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CASE REPORT OPEN ACCESS

Impact of Educational Intervention on Knowledge, Attitude, and Practice regarding Pharmacovigilance: A Comparative Study of Homeopathic Practitioners and Nursing Students in a Tertiary Care teaching Hospital

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A B S T R A C T

Introduction: Pharmacovigilance (PV) encompasses the science and activities related to detecting, assessing, understanding, and preventing adverse effects or other drug-related issues. Under-reporting of adverse drug reactions (ADRs) often stems from inadequate knowledge and awareness of Pharmacovigilance. This study evaluates the effectiveness of an educational intervention regarding Pharmacovigilance on knowledge, attitudes, and practices (KAP) among homeopathic practitioners and nursing students.

Objectives: To compare and evaluate the impact of educational intervention in the form of a Pharmacovigilance workshop on the knowledge, attitude and practice regarding Pharmacovigilance (PV) among homeopathic practitioners versus nursing students in a tertiary care teaching hospital.

Methodology: This prospective, cross-sectional, interventional study was carried out following approval from Institutional Ethics Committee which involved 186 participants (93 homeopathic practitioners and 93 nursing students) at a tertiary care hospital. A pre-validated questionnaire was administered before and after a 4-hour Pharmacovigilance workshop.

Results: The study revealed significant improvements in knowledge and attitude on Pharmacovigilance post-intervention, particularly among nursing students. Key findings included increased awareness of Pharmacovigilance, understanding of ADRs versus adverse drug events, and knowledge of India's ADR monitoring system. Nursing students showed greater improvement in recognizing ADR reporting as a professional duty and in practical reporting aspects. Homeopaths demonstrated a notable shift in attitudes towards their role in ADR reporting.

Conclusion: The study found statistically significant improvements in PV knowledge, attitudes, and practices among both groups, with nursing students showing more pronounced improvements. The educational intervention effectively enhanced understanding and engagement with Pharmacovigilance principles among participants.

Keywords: pharmacovigilance, adverse drug reactions, ADR, PvPI,

INTRODUCTION

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.[1]

As we know that none of the therapeutic drugs are devoid of adverse effects. Prescription of drugs should always be done in a judicious manner and with a satisfactory risk/benefit ratio.[2] The World Health Organization (WHO) defined "adverse drug reactions (ADRs)" as any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease or modification of physiological function.[3]

ADRs have emerged as a significant challenge for public health due to comorbidities, polypharmacy, and new medications and are considered as a major cause of patient morbidity and mortality.[4] According to an article in the Asian Journal of Pharmacology ADRs account for 5%–10% of all hospital admissions on a global scale and constitute a significant economic burden on patients in a resource poor setting like India.[5,6]

To enhance medicine safety monitoring, a critical aspect of high-quality healthcare, the Ministry of Health and Family Welfare (MoHFW), Government of India, launched the Pharmacovigilance Programme of India (PvPI) in 2010. This program aims to equip healthcare professionals with essential information on drug safety, recommend necessary regulatory interventions, and generate alerts for potential safety concerns.[7]

While pharmacovigilance activities include detecting and reporting medication errors, drug interactions, misuse, lack of efficacy, and counterfeit drugs, ADR reporting remains the primary focus.[10]

Efficient and effective ADR detection lies at the core of any PV programme and these reporting systems allow continuous monitoring of all drugs used in clinical settings and enable the creation of alerts for identifying new ADRs and their strength is entirely related to the actual rate reported by healthcare practitioners.[8]

However, numerous studies highlight that a significant barrier to effective ADR reporting is the lack of knowledge and awareness among healthcare practitioners and this deficiency often results in underreporting, which ultimately compromises patient safety.[9]

The key to creating a more robust surveillance culture is to ensure that all healthcare professionals who administer drugs are aware of how to monitor and report any difficulties that patients may experience combined with an integrated approach involving healthcare professionals from all specialties and backgrounds.[10]

As there is a paucity of studies that have done a comparative analysis on the impact of educational intervention on the knowledge, attitude and practice of Pharmacovigilance in various allied healthcare disciplines, this study was designed to compare the impact of educational intervention on the same among nursing students and homeopathic practitioners.

By examining these differences, the study aims to identify tailored educational interventions that can enhance KAP in both groups, ultimately contributing to improved patient safety and drug monitoring practices in diverse healthcare settings.

