Research Article

Evaluation of knowledge and perception toward adverse drug reactions among patients visiting tertiary-care teaching hospital

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Abstract

Background: Adverse drug reactions (ADRs) constitute important cause of morbidity and mortality affecting all age groups. Most of the studies in past have explored and reported knowledge and perception toward ADRs among health-care professionals, pharmacists, and medical students. But studies on awareness among patients are limited. To improve understanding of ADR and its reporting, it is important to find out the same among patients. **Aims and Objective:** To assess knowledge and perception toward ADR among patients visiting tertiary-care rural hospital, and to sensitize patients on ADR reporting system. **Materials and Methods:** This observational study was conducted at tertiary-care teaching hospital and 150 patients were selected randomly. Demographic details of respondents were noted and questionnaire regarding knowledge and perceptions was given to fill up. Data were analyzed by using descriptive statistics. **Result:** Demographic analysis showed that 59% patients were men, 56% were from rural areas, and 45% were graduates. Regarding knowledge about ADR, 78.6% patients were aware that medicines can cause ADRs and 33% had experienced side effects in past. None of the respondents were aware of ADR reporting center. Regarding perceptions toward ADR, 86.7% agreed to report ADR in future and 56% respondents believed ADR reporting may strengthen the patient safety. According to 70% patients, awareness campaign is the best way to educate them regarding ADR. **Conclusion:** Educational interventions are needed to improve awareness among patients regarding importance of ADR reporting.

KEY WORDS: Knowledge; perception; adverse drug reactions

Introduction

The World Health Organization defines an adverse drug reaction (ADR) as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological functions."[1] Side effects are unwanted but often unpredictable effects that occur at therapeutic doses and as a part of adverse reactions. They can be predicted from the pharmacological profile of a drug and are known to occur in a given percentage of drug recipients.[1] ADRs constitute an important cause of morbidity and mortality affecting all age groups.[2–4]

The Central Drugs Standard Control Organization (CDSCO), New Delhi, India, under the aegis of Ministry of Health and Family Welfare, Government of India, has initiated a nationwide pharmacovigilance program in July 2010 for monitoring ADR in the country to safeguard public health.[5] Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.[6]

Department of Pharmacology at Pramukhswami Medical College (PSMC), Gujarat, India, is one of the peripheral center for reporting of ADR.[7] All regional pharmacovigilance centers report

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ADRs to the national center and the final report is sent to the Uppsala Monitoring Centre in Sweden, a center for international service and scientific research toward patient safety.[8]

Spontaneous reporting of ADRs has played a major role in the detection of unsuspected, serious, and unusual ADRs previously undetected during the clinical trial phases. However, under-reporting still remains a major obstacle in the complete success of pharmacovigilance program.[9,10] This high rate of under-reporting is a matter of great concern, the reasons for which may be many.[11] This can delay detection of serious ADRs and consequently have a major negative impact on the public health.

Most of the studies in the past had explored and reported knowledge and perception toward ADR among health-care professionals, pharmacists, and medical students.[12,13] But studies on awareness among patients are limited.[14] Hence, this study aimed to find out the knowledge and perception toward ADR among patients visiting a tertiary-care teaching hospital.

OBJECTIVE

1. To assess knowledge and perception toward ADR among patients visiting a tertiary-care teaching hospital.
2. To sensitize patients on ADR reporting system.

Materials and Methods

This was a cross-sectional, observational, questionnaire-based study conducted at tertiary-care teaching hospital during September to October 2014. A prevalidated 12-item questionnaire containing open and close-ended questions regarding knowledge and perception toward ADRs was developed after referring previous studies conducted about pharmacovigilance and consumer pharmacovigilance.[14–16] The questionnaire was modified according to regional need and translated into vernacular (Gujarati) language. It was consensually validated by faculty members and then pretested on 10 patients.

The study was approved by institutional human research ethics committee of PSMC and waiver of written informed consent was obtained as the questionnaire was made anonymous. Fifty patients from each area (i.e., waiting area near Medicine outpatient department, outpatient Laboratory collection, and Pharmacy of Shree Krishna Hospital) were selected randomly on daily basis for 1 h. Inpatients and pediatric patients were excluded. Study purpose and research hypothesis were explained to patients. Respondents were explained about the procedure of filling the questionnaire and 10 min were allotted to them to fill up.

Questionnaire:

- Do you know whether medicines can cause side effects?
- Have you ever experienced any side effect after taking a medicine?
- Have you ever seen any side effect after taking medicine in other person?
- Have you ever reported an ADR?
- Are you taking any medicine other than modern medicine?
- Are you aware there is an ADR reporting center at this institute?
- There is an ADR reporting center in this institute would you like to report?
- What do you do when any side effect occurs to you due to consumption of any medication?
- In your opinion who is qualified to report ADR?
- According to you what could be the purpose of ADR reporting?
- Do you think the ADR reporting system is beneficial to public?
- According to you, which is the best way to educate patients regarding ADR reporting?

