Original Article

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Pharmacology Section

Pharmacovigilance Knowledge among Patients at a Teaching Hospital in Lalitpur District, Nepal

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ABSTRACT

Background: Consumer's knowledge and perception towards adverse drug reactions (ADR) can play an important role in ensuring a healthy lifestyle and proper use of medicines.

Aims: This study aimed to assess the knowledge and perception towards pharma covigilance in general and consumer pharma-covigilance in particular among out patients in a teaching hospital of Nepal.

Settings and Design: A descriptive cross-sectional study using qualitative and quantitative methods was carried out from 1st May to 3 June 2013.

Methods: Every fifth patient visiting the outpatient pharmacy was interviewed using a semi-structured questionnaire. Gender, age, educational qualification, profession and ethnicity were noted. Twenty-three patients were interviewed.

Results: There were 10 males and 13 females. The age of the respondents ranged from 11 to 50 years with a mean age of 27.8 (SD = 5.61) years. Seven (30.43%) respondents were students studying in different levels. Thirteen (56.52%) participants were from the Newar community. Majority of the patients (86.95%) knew ADRs may be caused by the medicines they consume and 18 (78.26%) were of the opinion that ADRs should be reported to doctors and other health care professionals including pharmacists.

Conclusion: Knowledge and perception were low in certain areas. There is a need for educational interventions for improving the awareness of patients and general public for ensuring medicine safety and promoting rational use of medicines.

Keywords: Adverse drug reaction, Consumers, Medicine safety

INTRODUCTION

(ADRs) are a major cause of morbidity and mortality worldwide [1,2]. The World Health Organization (WHO) defines an 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' [3].

In Nepal, the prevalence of ADRs was found to be 0.86%, the male to female ratio to be 0.85 and 10.81% of the ADRs were considered to be severe [4].

Pharmacovigilance was initiated in Nepal in 2004 by the Department of Drug Administration, The National Drug Regulatory Authority of Nepal, which operates the national pharmacovigilance centre and coordinates with the regional centres [5]. Nepal became a member of the International Pharmacovigilance Program [6]. KIST Medical College joined the programme as a regional centre from July 2008. There are six regional pharmacovigilance centres till now in Nepal which report ADRs to the national centre and the final report is sent to the Uppsala Monitoring Centre in Sweden, a centre for international service and scientific research towards patient safety [7].

Reporting of ADRs in Nepal is done on a voluntary basis by doctors, pharmacists, nurses, health assistants and other health care professionals. The pharmacovigilance program is still in infancy, has limited coverage and under-reporting is common.

METHODS

Study population and period: Patients visiting the outpatient pharmacy from 1st May to 3rd June 2013 were interviewed by the Pharm. D. interns posted there.

Study design: descriptive cross-sectional mixed type (qualitative and quantitative) survey.

Study area: KIST Medical College, Imadol Village Development Committee (VDC), Lalitpur district, Nepal.

Study population: Twenty three patients visiting the outpatient pharmacy of KIST Medical College Teaching hospital to purchase medicines after attending the outpatient department of the hospital were selected for this study.

Sampling method: The method used was systematic random sampling, i.e., every fifth patient visiting the outpatient pharmacy was interviewed using the questionnaire.

Development of the questionnaire: The questionnaire was developed after consulting previous studies conducted about pharmacovigilance and consumer pharmacovigilance [8,9]. The questionnaire was translated into Nepali language. The data collected were analysed manually after separating the open ended and close ended questions.

Demographics: Basic personal information like gender, age, ethnic/caste group, educational qualification, their profession and whether the respondent was originally from a village or town was noted.

Informed consent: Written informed consent was obtained from all participants. They were informed that their participation in this study was voluntary based on their interest and non participation would not affect the care they will receive.

Ethical approval: The study was approved by Institutional Research Committee of KIST Medical College.

RESULTS

Twenty-three of the 31 respondents participated. The overall response rate was 74% (10 males and 13 females). The age group ranged from 11-50 years with a mean age of 27.8 (SD = 5.61) years.

