

ORIGINAL RESEARCH

Knowledge, Attitude and Practice of Adverse Drug Reactions and Pharmacovigilance among medical undergraduates of second, third and fourth year in Government Medical College of Rajasthan

¹Dr. Madhulika Peter Samuel, ²Dr. Harsh Yadav

¹Associate Professor & Head, ²Assistant Professor, Department of Pharmacology, Shree Jagannath Pahadia Medical College, Bharatpur, Rajasthan, India

Corresponding Author

Dr. Madhulika Peter Samuel

Associate Professor & Head, Department of Pharmacology, Shree Jagannath Pahadia Medical College, Bharatpur, Rajasthan, India

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ABSTRACT

Background: World Health Organization (WHO) has defined Adverse Drug Reaction (ADR) as a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. ADR has a major impact on the cost of afflicted person, it causes around 0.2 – 24 % hospital admission as per previous report. But there are limited studies conducted on medical students, so, we conducted this study to assess knowledge, attitude and practice about Adverse Drug Reactions and Pharmacovigilance among medical undergraduates. **Methods:** This cross-sectional study was conducted among 400 MBBS students (both male and female) under the department of Pharmacology, Government Medical College, for a duration of 3 months. The self-filled questionnaire comprised of four main domains, i.e., demographic characteristics, knowledge, attitude and practice about ADR and PV including an introduction section which covered the details about objective and rationale for the study. The collected data was entered in the MS excel sheet. Chi-square analysis done to find association between the dependent and independent variables and a p value of <0.05 was considered to be statistically significant. **Results:** In our study, a total of 400 MBBS students (both male and female) were sent the google forms as questionnaire and 376 students responded back to the questionnaire. When students were asked, whether they are aware of Adverse Drug Reactions (ADR), 99.7% of students responded they were aware of it, but when asked to define the ADR, only 66.2% of students were able to correctly define it. Similarly, when students were asked, whether they are aware of the difference between ADR and Adverse Drug Events (ADE), 94.9% of students responded they were aware of it, but when asked to define the ADE, only 54.8% of students were able to correctly define it. When students were assessed for the practice of Adverse Drug Reactions and Pharmacovigilance, 28.1% of students disagreed with the fact that they never experienced ADR in life, but 42.4% of students agreed with on that they have noticed patient with any of the ADRs. Only 27.2% strongly agreed with the fact that they were trained in ADR reporting with ADR form. **Conclusion:** The medical undergraduate possess adequate knowledge with decline in attitude and practice of pharmacovigilance & ADR reporting. There should be regular awareness training program for students & regular workshops for healthcare professionals. The conclusion of the study is that medical students, who will become future healthcare providers, should be trained well right from undergraduate period. So students should realize the importance of reporting ADR in future for the welfare of the community.

Keywords: Adverse drug reaction, medical undergraduates, Pharmacovigilance, Health Care Professionals

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INTRODUCTION

World Health Organization (WHO) has defined Adverse Drug Reaction (ADR) as “a response to a

drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification

of physiological function” [1]. ADRs plays a significant role on the morbidity and mortality by adding up cost of intervention in the ongoing treatment, prolonging the stay of patient in hospital & prolonging relatives stay for patient, loss of income if admitted person is only earning one in family, etc., [2]. ADR has a major impact on the cost of afflicted person, it causes around 0.2 – 24 % hospital admission as per previous report [3,4,5].

India has Pharmacovigilance (PV) programme which collects all ADRs report, keeps its records, codes Adverse Drug Events (ADEs) and do ADRs analyses, assesses the reports and communicate the needful to other stakeholders. Pharmacovigilance according to WHO has defined as “the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems” [6,7].

India is one of the active member and contributor to Uppsala Monitoring Centre (UMC) international database, 0.5 % in 2012 which raised up to 2% in 2013 and stood seventh largest contributor for drug safety in UMC database [8]. There are many methods of ADR reporting but most common method is spontaneous reporting.

The spontaneous ADR reporting is voluntary method and should be reported by all Health Care Professionals (HCPs). HCPs (Clinicians, Dentists, Pharmacists and Nurse etc.,) play a noteworthy role to run Pharmacovigilance Programme successfully in India. Only 6-10% ADR cases were reported in previous data [9]. There are many reasons for under reporting but main is our HCPs are not trained to report ADR [10,11]. So, still there is lot of hard work required to enhance spontaneous ADR monitoring. The habit of HCPs only changes if we educate and improve skills of medical undergraduates about ADR reporting.

