

A Step to Improve Pharmacovigilance System: A Cross Sectional Study among Outpatients Visiting Multi Super Speciality Hospital in Kerala Established with ADR Monitoring Centre

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ABSTRACT

Objectives: To evaluate knowledge and awareness about ADR and Pharmacovigilance system among out patients visiting different department of a super speciality hospital. Secondary objective is to sensitize patients on ADR reporting system. **Materials and Methods:** A cross sectional study was conducted at multi super speciality hospital. The Outpatient visiting various departments of the hospital (KIMS Alshifa multi-specialty hospital Perinthalmanna) for medical care were randomly selected and demographic details of respondents were noted. Questionnaire regarding knowledge and perception towards ADR developed for the study. The questionnaire and demographic data form given in two languages (Malayalam and English). A patient information leaflets were prepared and distributed among the study participants. Patients were trained on usage of ADR PvPI app for self reporting ADR. The data analyzed by descriptive analysis. **Results:** This study investigated and assessed the knowledge and perceptions of ADR among out patients visiting tertiary care hospital. The study comprised of 50 patients. Most of the participants were not aware about Pharmacovigilance (56%), the important source on awareness on Pharmacovigilance was social media and internet. Around 15(30%) respondents have experienced ADR after taking medication, but only 10 patients reported it to their physician. Most of them don't consider ADR reporting as necessary. Difficulty in travelling and rush in the hospital were the other reasons for under reporting ADR. All the participants were not aware about the Pharmacovigilance centre at the institution. Most of them prefer to report ADR directly to their physician. About 96% of patients were not heard about the ADR PvPI app. **Conclusion:** All the participants were trained on how to use the ADR PvPI app for self reporting ADR. A patient information leaflet were distributed to all the participants to create an awareness about ADR and the leaflet included information on Pharmacovigilance centre of the institution and how to report ADR once occur.

Keywords: Pharmacovigilance, Adverse drug reactions, Drug safety, ADR PvPI.

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INTRODUCTION

According to World Health Organization ADR is defined as “any response to a drug which 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”. The definition excludes overdose, drug abuse, treatment failure and drug administration error.¹

Pharmacovigilance is the pharmaceutical science deals with the collection, detection, assessment, monitoring, and prevention of adverse effects.² Pharmacovigilance Programme of India was started in 1986 in which a formal ADR monitoring system having 12 centers was proposed. On 14th July 2010 the Government of India officially implemented the PV Program for India (PvPI).³ As adverse drug reactions (ADRs)



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are a major reason of patient morbidity and mortality, Spontaneous reporting of the same is very important in the Pharmacovigilance system to ensure patient safety. Patient self reporting of ADR may make an important contribution to drug safety because different ADRs not identified from Health care professionals reports alone. Most of the studies already conducted have explored and reported knowledge and perception toward ADRs among health-care Professionals medical students. But studies on awareness among patients are limited. To make awareness about ADR in patients and to improve the self reporting and to determine whether our Pharmacovigilance system could be improved, and identify reasons for under-reporting, a cross sectional study to evaluate knowledge and perception of ADR among patients visiting tertiary care hospital was carried out at Al-Shifa hospital Perinthalmanna between November 2021 and March 2022).

MATERIALS AND METHODS

This study aimed to evaluate Knowledge and perception towards adverse drug reactions among patient visiting different departments of a multi super speciality hospital and to sensitize patients on ADR reporting system.

Study Populations

The Outpatient visiting various departments at multi super speciality hospital (KIMS Al shifa multi-specialty hospital Perinthalmanna) for medical care.

Study Site

A multi super speciality hospital established with an ADR monitoring and reporting centre under Indian pharmacopeial commission and ministry of health and family welfare Govt. of india.

Study Design

A cross-sectional survey among patients visiting tertiary care hospital (KIMS Al Shifa multi-specialty hospital Perinthalmanna) was conducted between November 2021 and March 2022 using the questionnaire developed. The questionnaire were both open ended and closed ended to assess knowledge about ADR and pharmacovigilance.