Seven (30.43%) respondents were students studying in different levels, 6 (26.08%) were housewives, 3 (13.04%) of them were businessmen, 4 (17.39%) were teachers, 1 (4.34%) was doing government service and two participants did not mention their

profession. Thirteen (56.52%) participants were from the Newar community, 5 (21.73%) were Brahmins, 2 (8.68%) Chetris and 2 (8.68%) were from other communities. Four (17.39%) participants had not completed class ten, 6 (26.08%) had passed the school Leaving Examination Certificate (SLC), 8 (34.78%) had an intermediate degree which can be achieved after passing SLC examinations and only 5 (21.73%) had completed bachelor level of studies.

[Table/Fig-1-7] describe the response rates of the respondents for each statement used in the questionnaire. Respondents were explained that they can choose more than one option for their views, opinion and their understanding about pharmacovigilance and consumer pharmacovigilance. Hence, the total number of responses may be greater than the total number of patients.

Harmful response experienced after taking a medicine at normal doses	5(21.7%)
Side effects that you have experienced after taking medication	12(52.17%)
Any desired effects that you experience after taking a medicine	1(4.34%)
Don't know	7(30%)
An example of adverse drug reaction	
Sleepiness after taking cough syrup	8(34.78%)
Developing diarrhea after taking any antibiotic	6(26.08%)
Accident after taking cough syrup	3(13.04%)
Don't know	7(3.04%)

[Table/Fig-1]: Participants' understanding about an adverse drug reaction

To strengthen drug safety	12(52.17%)
To prevent recurrence of adverse drug reactions among other people	4(17.39%)
Just to fulfill requirements	0(0%)
To help the doctor easily diagnose the illness	3(13.04%)

[Table/Fig-2]: Participants' perception about the purpose of adverse drug reaction reporting

Children	4(17.39%)
Adults	1(4.34%)
Elderly	5(26.08%)
Anyone	12(52.17%)
Don't know	4(17.39%)

[Table/Fig-3]: Participants' knowledge about vulnerable group of people who are more likely to develop ADRs

Doctor	18(78.26%)
Pharmacists	4(17.39%)
Nurse	1(4.34%)
Department of drug administration	1(4.34%)

[Table/Fig-4]: Participants' opinion about the person to whom ADRs should be reported

Computerized	1(4.34%)
Filling in the form manually	1(4.34%)
Orally reporting to the physician	15(65.21%)
Face to face reporting at the adverse drug reaction reporting centre	2(13.04%)
Don't know	3(13.04%)

[Table/Fig-5]: The method/s of reporting adverse drug reactions can be

Consultation with the pharmacist	13(56.52%)
Label on medication	8(34.78%)
Awareness campaign	2(8.69%)
Published articles on ADRs in the newspaper	2(8.69%)
Others	1(4.34%)

[Table/Fig-6]: Respondents' perception about the most effective way to educate the consumer regarding ADR reporting

Do you think that the adverse drug reaction reporting system is beneficial to the public?	
a. Yes	22 (95.65%)
b. No	1(4.34%)
Do you think is it necessary to set up an adverse drug reaction reporting system for consumers at KIST Medical College, Imadol?	
a. Yes	20(86.95%)
b. No	3(13.04%)
If we develop a consumer adverse drug reaction reporting centre at KIST Medical College, would you like to report by coming there?	
a. Yes	23(100%)
b. No	0
Is the problem of adverse drug reaction severe in Nepal?	
a. Yes	22(95.65%)
b. No	1(4.34%)
Are you keen to know about possible adverse drug reactions that may be due to the medicine you consume?	
a. Yes	20(86.95%)
b. No	3(13.04%)

[Table/Fig-7]: Participants' responses to statements regarding consumer pharmacovigilance

DISCUSSION

Half the study patients understood ADRs as side effects that can occur after taking any medicine during their life time period. (WHO) defines an 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 [3]. Side effects are a part of adverse reactions. Side effects are unwanted but often unpredictable effects that occur at therapeutic doses. They can be predicted from the pharmacological profile of a drug and are known to occur in a given percentage of drug recipients [10].

In Nepal, there are various ethnic groups whose members have a common heritage, often consisting of a common language, a common culture often including a shared religion. Maximum number of patients was from the Newar community which might be an influence of the place where this hospital is situated.

