

Pharmacovigilance and adverse drug reaction reporting perspectives among interns and postgraduates of a teaching hospital

Sir,

Pharmacovigilance (PV) is the branch dealing with adverse drug reactions (ADRs), their recognition, and reporting. ADR is defined by the World Health Organization (WHO) as a response to a drug that is noxious, unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of a physiological function. PV is defined by the WHO as a science, with activities that relate to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.^[1] The literature depicts the incidence of ADR to be 2.4-6.5% even in western countries, with only 6-10% of all ADRs being reported.^[2] Issues and challenges in PV, in India, are gross underreporting of ADR mainly due to lack of adequately skilled resources and inadequate awareness of PV among physicians.^[3] However, there are no studies involving particularly interns and postgraduates (PGs) to know their PV and ADR reporting preparedness, as they are the first to attend any ADR in a teaching medical college setup thus playing a pivotal role in healthcare delivery. Hence, in the present study we analyzed the PV knowledge, ADR reporting behavior, and deterrents for ADR reporting, among interns and PGs from a medical college hospital, to understand the current status and need for future improvement.

This prospective observational questionnaire-based study, comprising of 24 objective questions, was conducted at a medical college hospital after obtaining ethical clearance. One hundred and fifty-four respondents participated in the study by answering the questionnaire independently without consulting each other. Data analysis using the SPSS software involved mean $\pm$ SD, percentages (%), and independent *t*-test. A *P* <

0.05 was considered statistically significant. The respondents were grouped and compared using the above statistical measures. The results and conclusions were drawn from the data analysis.

The present study included 154 respondents (60 interns and 94 postgraduates), aged 22-39 years (SD 2.44). Male: Female gender distribution was 37:23 among interns and 63:31 among PGs. Among interns 29 (48%), 41 (68%), 32 (53%), and 40 (67%) had completed medicine, surgery, obstetrics and gynecology (OBG), and ancillary internship postings, respectively. Among the PGs 38 (40%) belonged to the medicine and allied group and 56 (60%) belonged to the surgery and allied group.

Observations from the present study were as follows:

Our present study involved interns and PGs as there was a paucity of data pertaining to PV and ADR reporting among the same.

In the present study it was evident that the interns and PGs of both genders were equally poor in ADR reporting, as >65% had not reported any ADR. It is alarming and disheartening to note that, they have demonstrated the same trend seen among physicians and consultant prescribers.^[4,5]

Factors like ignorance, indifference, and complacency have been attributed to poor ADR reporting among professionals and consultants.^[6] Our present study involving interns and PGs revealed a difficulty to decide the occurrence of ADR as the major factor discouraging ADR reporting, while other factors included lack of time to report and non-remuneration for reporting.

Our present study confirmed the fact that routine clinical training during clinical postings and possessing a positive attitude toward PV, ADR reporting did not have much impact on spontaneous ADR reporting by interns and PGs, as there was no statistically significant difference of the mean pharmacovigilance score among the four subgroups of interns and two subgroups of PGs, as illustrated in [Tables 1 and 2].

Finally, we conclude that there is an absolute need for exclusive pharmacovigilance and ADR reporting training for interns and PGs of medical colleges to enhance their pharmacovigilance efficiency.

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Table 1: Responses to questionnaire

Questionnaire questions	Answer	Interns n=60 (%)	Postgraduates n=94 (%)
ADR definition	Correct	46 (77)	78 (83)
	Incorrect	14 (23)	16 (17)
Dose and ADR	Correct	50 (83)	80 (85)
	Incorrect	10 (17)	14 (15)
Molecular weight and ADR	Correct	10 (17)	16 (17)
	Incorrect	50 (83)	78 (83)
Genetic basis and ADR	Correct	53 (88)	78 (83)
	Incorrect	07 (12)	16 (17)
Classification of ADR	Correct	10 (17)	18 (19)
	Incorrect	50 (83)	76 (81)
Most common organ involvement in ADR	Correct	41 (68)	65 (69)
	Incorrect	19 (32)	29 (31)
ADR regulatory body in India	Correct	49 (82)	49 (52)
	Incorrect	11 (18)	45 (48)
Location of the central ADR monitoring cell in India	Correct	13 (22)	15 (16)
	Incorrect	47 (78)	79 (84)
Necessity of ADR reporting	Yes/positive attitude	58 (97)	92 (98)
	No/negative attitude	02 (3)	02 (2)
ADR reporting as a professional obligation	Yes/positive attitude	53 (88)	75 (80)
	No/negative attitude	07 (12)	19 (20)
Teaching pharmacovigilance in academic curriculum	Yes/positive attitude	56 (93)	82 (87)
	No/negative attitude	04 (7)	12 (13)
Willing to attend pharmacovigilance training workshop	Yes/positive attitude	54 (90)	75 (80)
	No/negative attitude	06 (10)	19 (20)
Personally seen ADR	Yes	15 (25)	40 (43)
	No	45 (75)	54 (57)
Shall consider ADR as a D/D even if not reported earlier by others	Yes	53 (88)	69 (73)
	No	07 (12)	25 (27)
Undergone ADR reporting training	Yes	13 (22)	17 (18)
	No	47 (78)	77 (82)
Number of ADRs reported personally	None	41 (68)	61 (65)
	<5	19 (32)	33 (35)
Factors discouraging ADR reporting	Difficulty to decide occurrence of ADR	50 (83)	51 (54)
	Lack of time to report	26 (43)	28 (30)
	Non-remuneration for reporting	24 (40)	24 (26)
	Un reporting may not affect data base	15 (25)	08 (9)

ADR=Adverse drug reaction

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Table 2: Pharmacovigilance score among interns and postgraduates

Interns	Mean	S. D
Completed medicine postings		
Yes	15.14	3.64
No	15.32	3.32
Completed surgery posting		
Yes	14.98	3.86
No	15.79	2.35
Completed OBG posting		
Yes	15.38	2.70
No	15.07	4.20
Completed ancillary posting		
Yes	15.08	4.03
No	15.60	2.06
Postgraduates		
PGs of medicine and allied departments	13.79	2.90
PGs of surgery and allied departments	13.70	2.68
Gender		
Males	14.20	3.52
Females	14.53	2.20

OBG=Obstetrics and gynecology, SD=Standard deviation

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