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Original Research Article

Evaluation of educational intervention on awareness of adverse drug reaction reporting among geriatric population in a tier II city of India

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ABSTRACT

Background: Adverse drug reactions in the geriatric population are a growing concern, given their susceptibility to medication-related complications. However, underreporting of ADRs remains a significant challenge in India. This study aimed to evaluate the impact of an educational intervention on ADR reporting awareness among the geriatric population in a Tier II city of India.
Methods: A pre-post intervention study was conducted in a Tier II city, involving a sample of geriatric individuals aged 60 and above. An educational intervention, consisting of workshops, pamphlets, and interactive sessions, was designed to enhance awareness of ADR reporting procedures. Pre-intervention and post-intervention assessments were conducted to measure changes in ADR reporting knowledge and willingness to report ADRs.
Results: A total of 71 responses were received. All participants demonstrated an increased understanding of the importance of reporting ADRs and were more willing to report such incidents to health care authorities after the intervention. The educational intervention significantly improved awareness of ADR reporting procedures among the geriatric population
Conclusions: The intention of the study was to assess the effectiveness of an educational programme on geriatric patients' awareness of the need to report adverse drug reactions to pharmacovigilance centres given that this age group is more prone to use multiple therapies. A large number of participants felt that increasing pharmacovigilance awareness and knowledge sharing will benefit society.

Keywords: Adverse drug reporting, Pharmacovigilance, Patient's direct reporting, Public awareness

INTRODUCTION

Health care providers are one of the main source of knowledge about drug safety. However, research has shown that either not at all or not properly, doctors report adverse drug reactions (ADRs). One of the possible reasons for under reporting by doctors is inability to give adequate time for ADR reporting. The combined patient and healthcare practitioner knowledge of ADRs has a considerable impact on the signal identification of novel, unusual, or serious ADRs. Although one of the main goals of pharmacovigilance was to identify, evaluate, comprehend, and take precautions against side effects in order to protect the public, patient self-reporting of ADRs was historically an underutilised resource. Due to underreporting, ADRs have proven difficult to report spontaneously, which is problematic for pharmacovigilance efforts and harmful to public health. ADR reporting programmes for consumers have been advocated in a number of nations either concurrently with or shortly after the installation of national pharmacovigilance systems.[1] The reasons why patients report ADRs and patient reporting programmes have been the subject of certain studies. Studies have also concentrated on the strategies used to encourage ADR

reporting as well as sociodemographic and economic characteristics as determinants of population ADR reporting.[2,3] The under-reporting of ADRs and the identification of new risks in a particular patient subgroup may be addressed by increasing the knowledge accessible regarding ADRs through drug users. Direct patient reporting has additionally shown that ADRs can be studied from a variety of perspectives. The signal detection of new, unusual, or serious ADRs is substantially influenced by the collective knowledge of ADRs held by patients and healthcare professionals. In the EU, the pharmacovigilance system underwent a major reform in 2012.[4-7] Among the major changes were the expansion of the definition of ADRs, the harmonization of several risk-based post marketing surveillance methods and the introduction of the legal right for individual citizens to report suspected ADRs directly to the authorities.[8] Most geriatric patients have chronic illnesses and are receiving multi therapies which could lead to polypharmacy. They are ignorant of the different drug interactions, adverse effects, and reporting procedures for these side effects to approved centres. All the more, the theme of pharmacovigilance 2022 was "Encouraging reporting of ADR by parents. Therefore, the aim of this study was to inform and empower the geriatric community regarding reporting adverse drug reactions".

METHODS

This study was conducted in tier II city of India. This was a prospective cross-sectional questionnaire-based study. This study instrument was self-administered, structured, predesigned, pretested and modified based on previous studies. The clearance from institutional ethics committee was obtained before the study. This study was done on 23rd September, 2022 during the second National pharmacovigilance week which was from 17th September to 23rd September, 2022 announced by Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC) for Pharmacovigilance Program of India (PvPI). The Geriatric participant in the study received a pre- and post-test questionnaire. The faculties had taken lecture on adverse drug reactions, pharmacovigilance, and how to report an adverse drug response to the pharmacovigilance centre. Role play interspersed by lectures centred on pharmacovigilance and how to properly report a medication reaction. Post-session, the individual was also given a questionnaire based on the usefulness of this awareness. Twenty questions on awareness of adverse drug reactions, pharmacovigilance, and reporting of ADRs were included in a pre- and post-questionnaire. Six questions were included in a post-session questionnaire regarding the value of this awareness. Incompletely filled questionnaires are excluded from the study.