Many studies have been conducted regarding knowledge, attitude & Practice (KAP) of ADR and PV among physicians, pharmacist, nurses and dentist etc., [12,13,14,15,16]. But there are limited studies conducted on medical students [17,18,19]. Today’s medical undergraduates will become clinicians one day and should be well verse with system of PvPI to report ADRs cases for health care safety of Indian population. So, we conducted this study to assess knowledge, attitude and practice about Adverse Drug Reactions and Pharmacovigilance among medical undergraduates of second, third and fourth year in Government Medical College of Rajasthan.

MATERIALS AND METHODS

STUDY DESIGN

This cross-sectional study was conducted among medical undergraduates under the department of

Pharmacology, Government Medical College, Bharatpur, Rajasthan, for duration of 3 months during July to August 2022.

STUDY POPULATION

A total 376 out of 400 MBBS students (both male and female) were included in the study after obtaining the informed consent. The sample size was decided by purposeful sampling. Total 400 students were comprised of three professional years of MBBS batches which includes, 150 students from 2nd professional year, 150 students from 3rd professional year and 100 students from 4th professional year. The students who didn’t filled questionnaire in respective time duration were excluded from the study.

DATA COLLECTION

The self-filled questionnaire as online Google form was used for data collection in our study. Questionnaire was pre-validated. Also, it was piloted among 20 medical undergraduates and changes required were made before sending it to the participants. This final and pretested questionnaire comprised of four main domains, i.e., demographic characteristics, knowledge, attitude and practice about ADR and PV including an introduction section which covered the details about objective and rationale for the study.

ETHICAL CONSIDERATION

The purpose of the study was explained to all participating students. All information of participants was kept confidential.

STATISTICAL ANALYSIS

The collected data was entered in the MS excel sheet. The data was analysed using SPSS version 22. The findings were expressed as percentage, frequency and mean \pm standard deviation (SD). Chi-square analysis done to find association between the dependent and independent variables and a p value of <0.05 was considered to be statistically significant.

RESULTS

In our study, a total of 400 MBBS students (both male and female) were sent the Google forms as questionnaire and 376 students responded back to the questionnaire. Most of students were in the age group of 20-22 years (69.7%). Also, most of students were males (61.7%). The most of students belonged to urban area (57.4%). Among enrolled subjects, 39.4% of students were in the 2nd year of MBBS, 36.7% were in 3rd year, remaining 23.9% of students were in 4th year of MBBS (Table 1).

Table 1: Demographic characteristics of the study participants

Variables	Frequency	%
Age group (in years)		
17-19	18	4.8
20-22	262	69.7
23 and above	96	25.5
Gender		
Male	232	61.7
Female	144	38.3
Residence		
Urban	216	57.4
Rural	159	42.3
MBBS year		
2nd year	148	39.4
3rd year	138	36.7
4th year	90	23.9

When students were asked, whether they are aware of Adverse Drug Reactions (ADR), 99.7% of students responded they were aware of it, but when asked to define the ADR, only 66.2% of students were able to correctly define it and as ADR is being taught in detail during 2nd year of MBBS, 75.0% of 2nd year MBBS students correctly defined the ADR and this difference was statistically significant (p<0.05). Similarly, when students were asked, whether they are aware of the difference between ADR and Adverse Drug Events

(ADE), 94.9% of students responded they were aware of it, but when asked to define the ADE, only 54.8% of students were able to correctly define it, 56.8% of 2nd year MBBS students correctly defined the ADE and 61.1% of 4th year MBBS students correctly defined the ADE and this difference was statistically significant (p<0.05). Only 78.5% of students were able to define the pharmacovigilance as per WHO (Table 2).