Basic personal information such as gender, age, educational qualification, their addiction, and whether the respondent was originally from a rural or urban area were noted. The data were expressed as mean ± SD and percentages. The data collected from the questionnaire was entered into SPSS software. χ^2-Test was used to see the association between variables. A p-value of less than 0.05 indicated statistical significance.

Results

In this study, 150 patients agreed to participate by giving verbal informed consent and 30 patients declined. Of 150 respondents, 88 (59%) were men and 62 (41%) were women. Eighty-four (56%) respondents belonged to rural areas whereas 66 (44%) were from urban areas. The age group ranged from 18 to 75 years with a mean age of 41.8 (SD = 15.3) years. Maximum (37; 25%) respondents aged between 31 and 40 years. Twenty-one (14%) respondents had education up to 1–7 standards, 61 (41%) were educated up to 8–12 standards, and remaining 68 (45%) were graduates.

Regarding knowledge about ADR, 118 (78.6%) respondents were aware that medicines can cause side effects; of them, 86.4% were from urban areas whereas 72.6% were from rural areas. The difference between awareness of respondents from urban and rural areas was statistically significant (p = 0.04) [Figure 1]. Statistically significant increasing trend in awareness as per education level was observed ($p < 0.001$) [Figure 2]. No significant difference was observed in this awareness of respondents from different age groups and gender.

Twenty-three (15%) respondents had answered about what do they understand by the term side effect and majority of them gave example of skin rashes.

Of total, 49 (33%) respondents had experienced side effects in the past after taking medicine and 59 (39.3%) had observed the same in others. None of the participants were taking any other medicine apart from modern (allopathic) medicine whereas only 45 (30%) had some knowledge about alternative (ayurvedic/homeopathic) medicines. None of the patients were aware that alternative medicine can also cause ADR.

None of the respondents were aware that there was an ADR reporting center available at this institute and they did not report any ADR till now.

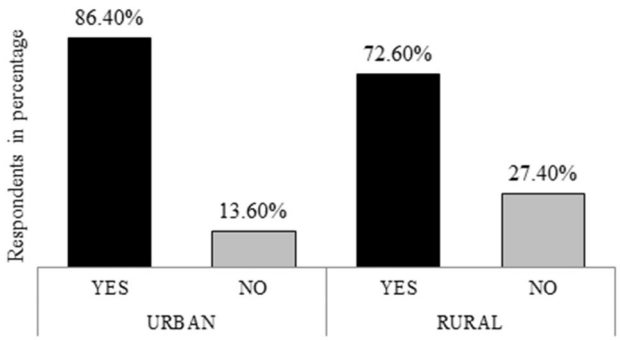

Figure 1: Respondents' awareness: whether medicines can cause side effect.

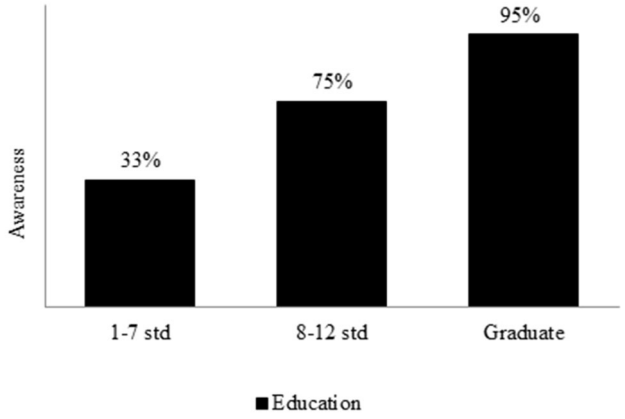

Figure 2: Respondents' awareness as per education level: whether medicines can cause side effect.

All (100%) respondents opined they should contact physician on occurrence of an ADR [Tables 1–3].

Of 150 respondents, 144 (96%) believed that reporting of ADR is beneficial for people. Regarding perceptions toward ADR, 130 (86.7%) respondents agreed to report ADRs at this institute in future when they come across the ADR.