RESULTS

A total of 71 responses were received, the majority of the participants were between 61 and 70 years old (49.3), females (42.3%) & Males (57.7%). All of the participants were educated but with different levels where (50%) had a bachelor's degree, more information about the participant demographics can be found in (Table 1). The participants were asked whether they had ever heard of the term "Pharmacovigilance". Many of the participants were familiar with this terminology. When asked if they were aware of the NPC in Surat city, SMIMER only 69% acknowledged previous knowledge of the centre (Table 2).

Table 1: Participants demographic characteristic.

Variables		%
Age	50-60	12.7
	61-70	49.3
	71-80	33.8
	81-90	4.2
Gender	Male	57.7
	Female	42.3
Qualification	Graduate	50
	High school	22.5
	School	27.5
Working Status	Working	22.5
	Retired	49.3
	Other	28.2
Marital Status	Married	95.8
	Unmarried	1.4
	Other	2.8

Post educational intervention feedback

Five questions regarding the educational intervention were asked to the participants after the session. Last question was an open-ended question asking for their suggestions to improve reporting by ADR's by patients (Table 3). Most of the participant were taking allopathic medication and were informed about the side effects of the drugs by the specialist. Large number of participants were too taking alternative medicine like Ayurvedic, Homeopathic, Naturopathy etc alongside the allopathic medication. 50% of the participant agreed that herbal medications were not safe to be taken along with allopathic medication.

DISCUSSION

The goal of the current study was to assess the geriatric population's knowledge of ADR reporting in a tier II city because it is crucial to know how well the older population in cities is educated about potential side effects of the medications they are taking. The study's findings show that while the general public is interested in learning more about ADRs and is aware of the advantages of reporting ADRs, they do not fully comprehend their critical role in doing so. Also, they lack enough knowledge of the possible severity of injury that could result from ADR. The majority of survey participants in our study (85.9%) were familiar with the term Pharmacovigilance.

Table 2: Public perception toward ADRs reporting.

Question	Response	Pre-test (%)	Post-test (%)
Do You know what is Pharmacovigilance?	Yes	85.9	94.4
	No	14.1	5.6
Do you know about Pharmacovigilance centre?	Yes	69	97.2
	No	31	2.8
If you have side effect of any drugs will you inform the doctor?	Yes	81.7	94.4
	No	18.3	5.6
Which of the following	Known/unknown	43.7	18.3
ADR can be reported?	Serious/non-serious	23.9	11.9
	Frequent/rare	8.5	7
	All of the above	23.9 (N=71)	63.4 (N=71)
Due to whom ADR occurs?	Medicine	54.9	60.6
	Doctors	35.2	56.3
	Yourself	28.2	54.9
	Don't know	21.1 (N≠71)	21.1 (N≠71)
Who can report ADR to the centre?	Doctor	76.1	77.5
	Nurse	14.1	47.9
	Pharmacist	22.5	52.1
	Patient	26.8 (N≠71)	80.3 (N≠71)

On the contrary, the overwhelming majority of survey participant (84.9%) in the study conducted by Ibrahim et al were unfamiliar regarding the same.[9,10] The possibility of vast difference in findings between the two study could be explained by the fact that majority of our survey participant were educated. Even though most of the participant knew what pharmacovigilance was, most of them were not sensitized about pharmacovigilance centre. Studies show that Patients and health care providers frequently disregard the guidelines for reporting an adverse drug reaction (ADR) as soon as they suspect one.[11-14]

Table 3: Positive feedback was received (n=71).

Post session feedback	Response (%)
Pharmacovigilance awareness seminar will benefit general public	94
Sharing of knowledge of pharmacovigilance with friends, relatives, etc	92
Reporting of adverse drug reaction	96
Vigilant of adverse drug reaction while taking medication	94

Many people also believe that only serious ADRs that impair daily life or necessitate hospitalisation are worthy of reporting, or they only selectively report new ADRs, which will result in underreporting. In contrast to the findings of the above studies, 81.7% of our study participant agreed on informing the side effect of any drug to their doctor. 43.7% of the study participants felt that known/Unknown adverse drug reaction can be reported while 23.9% felt that only serious/non serious adverse drug reaction should be reported. In the study conducted by Islam et al their findings suggested that the majority of the participants commented that both health care professionals (HCPs) and the consumers were responsible of reporting ADRs.[9] Similarly, in the study by Sales et.al, most respondents (73.2%) mentioned that ADR reporting should be done by HCPs.[10] Our findings were similar with the studies above where majority of the patients (76.1%) felt that the doctors are responsible for reporting of ADR while 26.8% felt that patients are responsible for reporting ADR. From these findings it can be observed that a large number of participants rely on HCPs as responsible persons to report potential ADRs.