In a study done in 1998, it was seen that ADRs to prescription only and over-the-counter (OTC) drugs resulted in the death of more than 100,000 Americans and seriously injured an additional 2.2 million each year [11]. This finding highlights the need for this type of study in Nepal where self medication is common mostly due to lack of qualified health care professionals in most areas of the country [12,13].

About half the participants agreed that any group of people can suffer from ADRs including the elderly, children and adults. Respondents were aware that if an ADR occurs then the suspected medicine has to be stopped and they should consult with doctors and other health care professionals. Majority of the patients 20 (86.95%) knew that ADRs may be caused by medicines.

Majority of the patients knew that ADRs should be reported to doctors, 18 (78.26%) to pharmacists and 4 (17.39%) to other health care professionals. Many patients did not know where and how to report ADRs. A study indicates the difficulties being faced by developing countries, where there is lack of trained pharmacists and personnel for safe practice of medicines [14].

Maximum number of respondents 22 (95.6%) had positive attitude towards ADR reporting and pharmacovigilance. These could contribute to preventing recurrence of such ADRs. Most effective way of reporting ADRs for consumers was by consulting with pharmacists and drug sellers in the community. This finding was supported by studies done in Nepal, which demonstrate the need

for qualified pharmacists in the community settings and community pharmacies to help prevent any medicine related problems [12, 14]. Despite the low literacy level (60.3%), poor economic status and other problems, consumer pharmacovigilance could play an important role in the country [14]. The data from consumer reporting will ensure reports are not only from a few doctors, but also from observations volunteered by a set of people of different levels of competence, cultural backgrounds and ethnicity who think their experiences worthy of reporting [14].

Low literacy rate may affect the public attitude towards direct to consumer drug advertising (DTCA) and can influence their use of medicines including promoting self medication. Though DTCA is not legal in Nepal, some herbal preparations are being advertized via television to the consumers. Twenty patients (86.95%) were willing to report ADRs by visiting KIST Medical College, once the centre is established at KIST Medical College. Development of consumer pharmacovigilance centre at KIST Medical College will be an important step towards initiation of consumer pharmacovigilance in Nepal. At present, there are no centres for patients and their relatives who use medicines in their day to day life to report ADRs.

A study done in Malaysia has shown the need for developing a separate ADR reporting form for consumers [8,9]. Some patients presumed that every hospital should have a provision for reporting ADRs by the consumers and those reports should be addressed appropriately. This view is being supported by a review of published literature and international experience which encourages reporting of ADRs by the patients to help see mass overcome many drug induced problems [15].

Patient's perception about the importance of ADR reporting. The common view shared by the patients was knowledge about adverse reactions would protect them from negative effects of the drugs. Unfortunately, the lack of centres and information sources from where consumers can obtain unbiased, impartial knowledge about medicines may be another limitation which can influence the practice of medicine use among consumers.

Developing such a centre for consumer pharmacovigilance at KIST Medical College is a great challenge but the authors are hopeful. Developing a separate ADR reporting form for consumers, and educating them about the significance and importance of ADRs would be helpful.

Consumer pharmacovigilance may be a good initiative for the DDA, as the regulator has an important role in ensuring medicine safety. The positive support from the DDA for initiation of this service and framing appropriate guidelines would be highly appreciated.

Strengths of the study: This type of study is a pioneer of its type in Nepal. An understanding about the current scenario of perception and awareness of pharmacovigilance among consumers in Nepal was obtained.

LIMITATIONS OF THE STUDY

Small sample size.
Results may be difficult to generalize to other populations.

Attitude of the healthcare professionals about pharmacovigilance has not been studied.

CONCLUSION

This study provides a baseline idea about the perception and knowledge towards pharmacovigilance among patients visiting an outpatient pharmacy at a teaching hospital in Nepal. Respondents showed fair awareness and knowledge about adverse drug reactions, its management and reporting among the consumers. They were unaware about the process of reporting ADRs and the possible benefits to them by doing so. The study explores a newer concept of promoting consumer pharmacovigilance in Nepal.

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