Table 2: Comparison of knowledge about Adverse Drug Reactions and Pharmacovigilance among medical undergraduates

Knowledge variables	2nd year	3rd year	4th year	Overall	P value
	Number (%)				
Do you know the definition of Adverse Drug Reactions (ADR)					
Yes	148 (100)	138 (100)	89 (98.9)	375 (99.7)	p=0.203
No	0 (0)	0 (0)	1 (1.1)	1 (0.3)	
Adverse Drug Reactions according to WHO has defined as					
Any unintended effect of a pharmaceutical product					
	34 (23.0)	42 (30.4)	32 (35.6)	108 (28.7)	p=0.000
A response to a drug that is noxious and unintended					
	111 (75.0)	93 (67.4)	45 (50.0)	249 (66.2)	
Direct action of drug often at high dose					
	1 (0.7)	1 (0.7)	1 (1.1)	3 (0.8)	
Indirect consequences of a primary action of the drug					
	2 (1.4)	2 (1.4)	12 (13.3)	16 (4.3)	
Do you know there is difference between ADR and ADE?					
Yes	144 (97.3)	132 (95.7)	81 (90.0)	357 (94.9)	p=0.040
No	4 (2.7)	6 (4.3)	9 (10.0)	19 (5.1)	
Adverse drug event is defined as					
The process of collecting and assessing ADRs					
	3 (2.0)	14 (10.0)	2 (2.2)	19 (5.1)	p=0.024
The science & activities relating to the detection, assessment, understanding & prevention of ADRs					
	40 (27.0)	33 (23.9)	18 (20.0)	91 (24.2)	
An unintended act or one that does not achieve its intended outcomes.					
	21 (14.2)	24 (17.4)	15 (16.7)	60 (16.0)	
Any untoward medical occurrence that may present during treatment with a medicine					
	84 (56.8)	67 (48.6)	55 (61.1)	206 (54.8)	
Do you know side effects and ADR are not interchangeable term?					

Yes	132 (89.2)	126 (91.3)	81 (90.0)	339 (90.2)	p=0.834
No	16 (10.8)	12 (8.7)	9 (10.0)	37 (9.8)	
Who can report ADR?					
Doctors	5 (3.4)	15 (10.9)	7 (7.8)	27 (7.2)	p=0.077
All HCP	141 (95.3)	119 (86.2)	79 (87.8)	339 (90.2)	
Pharmacists	2 (1.4)	4 (2.9)	4 (4.4)	10 (2.7)	
What are ADR reporting tools					
E mail: pvpi.ipc@gov.in					
	0 (0.0)	6 (4.3)	3 (3.3)	9 (2.4)	p=0.001
PvPI Helpline (Toll Free): 1800180 3024					
	2 (1.4)	0 (0.0)	6 (6.7)	8 (2.1)	
ADR Mobile App: ADRPvPI					
	0 (0.0)	1 (0.7)	2 (2.2)	3 (0.8)	
All are correct					
	146 (98.6)	131 (94.9)	79 (87.8)	356 (94.7)	
Do you know the definition of Pharmacovigilance?					
Yes	145 (98.0)	136 (98.6)	85 (94.4)	366 (97.3)	p=0.140
No	3 (2.0)	2 (1.4)	5 (5.6)	10 (2.7)	
Pharmacovigilance according to WHO has defined as					
The monitoring of adverse drug reactions of all drugs					
	27 (18.2)	16 (11.6)	13 (14.4)	56 (14.9)	p=0.174
To study the effects of drugs in human being					
	6 (4.1)	2 (1.4)	7 (7.8)	15 (4.0)	
Science and activities relating to detection, understanding, and prevention of adverse effects.					
	111 (75.0)	117 (84.8)	67 (74.4)	295 (78.5)	
To assess undesirable or unintended consequences of drug administration					
	4 (2.7)	3 (2.2)	3 (3.3)	10 (2.7)	
Where is PvPI-NCC located in India					
New Delhi	19 (12.8)	18 (13.0)	35 (38.9)	72 (19.1)	p=0.000
Faridabad	0 (0.0)	6 (4.3)	5 (5.6)	11 (2.9)	
Karnataka	1 (0.7)	1 (0.7)	4 (4.4)	6 (1.6)	
Ghaziabad	128 (86.5)	113 (81.9)	46 (51.1)	287 (76.3)	

The students were assessed about their attitude towards Adverse Drug Reactions and Pharmacovigilance, only 53.7% of students strongly agreed on that establishment of AMC should be mandatory in all hospitals, 75.5% of students strongly agreed on that ADR reporting is a professional responsibility of all healthcare professionals, 68.9% of

students strongly agreed on that ADR reporting should be compulsory in all medical colleges and 64.5% of students strongly agreed on that it is very important to report ADR. Surprisingly, 23.2% of students strongly agreed on that reporting of ADR could only be done by filling ADR form (Table 3).