MATERIAL & METHODS

Study Design

The study was a prospective, interventional, parallel group study conducted at a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee. The study involved 102 Homeopathic Practitioners and 110 Nursing Practitioners as participants, in two parallel groups. Participants of both groups were explained about the nature and purpose of the study and necessary consent was obtained. The study instrument was a self – developed, pre-validated, semi-structured questionnaire, consisting of open and close-ended questions. Appropriate instructions were given to the participants about the questionnaire. Participants were asked to fill the same questionnaire before and after the educational intervention – in the form of an educational Pharmacovigilance workshop of duration 4 hours, which included educative sessions such as orientation on Pharmacovigilance Programme of India (PvPI), ADR reporting and monitoring and a special session on how to fill ADR Reporting forms by the Central Drugs Standard Control Organization (CDSCO).

The following information was obtained: knowledge, attitude, and practice of Pharmacovigilance among participants, before and after the educational intervention.Incompletely filled forms were excluded and 186 fully filled questionnaires were included for statistical analysis, i.e. 93 in each group.

Statistical Analysis

Data was expressed as counts and percentages, wherever applicable. Data obtained during the pre – test and post – test was compared statistically in between the two groups, i.e., Homeopaths and Nursing Students, by applying the Chi Square Test using the software Graph Pad Prism version 8.4.2, and a 'p' value less than 0.05 was considered statistically significant.

RESULTS

There was a statistically significant difference seen in the improvement of knowledge post – intervention between the groups, in aspects such as awareness of Pharmacovigilance (p value <0.0001), if adverse drug reaction and adverse drug

event were the same (p value <0.0001), awareness about the existence of ADR monitoring system in India (p value <0.001), whether the participants knew how to report an ADR ('p' value = 0.0003), and the location of the national PV centre in India ('p' value = 0.003), the improvement being more among Nursing students. (Table 1). However, the baseline i.e. pre-intervention knowledge regarding the above aspects, was higher among Homeopaths. There was no statistically significant difference in improvement in participants knowledge about the meaning of adverse drug reaction ('p' value = 0.2124) and the regulatory body responsible for monitoring ADRs i.e. C.D.S.C.O. ('p' value =0.5845) and if the institute where the workshop was being conducted was a recognised centre for Pharmacovigilance (p value =0.06). The baseline knowledge regarding the latter, was already good among both groups. (Table 1)

There was a statistically significant difference seen in improvement in attitude post – intervention in participants' belief that ADR reporting was a professional obligation ('p' value =0.01), improvement being more in Nursing students.

On whether medical students can play a role in ADR reporting, there was a statistically significant difference in improvement of attitude, seen more among Homeopaths compared to Nursing students. (p value <0.0001). (Table 2)
However, there was no statistically significant difference in improvement seen between the two groups on the belief whether it is necessary to report only serious or unexpected ADRs (p value=0.76). (Table 2)
There was a statistically significant difference in improvement seen in practice related question about whether the participants had filled an ADR Reporting form by C.D.S.C.O., the improvement being more among Nursing students (p value <0.0001) (Table 3).

[Table 1] Comparison of knowledge of homeopaths and nursing students regarding Pharmacovigilance before and after intervention (n=93)

S.No	Questions	Homeopaths (Correct Answers)		Nursing Students (Correct Answers)		p value
		Pre-Intervention	Post-Intervention	Pre-Intervention	Post-Intervention	
1.	Are you aware of pharmacovigilance?	77 (82.79%)	84 (90.32%)	71 (76.34%)	93 (100%)	<0.0001
2.	Do you know the meaning of adverse drug reaction?	51 (54.8%)	84 (90.32%)	63 (67.74%)	88 (94.62%)	0.2124
3.	Are adverse drug reaction and adverse drug event same?	36 (38.7%)	38 (40.86%)	23	77	<0.0001
4.	Are you aware of existence of ADR reporting and monitoring system in India?	63 (67.74%)	83 (89.24%)	31 (33.33%)	83 (89.24%)	<0.0001
5.	Is GMCH Nagpur a recognized reporting centre for Pharmacovigilance?	79 (84.94)	83 (89.24%)	72 (77.41%)	91 (97.84%)	0.06
6.	Do you Know how to report an ADR?	58 (62.36%)	84 (90.32%)	30 (32.25%)	89 (95.69%)	0.0003
7.	Where is national pharmacovigilance Centre located in India? (Ghaziabad)	51 (54.83%)	81 (87.09%)	34 (36.59%)	91 (97.84%)	0.003
8.	In India, which regulatory body is responsible for monitoring ADRs? (CDSCO)	64 (68.81%)	85 (91.39%)	59 (63.44%)	80 (86%)	0.5845

