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Assessment Of Awareness, Knowledge And Methods Of Application Of Pharmacovigilance Among Internees And Postgraduates In A Government Hospital.

Dr.RadhikaRani.K.C¹, Dr.Hemanth.G.V², Dr.Vasundara devi.B³, Dr.Sadana.A⁴, Dr.G.Prameela⁵

1(Associate Professor, Department Of Pharmacology, Sri Venkateswara Medical College, Tirupati, NTRUHS, India)

2(Senior Resident, Department Of Pharmacology, Sri Venkateswara Medical College, Tirupati, NTRUHS, India)

3(Professor And Head, Department Of Pharmacology, Sri Venkateswara Medical College, Tirupati, NTRUHS, India)

4(Assistant Professor, Department Of Ophthalmology, Sri Venkateswara Medical College, Tirupati, NTRUHS, India)

5(Assistant Professor, Department Of Obstetrics & Gynaecology, Sri Venkateswara Medical College, Tirupati, NTRUHS, India)

Corresponding Author: Dr.RadhikaRani.K.C

Email: radhikakc1120@gmail.com

Abstract:

Background: Pharmacovigilance is “The science and activities which are related to the detection, assessment, understanding and the prevention of adverse effects or any other drug related problems^[1]”. This study assessed awareness, knowledge and methods of application of pharmacovigilance among medical professionals.

Materials and Methods: A total of 250 students were participated in the study, comprising of postgraduates and Internees. The study Instrument was a pre designed Questionnaire which consists of 25 questions related to basic awareness, student’s knowledge and methods of application about pharmacovigilance The questionnaire was analyzed question wise and their percentage value was calculated and their responses were documented.

Results: The study showed that after analyzing the questionnaire 47.5% of internees, 51.1% of P.G students were aware of pharmacovigilance and it is mandatory to have pharmacovigilance center in every medical college. Only 15% of internees and 23.3% P.G students are aware about exact meaning of pharmacovigilance. knowledge percentage of internees and pgs about pharmacovigilance programme is 11% &14.6% respectively with a p value of 0.421. Only 39.3% of internees, 41.3% of PGs only knows the different methodologies employed to assess causality of adverse effects.

Conclusion: The results of our study shows that there is great need to conduct pharmacovigilance programme to promote the reporting of ADR and to improve the knowledge about the process of ADR reporting system.

Keywords: Adverse drug reaction, Awareness, knowledge, methods of application, Pharmacovigilance.

I. INTRODUCTION:

Pharmacovigilance is by definition “The science and activities which are related to the detection, assessment, understanding and the prevention of adverse effects or any other drug related problems^[1]. The entire network works in coordination to improve the ADR reporting in our country^[2].

Pharmacovigilance is a systematic and structured process for the monitoring and detection of adverse drug reactions (ADRs) in a given context ^[3]. Pharmacovigilance has constantly grown its importance in last few years, relating to the increasing incidence of adverse drug reactions (ADRs) ^[4,5]. Pharmacovigilance is an arm of patient care and surveillance. It aims at getting the best outcome from treatment with medicine. Adverse drug reactions (ADRs) are common causes of morbidity and mortality in both hospital and community settings. Adverse drug reactions (ADRs) are global problems of major concern. They affect both children and adults with varying magnitudes, causing morbidity and mortality^[6,7]. ADRs are responsible for about 5% to 20% of hospital admissions^[6,7].

World Health Organization (WHO) defines Pharmacovigilance “as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems^[8]. India ranks below 1% in terms of ADR reporting against the world rate of 5%^[9]. To overcome this problem, the Ministry of Health and Family Welfare, Govt. of India, has initiated the National Pharmacovigilance Programme. The purpose of this programme is to collect the data, analyze it and to use the inferences to recommend informed regulatory interventions, besides communicating the risks to the health care professionals and the public. This programme is coordinated by the National Pharmacovigilance Centre at the Central Drugs Standard Control Organization (CDSCO) in New Delhi. The National Centre is operating under the supervision of the National Pharmacovigilance Advisory Committee, to

recommend procedures and guidelines for regulatory interventions. This committee oversees the performance of two zonal, five regional and twenty six peripheral pharmacovigilance centers.

World Health Organization (WHO) defines ADR as “Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis of disease, or for the modification of physiological function.

Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitude that are associated with high degree of underreporting ^[10,11]. Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. The Pharmacovigilance Programme of India (PvPI) like most others around the world suffers from underreporting of ADRs by the healthcare professionals; this can delay the detection of important ADRs. However, the Indian national Pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India^[12]

Few studies had been carried out in different countries to assess the knowledge of pharmacovigilance among the medical students and practitioners. In the U.K., 57% of the medical schools assessed the students’ knowledge on the yellow card scheme^[13]. In France, a survey which was conducted among medical residents, showed that a majority lacked knowledge on pharmacovigilance ^[14]. A study which was conducted in Nigeria revealed an inadequate knowledge on pharmacovigilance among resident doctors^[15]. A study which was designed to investigate the awareness of pharmacovigilance among the health care professionals in Jiangsu, China, showed that significant differences existed in the awareness of pharmacovigilance across regions, hospital classes and professions^[16]. A study which was conducted at a Nepalese hospital also showed low KAP scores and it suggested the

need for educational and managerial interventions [17].

In India, few studies were carried out, which mainly emphasized on the actual process of the ADR reporting. A study which was conducted at 3 different private hospitals in Mysore recommended that several studies of a similar kind, especially in the community setup, needed to be conducted, to know the attitudes of other health care professionals towards the ADR reporting [18].

A majority of India's population prefers government hospitals when they are in need of health care facilities. So, these hospitals can be a good source for generating an ADR database. However, the Herculean task is to foster a culture of reporting among the clinicians, especially among the junior doctors, as they are more closely associated with the patient care. The present low level of ADR reporting is mostly due to a lack of awareness and training and time constraints [19]. Hence, the present study was designed with the following objectives:

TO ASSESS:

1. a. The awareness on pharmacovigilance .
- b. The knowledge on pharmacovigilance.
- c. The methods of application of pharmacovigilance among the internees and postgraduates.
2. To compare the results among the two groups.

III.RESULTS

TABLE - I

	Internees	PGs	Chi square value	df	p value
Q 1. Pharmacovigilance Awareness	47.5%	51.6%	2.751 ^a	1	0.097
Q 2 Is Pharmacovigilance Unit Mandatory	47.5%	51.1%	5.905 ^a	1	0.015
Q 3. Definition of Pharmacovigilance	15.1%	23.3%	31.833 ^a	1	0

II. MATERIALS AND METHODS:

A total of 250 students will be participating in the study, comprising of postgraduates and Internees. Approval from the Institutional Research Committee was obtained before the start of the study. Informed consent was obtained from the students. The study Instrument was a pre designed Questionnaire which was instructed to obtain the information about the knowledge of Pharmacovigilance and ADR reporting. The questionnaire consists of 25 questions out of which 5 questions related to basic awareness about pharmacovigilance, 7 questions related to student's knowledge. and 13 questions related to methods of application. The questionnaire was handed over to them after explaining them the purpose of the study. The doctors were requested to complete the questionnaire and hand it back immediately. Those who were busy at that moment, were requested to submit the next day. The questionnaire was analyzed question wise and their percentage value was calculated., and their responses were documented. The filled questionnaires were evaluated as per the study objectives. The various parameters such as sex distribution, professional status, educational qualifications, and the scores were analyzed. The data obtained were entered in Microsoft excel spread sheet and the statistical calculations were executed. The level of statistical significance was set at p<0.05.

Q 4.Pharmacovigilance Includes	47.0%	48.4%	9.447 ^a	1	0.002
Q 5. Aim of Pharmacovigilance	45.7%	46.1%	5.819 ^a	1	0.016