Table 3: Comparison of attitude about Adverse Drug Reactions and Pharmacovigilance among medical undergraduates

Attitude variables	2nd year	3rd year	4th year	Overall	P value
	Number (%)				
Do you agree that ADR reporting is a professional responsibility of all healthcare professionals?					
Strongly agree	115 (77.7)	105 (76.1)	64 (71.1)	284 (75.5)	p=0.430
Agree	31 (20.9)	28 (20.3)	24 (26.7)	83 (22.1)	
Neutral	1 (0.7)	5 (3.6)	2 (2.2)	8 (2.1)	
Disagree	1 (0.7)	0 (0)	0 (0)	1 (0.3)	
Do you agree all healthcare professionals should be trained in ADR reporting?					
Strongly agree	109 (73.6)	89 (64.5)	64 (71.1)	262 (69.7)	p=0.823
Agree	33 (22.3)	43 (31.2)	24 (26.7)	100 (26.6)	
Neutral	4 (2.7)	4 (2.9)	2 (2.2)	10 (2.7)	
Disagree	1 (0.7)	1 (0.7)	0 (0)	2 (0.5)	
Strongly disagree	1 (0.7)	1 (0.7)	0 (0)	2 (0.5)	
Do you agree that ADR reporting should be compulsory in all medical colleges					

Strongly agree	110 (74.3)	88 (63.8)	61 (67.8)	259 (68.9)	p=0.444
Agree	34 (23.0)	43 (31.2)	27 (30.0)	104 (27.7)	
Neutral	4 (2.7)	6 (4.3)	2 (2.2)	12 (3.2)	
Disagree	0 (0)	1 (0.7)	0 (0)	1 (0.3)	
Do you agree that establishment of AMC should be mandatory in all hospitals					
Strongly agree	87 (58.8)	69 (50.0)	46 (51.1)	202 (53.7)	p=0.129
Agree	51 (34.5)	54 (39.1)	36 (40.0)	141 (37.5)	
Neutral	7 (4.7)	15 (10.9)	8 (8.9)	30 (8.0)	
Disagree	3 (2)	0 (0)	0 (0)	3 (0.8)	
Do you agree reporting of ADR could only be done by filling ADR form					
Strongly agree	32 (21.6)	30 (21.9)	25 (27.8)	87 (23.2)	p=0.064
Agree	45 (30.4)	36 (26.3)	27 (30.0)	108 (28.8)	
Neutral	21 (14.2)	34 (24.8)	24 (26.7)	79 (21.1)	
Disagree	37 (25.0)	29 (21.2)	12 (13.3)	78 (20.8)	
Strongly disagree	13 (8.8)	8 (5.8)	2 (2.2)	23 (6.1)	
Are you agree that four mandatory fields in ADR form which needs to fill completely before submission					
Strongly agree	60 (40.8)	53 (38.7)	33 (37.9)	146 (39.4)	p=0.014
Agree	69 (46.9)	63 (46)	32 (36.8)	164 (44.2)	
Neutral	12 (8.2)	20 (14.6)	21 (24.1)	53 (14.3)	
Disagree	5 (3.4)	0 (0)	0 (0)	5 (1.3)	
Strongly disagree	1 (0.7)	1 (0.7)	1 (1.1)	3 (0.8)	
Do you agree filled ADR form needs to be submitted in Adverse drug reaction Monitoring Centre (AMC)					
Strongly agree	75 (50.7)	67 (48.9)	38 (42.2)	180 (48.0)	p=0.510
Agree	57 (38.5)	54 (39.4)	40 (44.4)	151 (40.3)	
Neutral	8 (5.4)	12 (8.8)	10 (11.1)	30 (8.0)	
Disagree	6 (4.1)	4 (2.9)	1 (1.1)	11 (2.9)	
Strongly disagree	2 (1.4)	0 (0)	1 (1.1)	3 (0.8)	
Do you agree Vigiflow is web-based Individual Case Study Report management system created & maintained by Uppsala Monitoring Centre (UMC)					
Strongly agree	64 (44.4)	49 (35.8)	21 (24.4)	134 (36.5)	p=0.048
Agree	49 (34)	61 (44.5)	35 (40.7)	145 (39.5)	
Neutral	27 (18.8)	25 (18.2)	28 (32.6)	80 (21.8)	
Disagree	3 (2.1)	2 (1.5)	1 (1.2)	6 (1.6)	
Strongly disagree	1 (0.7)	0 (0)	1 (1.2)	2 (0.5)	
Do you think version 1.4 is the latest version of ADR form?					
Strongly agree	78 (54.2)	34 (25)	18 (21.2)	130 (35.6)	p=0.000
Agree	33 (22.9)	40 (29.4)	20 (23.5)	93 (25.5)	
Neutral	20 (13.9)	60 (44.1)	44 (51.8)	124 (34)	
Disagree	9 (6.3)	2 (1.5)	1 (1.2)	12 (3.3)	
Strongly disagree	4 (2.8)	0 (0)	2 (2.4)	6 (1.6)	
Do you think it is very important to report ADR					
Strongly agree	99 (66.9)	83 (60.1)	60 (67.4)	242 (64.5)	p=0.140
Agree	44 (29.7)	49 (35.5)	23 (25.8)	116 (30.9)	
Neutral	5 (3.4)	6 (4.3)	3 (3.4)	14 (3.7)	
Disagree	0 (0)	0 (0)	2 (2.2)	2 (0.5)	
Strongly disagree	0 (0)	0 (0)	1 (1.1)	1 (0.3)	