Inclusion Criteria

Out patients visiting different outpatient department of the hospital

Exclusion Criteria

- In patients and patients visiting emergency care of the department.
- Patients visiting gynecology department.
- Patients below 18 years of age.

Data analysis was done by descriptive analysis

RESULTS

A total of 50 eligible patients were included in the study. In which 27 (54%) were men and 23 (46%) were women. Respondents were aged between 18 to 70 years. 15 respondents (30%) were having primary education. 21(42%) were educated up to high school and remaining 14 (28%) were graduates. Most of them have co morbid conditions like hypertension, diabetes, thyroid, Hyperlipidemia (80%). About 35(70%) respondents used to take medications without prescriptions which include antibiotics, medications for fever, cough, cold etc. About 20 (40%) participants are taking medicines other than allopathy. 15 patients (30%) are on ayurvedhic treatment and 5 patients (10%) are receiving concurrent homeopathic treatment (Table 1). They are not aware about ADR caused by alternative medicines. About 52% of patients were not aware about their medications and its uses (Figure 1).

More patients reported that they received counseling from pharmacists regarding elements of medication use (Figure 2). But 80% of the patients were not informed about the possible ADR of drugs by pharmacist (Figure 3).

Knowledge and awareness of Pharmacovigilance and ADR reporting system among patients

Most of the participants, about 56% (28 respondents) were not aware about Pharmacovigilance . Better

Table 1: Patient details regarding co morbidities, usage of OTC and alternative system of medicine.

Details of patients	No of patients (N)	Frequency (%)
Taking medication for more than one disease condition	40	80
Taking any OTC medications?	35	70
Taking other system of medicine	20	40%
Ayurveda	15	30
Homeopathy	5	10

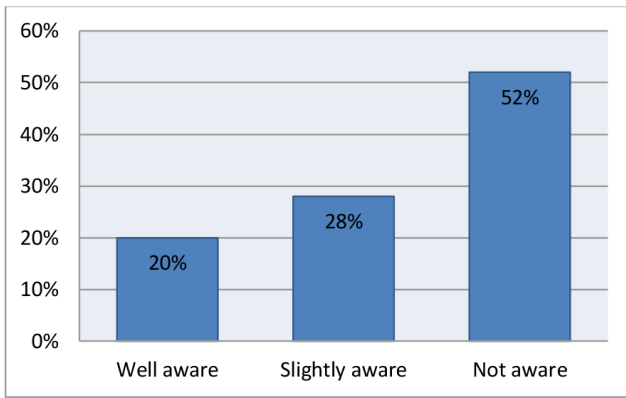


Figure 1: Patients awareness about their medications.

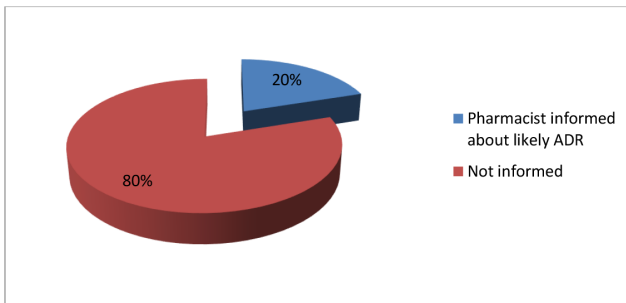


Figure 2: Pharmacist informed patients about ADR of their medications.

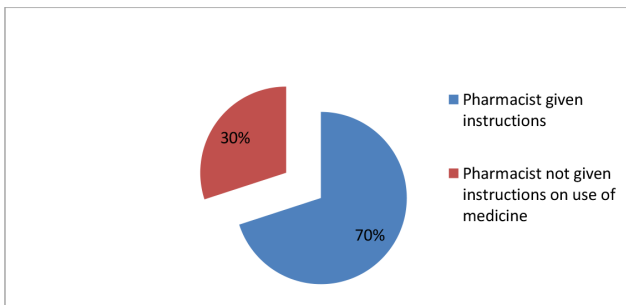


Figure 3: Pharmacist given instruction on their use of medicine.