[Table 2] Comparison of attitude of homeopaths and nursing students regarding Pharmacovigilance before and after intervention (n=93)

S.No	Questions	Homeopaths (Correct Answers)		Nursing Students (Correct Answers)		p value
		Pre-Intervention	Post-Intervention	Pre-Intervention	Post-Intervention	
1.	Do you think that reporting an ADR is a professional obligation?	44 (47.31%)	62 (66.66%)	27(29.03)	49	0.01
2.	Do you think that medical students can play a role in ADR reporting?	54 (58.06%)	83 (89.24%)	84(90.32)	91(97.84)	<0.0001
3.	Do you think it is necessary to only report serious or unexpected ADRs?	58 (62.36%)	70 (75.26%)	61 (65.59%)	64 (68.81%)	0.76

[Table 3] Comparison of practice of homeopaths and nursing students regarding Pharmacovigilance before and after intervention (n=93)

S.No	Questions	Homeopaths		Nursing Students		p value
		Pre-Intervention	Post-Intervention	Pre-Intervention	Post-Intervention	p value
1.	Have you ever filled an ADR reporting form by CDSCO?	31 (33.33%)	84 (90.32%)	6 (6.45%)	62 (66.66%)	<0.0001

Figure 1 – Knowledge of Participants about the type of drugs that need ADR Reporting

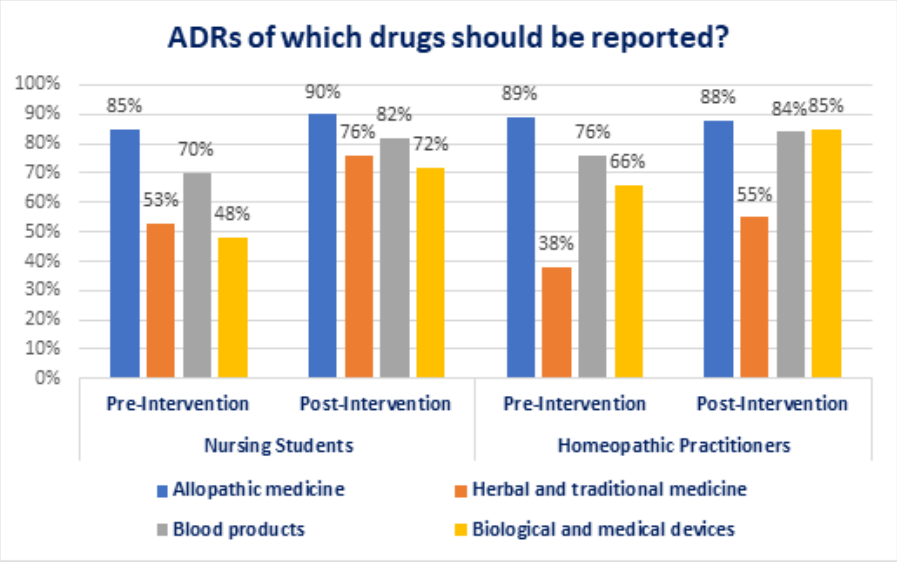
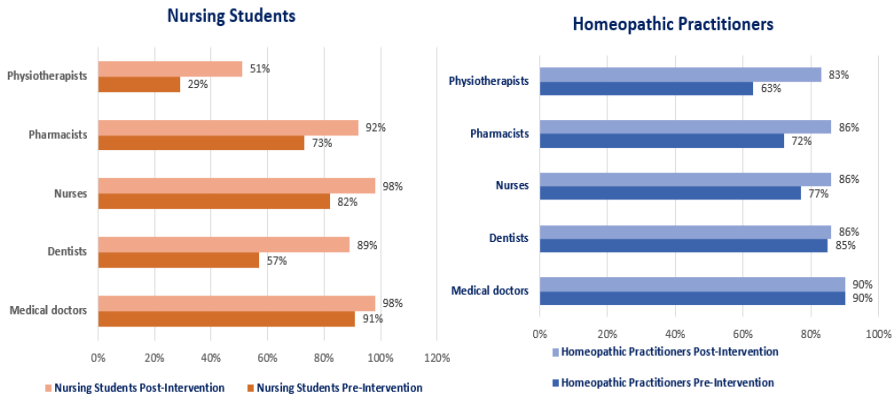


Figure 2 – Knowledge of Participants About the Health Care Professionals Qualified to report Adverse Drug Reactions (ADRs)



DISCUSSION

The present study compares the impact of educational intervention on the knowledge, attitude and practice about Pharmacovigilance among Homeopaths and Nursing Students.

