actively involved in pharmacovigilance related practices such as attending workshops or training on PV, and doing research or thesis project on ADR related topics were substantially more likely to report ADRs.

In the multivariate logistic regression analysis, after adjustment of confounding variables, knowledge score, attitude score, practice score, and AMC visit status remained significantly associated with ADR reporting, and AMC visit status is the strongest predictor of ADR reporting. This suggests that direct exposure to pharmacovigilance activities and institutional support systems plays a significant role in improving ADR reporting. Study by Radhakrishnan et al demonstrated increased awareness and enhanced ADR reporting behaviour among healthcare professionals following continued educational intervention training programs.[14] Similarly, Cosentino et al, and Figueiras et al, also concluded that regular educational interventions and continuous reinforcement strategies can substantially improve spontaneous ADR reporting practices among healthcare workers.[15,16] In contrast to our study, Alshammari et al and Tadvi et al in 2018, reported that poor knowledge and awareness regarding PV despite having favourable attitude contributed to poor reporting practices among healthcare professionals.[17,18]

Mulchandani et al in 2019 reviewed the current scenario of ADR reporting in India and identified substantial gap in knowledge, attitude, and practice regarding PV among healthcare workers and identified reasons such as inadequate knowledge and awareness, lack of formal training, uncertainty regarding what and how to report, lack of time, fear of legal consequences, and negative perceptions toward reporting. The authors highlighted the importance of educational interventions, continuous medical education (CME) programs, workshops, simplified reporting system, and regular feedback mechanism to enhance ADR reporting.[19]

Limitations

Since our study was conducted in a single tertiary care hospital (AMCH, Dibrugarh), this limits the generalizability of the findings. Again, the study included only postgraduate resident doctors, excluding other healthcare professionals such as interns, senior consultants, nurses, pharmacists, which restricts the comprehensiveness of the overall pharmacovigilance practice landscape.

CONCLUSION

To conclude all the three domains of KAP are equally important to enhance reporting of ADRs. In our study attitude, practice and exposure to ADR monitoring centre emerged as an important determinant of ADR reporting. The findings emphasized the need of regular educational interventions such as CME, workshops, seminars, and case-based discussions, and institutional supports like availability of ADR reporting forms in each patient′s bed-tickets in wards as well in OPDs, regular feedback mechanisms and reward system, faculty mentorships in order to improve reporting practice and patient′s safety.

This study contributes to the existing body of knowledge by providing a comprehensive assessment of KAP regarding PV and ADR reporting among postgraduate medical residents in a tertiary care teaching institute. While several previous studies have primarily focused on descriptive evaluation of KAP domains, the present study extends understanding by exploring the relationship between these domains and identifying factors influencing ADR reporting behaviour.

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