Table 2: Educational qualification and awareness on Pharmacovigilance		
Educational qualification	no of participants (n= 50)	No of respondents aware about Pharmacovigilance
Primary education	15	3
High school	21	7
Graduates	14	12

Pharmacovigilance awareness (24%) was observed with secondary or tertiary educational status compared to those with lower educational qualification (Table 2). 11 (22%) patients had heard of the term “Pharmacovigilance” through the social media platform (Table 3).

Table 3: sources of awareness on Pharmacovigilance.		
Source	no of participants	Frequency (%)
Social media	11	22
Internet	5	10
Newspaper	3	6
Television	2	4
Radio	1	2

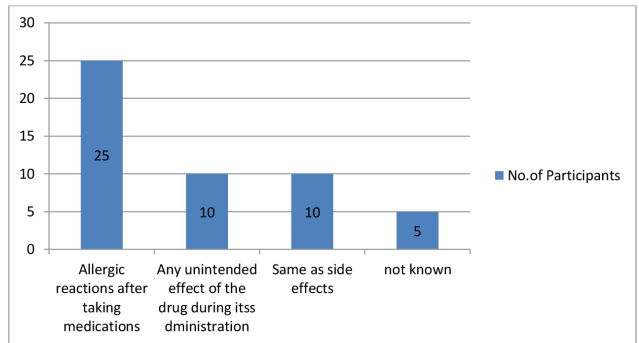


Figure 4: Patients understanding on ADR.

Table 4: Adverse drug reaction practice among patients.		
Adverse drug reaction reporting practice among patients	No of patients (N)	Frequency (%)
Patients Experienced any unexpected/expected reaction after taking medications	15	30
Informed about the ADR to physician?	10	20

Sources of awareness on Pharmacovigilance

Ten (20%) had knowledge about short message service (SMS) alert short code for reporting experienced ADRs, through advertisement and online source. 2 (4%) respondents have heard of ADR PvPI app through internet. But they were not aware about the ADR Reporting center in the hospital. 96% were not heard about ADR PvPI App for reporting ADR (Figure 4). 4% were heard about the ADR PvPI app for self reporting ADR and their source of knowledge were social media.

Adverse Drug Reaction Reporting Practice among Patients

All the participants (100%) were not aware about the Pharmacovigilance centre of the hospital and no one yet reported ADR to Pharmacovigilance centre. No out patients were not ever been trained on ADR reporting. 30% of patients experienced any unexpected reactions after taking medications. Among the 15 patients experienced ADR only 10 patients were reported it to their physician (Table 4).

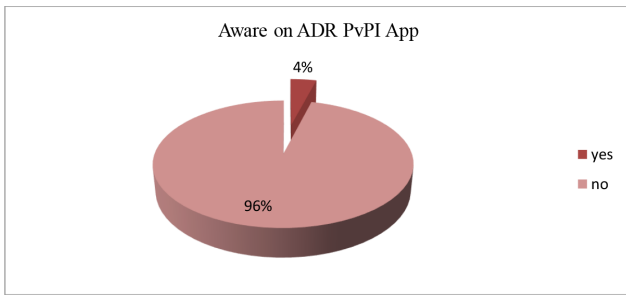


Figure 5: out patients awareness about ADR PvPI App.

Table 5: Reasons for under reporting ADR by the patients.

Reasons why patients do not report experienced ADR	No of patients	Frequency %
Difficulty in travelling	1	20
Rush in the hospital	1	20
Not consider ADR reporting important	3	60
Others	0	0



Figure 6: Patient information leaflet.

Table 6: Preferred method of ADR reporting by the patients.