When students were assessed for the practice of Adverse Drug Reactions and Pharmacovigilance, 28.1% of students disagreed with the fact that they never experienced ADR in life, but 42.4% of students agreed with on that they have noticed patient with any of the ADRs. It was seen that only 32.7% of students strongly agreed on that they can download ADR form

easily from internet to report ADR case and only 27.2% strongly agreed with the fact that they were trained in ADR reporting with ADR form. Nearly one fourth of the students (23.7%) disagreed with on that about the reporting of ADR is a time-consuming process (Table 4).

Table 4: Comparison of practice about Adverse Drug Reactions and Pharmacovigilance among medical undergraduates

Practice variables	2nd year	3rd year	4th year	Overall	P value
	Number (%)				
Have you experienced ADR in your life					
Strongly agree	29 (19.7)	26 (19)	8 (8.9)	63 (16.8)	p=0.016
Agree	39 (26.5)	41 (29.9)	23 (25.6)	103 (27.5)	
Neutral	21 (14.3)	30 (21.9)	28 (31.1)	79 (21.1)	
Disagree	46 (31.3)	30 (21.9)	29 (32.2)	105 (28.1)	
Strongly Disagree	12 (8.2)	10 (7.3)	2 (2.2)	24 (6.4)	
Have you noticed patient with any of the ADRs					
Strongly agree	33 (22.4)	26 (19.1)	15 (16.7)	74 (19.8)	p=0.022
Agree	70 (47.6)	49 (36.0)	39 (43.3)	158 (42.4)	
Neutral	14 (9.5)	34 (25.0)	24 (26.7)	72 (19.3)	
Disagree	23 (15.6)	23 (16.9)	10 (11.1)	56 (15.0)	
Strongly disagree	7 (4.8)	4 (2.9)	2 (2.2)	13 (3.5)	
I can download ADR form easily from internet to report ADR case.					
Strongly agree	71 (48)	41 (29.7)	11 (12.2)	123 (32.7)	p=0.000
Agree	61 (41.2)	65 (47.1)	40 (44.4)	166 (44.1)	
Neutral	9 (6.1)	29 (21.0)	36 (40.0)	74 (19.7)	
Disagree	5 (3.4)	3 (2.2)	3 (3.3)	11 (2.9)	
Strongly disagree	2 (1.4)	0 (0)	0 (0)	2 (0.5)	
All ADR should be analyzed by using WHO causality assessment scale					
Strongly agree	86 (58.1)	36 (26.3)	17 (19.1)	139 (37.2)	p=0.000
Agree	53 (35.8)	78 (56.9)	53 (59.6)	184 (49.2)	
Neutral	7 (4.7)	22 (16.1)	17 (19.1)	46 (12.3)	
Disagree	0 (0)	1 (0.7)	1 (1.1)	2 (0.5)	
Strongly Disagree	2 (1.4)	0 (0)	1 (1.1)	3 (0.8)	
ADR reporting will be beneficial for patient and doctor					
Strongly agree	103 (70.5)	78 (56.9)	48 (53.3)	229 (61.4)	p=0.005
Agree	39 (26.7)	52 (38.0)	31 (34.4)	122 (32.7)	
Neutral	4 (2.7)	7 (5.1)	11 (12.2)	22 (5.9)	
I am trained in ADR reporting with ADR form					
Strongly agree	46 (31.5)	48 (35)	7 (7.9)	101 (27.2)	p=0.000
Agree	67 (45.9)	67 (48.9)	19 (21.3)	153 (41.1)	
Neutral	23 (15.8)	18 (13.1)	39 (43.8)	80 (21.5)	