Strengths

Our study is one of its kind for the reason being that we conducted an educational intervention through role play for better understanding of the geriatric participants. We believe that the impact of visual aids enhances the learning process. Hence to educate the geriatric group of participants, our students performed a role play to demonstrate "who what when how to report adverse drug reaction." Post the session, open-ended questions were asked to the respondents regarding the impact of educational intervention and the knowledge which they gained from the same. Participants became more vigilant of adverse drug reactions while taking medicine and reported any such reactions. The participant believe that awareness and sharing of knowledge of pharmacovigilance with friends, relatives etc will be benefit to general public also.

CONCLUSION

The intention of the study was to assess the effectiveness of an educational programme on geriatric patients' awareness of the need to report adverse drug reactions to

pharmacovigilance centres given that this age group is more prone to use multiple therapies. A large number of participants felt that increasing pharmacovigilance awareness and knowledge sharing will benefit society.

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REFERENCES

1. Durrieu G, Jacquot J, Mège M, Bondon-Guitton E, Rousseau V, Montastruc F, et al. Completeness of Spontaneous Adverse Drug Reaction Reports Sent by General Practitioners to a Regional Pharmacovigilance Centre: A Descriptive Study. Drug Saf. 2016; 39(12):1189-1195.
2. Inácio P, Cavaco A, Airaksinen M. The value of patient reporting to the pharmacovigilance system: a systematic review. Br J Clin Pharmacol. 2017;83(2): 227-246.
3. Adisa R, Adeniyi OR, Fakeye TO. Knowledge, awareness, perception and reporting of experienced adverse drug reactions among outpatients in Nigeria. Int J Clin Pharm. 2019;41(4):1062-1073.
4. Al Dweik R, Stacey D, Kohen D, Yaya S. Factors affecting patient reporting of adverse drug reactions: a systematic review. Br J Clin Pharmacol. 2017;83(4): 875-83.
5. van Hunsel F, de Waal S, Härmark L. The contribution of direct patient reported ADRs to drug safety signals in the Netherlands from 2010 to 2015. Pharmacoepidemiol Drug Saf. 2017;26(8):977-983.
6. Ribeiro-Vaz I, Silva AM, Costa Santos C, Cruz-Correia R. How to promote adverse drug reaction reports using information systems - a systematic review and meta-analysis. BMC Med Inform Decis Mak. 2016;16:27.
7. Borg JJ, Aislaitner G, Pirozynski M, Mifsud S. Strengthening and rationalizing pharmacovigilance in the EU: where is Europe heading to? A review of the new EU legislation on pharmacovigilance. Drug Saf. 2011;34:187-97.
8. Steurbaut S, Hanssens Y. Pharmacovigilance: empowering healthcare professionals and patients. Int J Clin Pharm. 2014;36:859-62.
9. Sales I, Aljadhey H, Albogami Y, Mahmoud MA. Public awareness and perception toward Adverse Drug Reactions reporting in Riyadh, Saudi Arabia. Saudi Pharm J. 2017;25(6):868-872.
10. Islam A, Al-Karasneh AF, Naqvi AA, Al-Shayban DM, Al-Hayek F, Al-Badrani S, et al. Public Awareness about Medicine Information, Safety, and Adverse Drug Reaction (ADR) Reporting in Dammam, Saudi Arabia. Pharmacy. 2020;8:222.
11. Pal SN, Duncombe C, Falzon D, Olsson S. WHO strategy for collecting safety data in public health programmes: complementing spontaneous reporting systems. Drug Saf. 2013;36(2):75-81.
12. Lorimer S, Cox A, Langford NJ. A patient's perspective: the impact of adverse drug reactions on patients and their views on reporting. J Clin Pharm Ther. 2012;37(2):148-52.
13. Krska J, Jones L, Mckinney J, Wilson C. Medicine safety: experiences and perceptions of the general public in Liverpool. Pharmacoepidemiol Drug Saf. 2011;20(10):1098-103.
14. Matos C, Van Hunsel F, Joaquim J. Are consumers ready to take part in the Pharmacovigilance System? a Portuguese preliminary study concerning ADR reporting. Eur J Clin Pharmacol. 2015;71(7):883-90.

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