Preferred methods of ADR reporting	No of patients	Frequency %
Phone call	8	16
Directly reporting to physician	40	80
Filling medicine side effect report reporting form	2	4

Reason for under reporting ADR by the Patients

Suggested reasons for non-report of experienced ADRs included ignorance of the importance of ADR reporting, as well as unserious nature of the ADRs, Rush in the hospital is another reason for not reporting ADR Table 5.

Preferred methods of ADR reporting by the patients

Most of the patients prefer direct reporting to the physician see Table 6.

DISCUSSION

This cross-sectional study was conducted to evaluate the knowledge and perception towards ADR among out patients. 50 eligible participants were included in this study. Knowledge and attitudes among respondents differ with different demographics characteristics. Study participants were aged between 18 to 70 years with equal gender distribution. Regarding educational qualifications 15 (30%) having primary education, 21(42%) were educated upto high school and remaining 14(28%) were graduates. Regarding their occupation, 24% of them work at private sector, 20% work at public sector, 46% of them are unemployed and the remaining 10% were those occupied in other jobs. Most of them have co morbid conditions like hypertension, diabetes, thyroid, hyperlipidemia. According to the study onducted by Bassi *et al.* Patients with comorbidity were three times more likely to have adverse drug reaction than those without comorbidity.⁶ About 35(70%) respondents used to take medications without prescriptions which include antibiotics, medications for fever, cough and cold (Table 1). over the counter medicines are considered as safe, but they can also cause ADR. This was supported by the study conducted by Bukic J *et al.*⁷ More over here irrationally patients were dispensed with antibiotics which is not coming under OTC medications. About 40% participants are taking medicines other than allopathy which include ayurveda, siddha, unani and homeo medicines (Table 1). Integrative medicine may leads to drug interaction and adverse effects.⁸ Patients were not aware about the same. About 52% of patients were not aware about their medications and its uses (Figure 1). More patients reported they had received counseling from pharmacists (70%) regarding their medication use (Figure 3). But 80% of the patients were not informed about the possible ADR of drugs by pharmacist (Figure 2). Pharmacist have a keyrole in preventing ADR among outpatients. In a study conducted by Schnipper JL *et al.* it shown that Pateint counseling is associated with a lower rate of preventable adver effects among outpatients.⁹

Under reporting is a major problem in ADR Reporting program. It creates a negative impact on Public Health.⁵ All the participants were not aware of the ADR Reporting center established in the hospital. Hence they have not reported any ADR so far due to lack of awareness. Only few of them are aware about ADR PvPI Application. They can also use help line number 1800-180-3024 to report ADR.

Regarding knowledge about ADR, 50% participants responded that ADR is an “allergic reactions after taking

medications”, 20% clearly understood ADR as “Any unintended effect of the drug during its administration” and 20% considered ADR “same as side effect”, and 10% not all know about ADR (Figure 4). This is contrary to the study by Joshi *et al.*¹⁰ where majority of the patients understood that ADR is same as side effects.

Regarding awareness on Pharmacovigilance Most of the participants, about 56% were not aware about Pharmacovigilance. In which better pharmacovigilance awareness (24%) was observed with secondary/tertiary educational status compared to those with lower educational qualification (Table 2). This was similar to the study by adisa *et al.*¹¹ Their source of knowledge was social media (22%), internet (10%), news paper (6%), television (4%) and radio (2%) Table 3. The role of social media in pharmacovigilance has been gaining in interest, it include social media sources such as twitter and facebook. A review article published in British journal of clinical Pharmacology explicate the influence of social media in Pharmacovigilance system.¹² Utilization of social media in pharmacovigilance system such as ADR discussion and reporting is a future scope, but it require careful observation from a regulatory and ethical concept.