Disagree	5 (3.4)	3 (2.2)	21 (23.6)	29 (7.8)	
Strongly disagree	5 (3.4)	1 (0.7)	3 (3.4)	9 (2.4)	
Using ADR app is easier than filling ADR form.					
Strongly agree	51 (34.5)	41 (29.9)	14 (15.7)	106 (28.3)	p=0.195
Agree	53 (35.8)	53 (38.7)	39 (43.8)	145 (38.8)	
Neutral	40 (27.0)	39 (28.5)	33 (37.1)	112 (29.9)	
Disagree	3 (2.0)	3 (2.2)	3 (3.4)	9 (2.4)	
Strongly disagree	1 (0.7)	1 (0.7)	0 (0)	2 (0.5)	
Reporting ADR is time consuming process					
Strongly agree	19 (12.8)	14 (10.1)	5 (5.6)	38 (10.1)	p=0.002
Agree	46 (31.1)	51 (37.0)	23 (25.6)	120 (31.9)	
Neutral	36 (24.3)	38 (27.5)	39 (43.3)	113 (30.1)	
Disagree	34 (23.0)	32 (23.2)	23 (25.6)	89 (23.7)	
Strongly disagree	13 (8.8)	3 (2.2)	0 (0)	16 (4.3)	
Spontaneous ADR reporting is the most commonly used method of reporting ADR					
Strongly agree	32 (21.6)	20 (14.5)	10 (11.1)	62 (16.5)	p=0.462
Agree	58 (39.2)	53 (38.4)	39 (43.3)	150 (39.9)	
Neutral	53 (35.8)	61 (44.2)	39 (43.3)	153 (40.7)	
Disagree	4 (2.7)	4 (2.9)	2 (2.2)	10 (2.7)	
Strongly disagree	1 (0.7)	0 (0)	0 (0)	1 (0.3)	

DISCUSSION

Drug safety surveillance requires a spontaneous reporting mechanism for adverse drug reactions (ADRs), but under-reporting is a well-known problem. Many studies on the knowledge, attitude, and practise (KAP) of ADR and PV among doctors, pharmacists, nurses, and dentists, etc., have been undertaken [12,13,14,15,16]. However, few studies have been carried out on medical students [17,18,19].

In this study, 66.2% of participants knew the WHO definition of ADR, and 78.5% had heard of pharmacovigilance. The awareness of WHO definition of ADR among second, third and fourth year students was observed as 75.0%, 67.4% and 50.0%, respectively whereas the awareness of pharmacovigilance definition of ADR among second, third and fourth year students was observed as 75.0%, 84.8% and

74.4% respectively. According to Kulkarni et al., study a similar finding was observed where 87% of undergraduate medical undergraduate students, had heard the word and 65% were aware of its meaning [20]. In a study by Parthiban et al., it was shown that while 81% of participants had heard of "pharmacovigilance," only 53% were aware of how it is related to ADR reporting [21]. The findings of the present investigation coincide with similar study performed out by Upadhyaya et al., [22]. Studies by Gupta et al., Meher et al., and Pimpalkhute et al., showed that 62.4, 41% and 67.85% of students were aware of the pharmacovigilance definition respectively [23,24,25].