TABLE - II

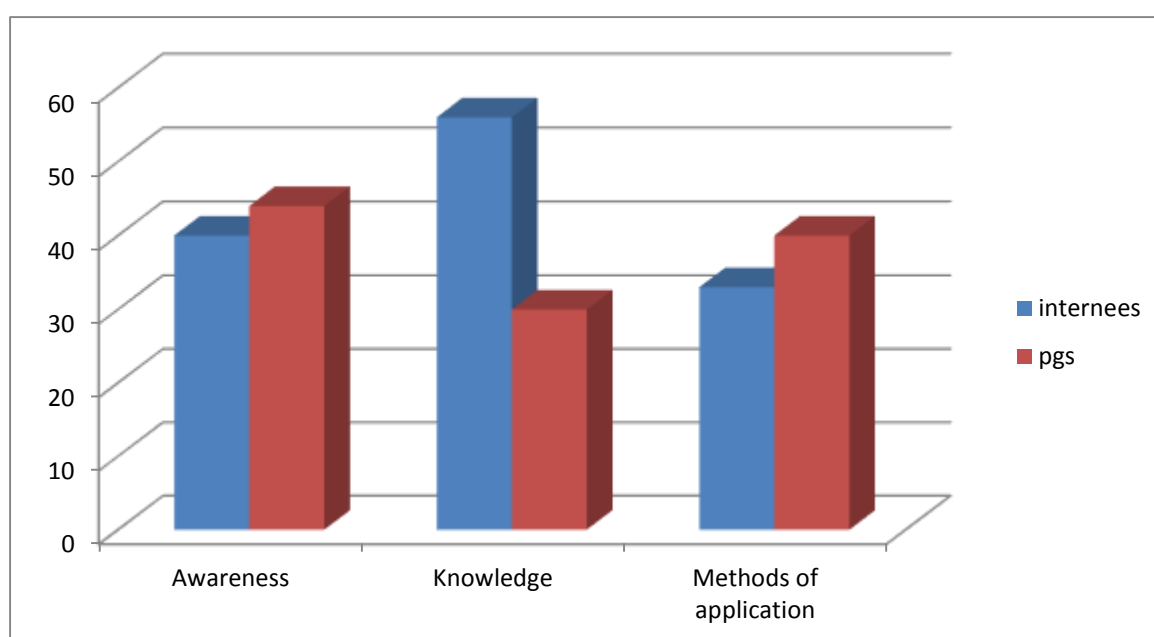
	Internees	PGs	Chi square value	df	p value
Q 6. NPP in India is Governed by	5.9%	25.1%	. ^a		
Q 7.NPP Inaugurated in which year	11.0%	14.6%	10.250 ^a	1	0.001
Q 8.AIMS New Delhi is	45.2%	42.9%	19.905 ^a	1	0
Q 9. Responsibility of Pharmacovigilance in Clinical Research	47.5%	50.7%	60.294 ^a	1	0
Q 10. Schedule Y	23.7%	17.8%	8.552 ^a	1	0.003
Q 11. Archiving Period	8.7%	3.2%	25.197 ^a	1	0
Q 12. Is Audit Mandatory	47.5%	52.5%	63.969 ^a	1	0

TABLE – III

	Internees	PGs	Chi square value	df	p value
Q 13.Co-ordinator Eligibility at ZPC	21.0%	8.2%	1.825 ^a	1	0.177
Q 14. Most Common ADR	38.4%	49.8%	3.677 ^a	1	0.055
Q 15.Serious ADR	46.1%	46.6%	5.021 ^a	1	0.025
Q 16.ADR Reporting Done by	47.5%	43.4%	.647 ^a	1	0.421
Q 17. ADRs To Be Reported	26.9%	21.5%	3.685 ^a	1	0.055
Q 18. ADR Report Submission	3.7%	30.1%	7.746 ^a	1	0.005
Q 19.ADR Assessment Scale	39.3%	41.1%	21.565 ^a	1	0
Q 20.ADR Forms are called	45.2%	43.4%	5.717 ^a	1	0.017
Q 21. Mandatory Elements To Be Recorded	47.5%	50.2%	5.501 ^a	1	0.019

Q 22. Dechallenge Not Applicable in	18.7%	38.4%	.680 ^a	1	0.41
Q 23. ADR Synonymous To Adverse Event	36.5%	43.4%	4.627 ^a	1	0.031
Q 24. Common ADRs are Reported or not	16.9%	46.1%	1.100 ^a	1	0.294
Q 25.Can Non Medical People report ADRs	47.5%	52.5%	. ^a		

Fig:I Scores of Awareness, Knowledge and Methods of application



IV.DISCUSSION

To the best of our knowledge, this study evaluated the Awareness, knowledge, methods of application of Pharmacovigilance among medical students, in S.V.R.R.G.Hospital Tirupati. The study among the medical students (Internees, PGs) showed an overall response rate of 90%, this numeral can be regarded as very high, especially when compared with those of other studies on the same topic carried out among medical students. The response rate attained was within the accepted range for survey research. In order to maximize the response rate and minimize response bias, the

questionnaire was administered personally to the participants by the facilitator.