Ten (20%) patients had knowledge of the short message service (SMS) alert short code for reporting experienced ADRs, through advertisement and online source. About 96% were not heard about ADR PvPI App for reporting ADR (Figure 5), 4% were heard about the ADR PvPI app for self reporting ADR and their source of knowledge was social media. Eventhough Govt of india launched the ADR PvPI app in 2017, still people are unawre about it. The app enabling all health care professionals and consumers to instantly report ADR.¹³ All the participants (100%) were not aware about the Pharmacovigilance centre of the hospital and no one yet reported ADR to Pharmacovigilance centre. The previous year record of the Pharmacovigilance centre of the institution reveals that all the ADR reported were from IP patients and it is reported by health care professionals only. It is the only regional Pharmacovigilance center in malappuram, kerala. Out patients reflect the community. This indicates that it is high time to impart education and training among the public. No out patients were not ever been trained on ADR reporting. 30% of patients experienced adverse reactions after taking medications. Among the 15 patients experienced ADR only 10 patients were reported it to their physician (Table 4). The reasons why patients did not report the experienced ADRs were ignorance of the importance of ADR reporting (60%), Rush in the hospital (20%) and difficulty in travelling (20%) see Table 5. Most of the patients prefer direct reporting to the physician (Table 6). So to improve pharmacovigilance system

patients should be familiar with available ADR reporting system. All the participants were educated about ADR reporting system with the help of Patient information leaflets (Figure 6) and they were trained on using ADR PvPI mobile application for self reporting ADR. All (100%) the respondent agree to report to physician/ADR Reporting center on occurrence of ADR in future. They agree that it is beneficial for people for ensuring their safety.

CONCLUSION

This study provides a baseline data about the knowledge of ADR and Pharmacovigilance system among patients visiting an outpatient departments at multi super speciality hospital. Outpatients demonstrated low level of knowledge about ADRs and Pharmacovigilance concept. Practice of ADR reporting were also negligible; only a few patients reported the experienced ADRs. It indicates the need of education and training on Pharmacovigilance concept among outpatients. In case of inpatients once ADR occur after administration of medication health care professionals are available to find and report the ADR on the same. But in out patients they should have some basic knowledge about likely ADR, especially those who are taking medications for chronic diseases and those who take concomitant alternative therapy. Govt. Of india launched ADR PvPI app for ADR reporting but most of the patients were not aware about it, and they don't know how to use this app for self reporting ADR. By providing patient information leaflets and a hand on training on use of ADR PvPI app we could create certain level of awareness among out patients. The hospital is established with ADR reporting centre but all the study participants were not aware about the same. It implies that the concept of Pharmacovigilance is still far from outpatients and general public. Conducting educational programs and providing an encouraging environment for ADR reporting will definitely increase ADR reporting rates and support Pharmacovigilance activities.

Strengths of the Study

Patient reporting make an important contribution to drug safety. Most of the studies covered knowledge and perception toward ADRs among various health care Professionals. But studies on awareness among out patients are limited. Patients safety should begin from them. In case of inpatients health care professionals are always available to identify and report the ADR once it occur after administration. But it is a different situation in terms of outpatients. Patient informational leaflets were distributed to all the participants. Investigators trained Patients on use of ADR PvPI app for self reporting ADR.

Limitations of the Study

Patients were from single center so results may be difficult to generalize to other populations of the country. There may be difference in the knowledge and perspective of people in a developing country like India and people in other developed countries. The study participants were from Kerala and the result may not be generalizable to patients from other states. Involving more patients from other states would have given a better understanding about the knowledge and perception of ADR among patients across the country and community. We were unable to interview and educate more people as the study period was in the time of COVID outbreak. So sample size obtained was small.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

ADR: Adverse drug reactions; **PvPI:** Pharmacovigilance Programme of India.

SUMMARY

Knowledge and perception towards ADR reporting was evaluated by using questionnaire prepared. The study reveals 100% unawareness among outpatients representing public health about the regional pharmacovigilance centre at the institution they visited frequently. Patients were educated about ADR reporting with the help of a patient information leaflet prepared (Figure 6). They were trained

on use of ADR PvPI app for self-reporting ADR.

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