There was an improvement seen in all aspects of knowledge in both the groups following the educational intervention, however, a statistically significant difference in improvement in knowledge was seen more in nursing students as compared to Homeopaths, except for knowledge regarding the meaning of adverse drug reaction, where participants already had good knowledge.

Similar findings were seen in a study conducted by Rajesh et. al.[11] that found enhanced awareness about Pharmacovigilance among health professionals, post educational intervention.

It was surprising to see that knowledge regarding difference between the terms adverse drug reaction and adverse drug event escalated significantly more among the Nursing students from 25% to 83%, whereas this improvement was merely 39% to 41% among Homeopaths.

A similar finding was seen in a study conducted by Gosavi et. al., where there was a statistically significant improvement regarding the same among nursing students.[12]

Knowledge regarding how to report an ADR had increased significantly in both groups, following the educational intervention, which is as an encouraging fact.

Knowledge that ADRs should be reported for herbal and traditional medicines, blood products, biological and medical devices improved in both the groups, following the educational intervention.

Similarly, the awareness that other healthcare professionals such as dentists, nurses, pharmacists and physiotherapists are also qualified to report ADRs, improved in both groups, after the intervention.

It cannot be reiterated enough that to improve ADR Reporting, an intensive monitoring approach is essential, and this should involve creation of an ADR monitoring network within the hospital that cohesively includes Nurses.[13]

After the educational intervention, 66% Homeopaths believed that ADR reporting is a professional obligation, while only 49% nursing students believed the same following the intervention. Both groups improved in their attitude that medical students can play a role in ADR Reporting post – intervention, with a greater improvement seen among Homeopaths.

These findings are resonated in a study conducted by Tandon et al about underreporting of ADRs in India, that has called for a multi – pronged approach that involves professionals from allied disciplines, such as house officers, interns, nurses and pharmacists to tackle the issue of under-reporting of ADRs in India.[14]

In terms of practice related questions, only a minority of study participants in both groups had filled an ADR reporting form by CDSCO before the intervention, but following the intervention, the number of nursing students who had filled the form increased from 6% to 62%, the improvement being statistically more significant, as compared to the Homeopaths. Homeopaths, who are already practising doctors show a good baseline knowledge regarding Pharmacovigilance. However,

Nursing students, who are at a very nascent stage of medical education training, show an overall greater improvement in knowledge, attitude and practice regarding Pharmacovigilance, which emphasises the importance of Pharmacovigilance related training early in education of allied healthcare professions.

A review of literature conducted by Reumerman & Tichelaar et al that evaluates the pharmacovigilance competencies in healthcare students of different disciplines, highlights the importance of repeated clinical training and student participation in pharmacovigilance tasks, as well as real-life learning initiatives to not only improve knowledge, but also assist healthcare professionals to meet their pharmacovigilance obligations.[15]

Thus, based on the findings of our study, we propose educational interventions be initiated early in medical education, across all disciplines, to further strengthen Pharmacovigilance at ground level. This can involve actual tasks such as teaching students about how to fill ADR reporting forms, how to identify ADRs clinically, by perhaps, simulating real-life clinic-based adverse drug reaction scenarios, and teach them ways to improve doctor - patient communication to enhance patient safety, and thereby, ensure a robust and efficient surveillance system.

CONCLUSION

The study found a statistically significant improvement in knowledge, attitude and practice regarding Pharmacovigilance among Homeopathic Practitioners and Nursing students, however the difference in improvement was more among the Nursing students.

Limitations

Our study is limited by a lack of long-term follow –up of study participants to better understand the long – term effects of the educational intervention on practice of Pharmacovigilance.
Study is also confined to a single tertiary care hospital which might limit its generalizability.

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