The study showed that participants who attended the interactive educational intervention session on Pharmacovigilance and ADR reporting were much satisfied, and considered more effective and valuable. In our study, one focus of educational intervention was to increase the participant's awareness to Pharmacovigilance topics, regulatory body responsible for monitoring of ADRs, and the International- scenario on Pharmacovigilance. This educational intervention program encouraged the participants to pursue

career in Pharmacovigilance as their future perspective.

In Table No.1 Question showed that 66.7% of female students 32.4% of male students are aware of pharmacovigilance and 47.5% of internees and 51.6% of P.G students are aware of pharmacovigilance. With a significant p value of (0.045) by applying chisquare test pharmacovigilance . . Question 2 showed that . 47.5% of internees , 51.1% of P.G students are aware of that it is mandatory to have pharmacovigilance center in every medical college with a p value of 0.97 that is not significant. Question 3 and 4 shows there is a significant association between gender and response given is 21% Of females and 17.4% of males with p value of <0.0003 which is highly significant by applying chi square test.

By seeing education in table. 15% of internees and 23.3% P.G students are aware about exact meaning of pharmacovigilance. This indicating that training programme should be conducted to improve the awareness about pharmacovigilance from internees level. From table 45.75% of internees and P.G students are aware of aim of pharmacovigilance with the p value of 0.025 that is highly significant.

In Table no.II the knowledge percentage of internees and pgs about pharmacovigilance programme is 11% &14.6% respectively with a p value of 0.421. A considerable number were ignorant about pharmacovigilance programme. 45% of internees and 52% of pg students have knowledge about national pharmacovigilance center New Delhi AIIMS with a p value of (. 002). A considerable number were ignorant about schedule Y.23.7% IINTERNES AND 34.75% PG do not have knowledge about schedule y with a p value of .016%. very few percentage of internees 8.7%and pgs 3'2% have knowledge about when archiving is done with a p value of (.005) which is significant.

47.5%of internees answered correctly, 66.7%of P.G students have knowledge that clinical research in pharmacovigilance is the

responsibility of sponsors, investigators, ethical committee members with a P-value of (0.05) Question 10 23.7%of internees answered correctly, 31.5%of P.G students answered correctly. Question 11 showed that 3.2%of female students answered correctly, 6.8%of male s8.7%of internees answered correctly, 5.0%of P.G students answered correctly. Question 12 showed that 52.5%of female students answered correctly, 33.3%of male students answered correctly and 47.5%of internees answered correctly, 66.7%of P.G students answered correctly.

In Table.no III the methods of application of pharmacovigilance 24.2% of internees and 9.6% Of PGs only know the order of ADR reporting with a P value of 0.2 Majority of health care professionals doesn't know about by which order the ADR reporting will be done. Only 39.3% of internees, 41.3% of PGs only knows the different methodologies employed to assess causality of adverse effects. Majority of internees 45.2% and PGs 43.4% have the knowledge that yellow cards are ADR forms with P value of 0.00. 18.7% internees and 38.7% PGs were sure when a dechallenge was not applicable in case of ADR reaction.

65.8% of internees and 32% Of PGs know what elements are mandatory to record in pharmacovigilance. 18.7% of internees and 38.4% Of PGs are know when the dechallenge is not applicable. 36.5 % of internees and 43.4% Of PGs know that Adverse drug reaction is not synonymous to adverse event. 16.9% of internees and 46.1% Of PGs know that common ADRs like headache, vomiting, fever should also be reported. 47.5% of internees and 52.5% Of PGs know that non medical persons can also report ADRs to a nearby medical person by means of oral, telecommunication and email. 38.4% of internees and 49.8% Of PGs know the most common type of ADR which is type A. 46.1% of internees and 46.6% Of PGs know the definition of serious adverse event. 47.5% of internees and 43.4% Of PGs know that ADR reporting can be done by all doctors, pharmacists and nurses. only 21% of

internees and 8.2% Of PGs know the eligibility of coordinator at zonal ppharmacovigilance centre.

V.CONCLUSION

In conclusion the results of our study demonstrates that 40% of internees and 44% of postgraduates were aware of pharmacovigilance. 56% Of internees and 30% of postgraduates have knowledge about pharmacovigilance programme. Only few percent i.e 33% Of internees and 40% of postgraduates know different methods of application of pharmacovigilance. This strongly suggests there is great need to conduct pharmacovigilance programme to promote the reporting of ADR and to improve the knowledge about the process of ADR reporting system.

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