In this study, 76.3% of the participants correctly identified the PvPI-NCC of India as the Indian Pharmacopoeia Commission (IPC), Ghaziabad, (U.P.). Correctly identification of the PvPI-NCC of India as the Indian Pharmacopoeia Commission (IPC), Ghaziabad, (U.P.) among second, third- and fourth-year students was observed as 86.5%, 81.9% and 51.1% respectively. In a study by Parthiban et al., only 17.4% of the students were aware of the National Pharmacovigilance Center, which further indicated as a lack of knowledge about the PvPI-NCC [21]. 34% of students in a study by Meher et al., were aware of the National Pharmacovigilance Center [25]. In the current study, 90.2% of the participants said that all HCPs (doctors, nurses, and pharmacists) should report adverse drug reactions (ADR) when they happen. But, only 40% of students agreed in a study by Meher et al., that all HCPs (doctors, nurses, and pharmacists) should report ADR as they happen [25]. In the studies by Parthiban et al., and Hema et al., [21,26], undergraduate students and interns also provided responses demonstrating a strong understanding of ADR reporting centres.

In this study, nearly one-fourth of the participants (23.7%) disagreed that reporting ADR requires a lot of time. Disagreement about that the reporting ADR requires a lot of time among second, third- and fourth-year students was observed as 23.0%, 23.2%, and 25.6%, respectively. However, the majority of students

in a study by Upadhyaya et al., stated that ADR reporting and monitoring were given very little time since they were unaware of pharmacovigilance and ADR [22]. In order to break through the barriers and spread awareness about ADR reporting, it is essential to have strong understanding about it. Only 22.8%, 15%, and 12.4% of students, have ever reported an adverse drug reaction to a pharmacovigilance centre, according to studies by Gupta et al., Muraraiah et al., and Desai et al., respectively [23,27,28]. The studies by Dhananjay et al., Ganesan et al., and Agarwal et al., likewise demonstrated a lack of reporting practices [20,29,30].

Only 27.2% of the participants in this study strongly agreed that they had received training in ADR reporting using the ADR form. The agreement about that they had received training in ADR reporting using the ADR form among second, third- and fourth-year students was observed as 31.5%, 35.0% and 7.9% respectively. According to a research by Gupta et al., 92.1% of respondents said this subject should be covered in the curriculum [23]. Indifference to reporting, a lack of interest in registering, and a lack of time for too many activities in the clinical routine are some of the reasons for underreporting [31]. This gap can be closed by making registration forms easier to access, streamlining paperwork, providing toll-free support, offering financial incentives, opening more ADR centres, and facilitating communication between registrars and pharmacovigilance centres, which can increase the notification rates of medication-related problems [32,33,34].

In our study, findings of knowledge component of ADR & pharmacovigilance were similar in 2nd, 3rd & 4th year students. The results of attitude and practice components were dissimilar in 3rd & 4th year as compared to 2nd year students. The reason might be 2nd year students were presently studying about ADR reporting & pharmacovigilance according to new curriculum. There are specific competencies which deal with ADR & pharmacovigilance in theory and practical as per new Competency based curriculum in pharmacology. The more concern matter is that these competencies are not come under certifiable competency. A certifiable competency gives students a better reason to read about ADR topic more seriously. The students of 3rd year & 4th year not able to recall because lack of emphasis on ADR reporting in these professional year of MBBS. This can be taken care by providing awareness program for each MBBS batches in the institution. When students have been experienced that there is lack of ADR reporting & underreporting by HCPs further decrease student's attitude & practice as well.

As a result, it is now necessary to design appropriate ways to encourage student to remember essential topic of ADR. Similarly we need to make proper strategy to encourage HCP & enhancing ADR reporting. The issue of underreporting must be addressed, and effective training facilities, educational and awareness efforts

regarding boosting ADR reporting, and giving topics like pharmacovigilance or ADR reporting etc., priority as elective topic for undergraduates in pharmacology.

CONCLUSION

The undergraduate medical students possess knowledge of pharmacovigilance and ADR reporting in all professional years. However there was decline in the attitude & practice more in 3rd & 4th years of MBBS Batches. There is necessity to provide regular awareness & training program in each professional year. There should be regular awareness workshops for healthcare professionals and students. This study comes to the conclusion that medical students, who will become future healthcare providers, should be trained well from undergraduate period. So they should well verse with the pharmacovigilance system and realized the importance of reporting ADR in future for the welfare of the community.

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