Table 1: Respondents' opinion about the person qualified to report an ADR

In your opinion who is qualified to report ADR?	Response
Medical practitioner	128 (85.33%)
Nurses	2 (1.33%)
Pharmacist	1 (0.67%)
Patient/consumer	7 (4.67%)
All of the above	12 (8%)

Table 2: Respondents' perception about the purpose of ADR reporting

According to you what could be the purpose of ADR reporting?	Response
To strengthen patient safety	84 (56%)
To prevent recurrence of ADR in the same person	58 (39%)
Just for requirements	0
To help the doctor for easy diagnosis	8 (5%)

Table 3: Respondents' perception about the best way to educate patients regarding ADR reporting

According to you, what is the best way to educate patients regarding ADR reporting?	Response
Awareness campaign	105 (70%)
By reading packet insert	1 (0.67%)
Published articles regarding ADR in newspapers	4 (2.67%)
By talking with prescribing physician	40 (26.67%)

Discussion

Most of the studies in the past had explored and reported knowledge and perception toward ADR among health-care professionals, pharmacists, and medical students as study population; but studies on awareness among patients are limited.[12–14] This study was conducted to find out awareness of ADR among the patients who actually experienced the same.

Majority of respondents belonged to rural areas. This study showed that majority study patients understood ADRs as side effects that can occur after taking any medicine. Study conducted by Jha et al.[14] had also showed similar results. This study found that respondents from urban areas were more aware about ADR than those from rural areas. Increasing trend in awareness as per education level was observed.

Approximately one-third of respondents had experienced side effects after taking a medicine in the past. A study conducted by Elkalmi et al.[15] in Malaysia showed same results. In this study, irrespective of their educational background, participants did not report any experience of side effects due to their medications.

Underreporting is a major threat to success of pharmacovigilance program and is a matter of great concern. None of the respondents were aware of the fact that there was an ADR reporting center at this institute and they did not report any ADR till now. Lack of awareness among them is also one of the reasons responsible for underreporting of ADR. This also highlights that patients might not have proper knowledge about the adverse effects of their prescribed medications. A study conducted in the United Kingdom reported poor knowledge of the potential side effects of their medications.[16] Spontaneous reporting of ADR can be significantly increased if the patients are aware of ADR and its reporting system. It is, therefore, important to give adequate and sufficient information about their medications and to inform the patient about the

reporting of any unexpected symptoms to their doctors or pharmacists. It is necessary to promote safe use of medicines.

Majority of the respondents had perception that ADR reporting can improve patient safety and prevent recurrence of ADR. Maximum number of respondents had positive attitude toward ADR reporting agreed to report ADRs at this institute in future when they come across the ADR. The common view shared by most of (96%) respondents that reporting of ADR is beneficial for people whereas a study conducted in Nepal also showed similar results regarding this.[14]

The patients believed that knowledge about adverse reactions would protect them from negative effects of the drugs. In this study, according to most of the patients, information regarding ADR and its reporting can be given by awareness campaign and prescribing doctors. While similar study showed that majority of participants opined that consultation with pharmacist is the best way to educate patients.[14] Sources of information such as campaigns, the Internet, newspapers, and television seem to play a key role in increasing awareness of the pharmacovigilance program and existence of adverse drug reaction monitoring centers.

Studies conducted by Ahmed et al.[17] and Palaian et al.[18] in Malaysia have shown the need for developing a separate ADR reporting form for consumers. ADR reporting form for consumers is available in India since August 2014, but educating consumers about the significance and importance of ADR reporting is required.[19] They should be encouraged to fill consumer ADR form and those reports should be addressed appropriately. They can also directly mail the form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com or can call on helpline number 1800-180-3024 to report ADR. This view is being supported by a review of published literature and international experience.[20]

A study from France in 2002 reported that consumers were asked to make telephone calls for registering the side effects to pharmaceutical companies and the companies entered these reports to drug safety database.[21] Greater awareness among consumers will reduce the harmful effects and suffering caused by medicines.[22] Consumer reporting can promote consumer rights and equity.[23] The Yellow Card Scheme is the UK system for collecting information on suspected ADRs to medicines. The scheme allows the safety of the medicines and vaccines that are on the market to be monitored.[24]

Basically two main domains should be covered in the process of educating patients:

1. Patients should be aware of ADR so that they can recognize any unusual effect of medicine and contact doctor to report the same.
2. Patients should know the existence and importance of ADR reporting system.

Strengths of the Study

Studies to explore and report the knowledge and perception toward ADR among patients are limited and this study is a pioneer in India. An understanding about the current scenario of perception and awareness of pharmacovigilance among consumers in India was obtained.

Limitations of the Study

Patients were from single center so results may be difficult to generalize to other populations of the country.

Conclusion

This study provides a baseline idea about the knowledge and perception toward ADRs among patients visiting an outpatient department at tertiary-care teaching hospital in India. Respondents were unaware about the process of reporting ADRs, reporting by the consumers, and the possible benefits to them by doing so. There is a strong need to do the work to make consumers aware about the same. Educational interventions are needed to improve awareness among patients regarding importance of ADR reporting.

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