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Original Research Article

Study of proportion and pattern of adverse drug events among patients coming to health centers in urban and rural areas

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ABSTRACT

Background: Adverse drug events (ADE) are rated as the fifth leading cause of death among all diseases. Approximately 5-8% of all hospitalization worldwide is due to ADE. The present study was conducted with the aim of analyzing the pattern of Adverse Drug events in patients coming to urban and rural health care centres, their manifestations and severity.
Methods: The study type useful in this study was cross sectional study. This method is helpful to find the exact duration of occurrence of ADE after administration of drug and to know what kind of adverse event patient is suffering from.
Results: There are many studies done in peripheral health care centres regarding ADE in India. In our study, out of 250 patients, 125 were from urban and 125 were from rural. Among the 125 patients from urban 3.2% (4 cases) adverse drug events- reported. Among the 125 patients from rural 4% (5 cases)adverse drug events- reported.
Conclusions: This study provides a baseline idea about the knowledge and perception toward ADEs among patients visiting an outpatient department at urban and rural hospital in India. Respondents were unaware about the process of reporting ADEs, 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 ADE reporting.

Keywords: Adverse drug events, Peripheral health care centres, Urban and rural population

INTRODUCTION

From earliest times, pharmaceutical formulations have been recognized as potentially dangerous. Public and professional concern about this matter first arouse at late 19thcentury. In 1922, the first case of jaundice associated with the use of salvarsan, an organic arsinalic used in the treatment of syphilis, was enquired.

Later on many case of adverse effect of drugs have been reported. Like Steven Johnson syndrome for sulfa drugs. Teratogenic drugs during pregnancy. Death was also reported later on due to ADE. Many cases of ADE have been reported in India. Adverse event monitoring and reporting are very important in identifying the adverse events trends in local population (Phatak and Nagari, 2003).[1]

National pharmacovigilance program monitors adverse drug events and helps to improve the safety of medicines prescribed. Health and Family Welfare had initiated the National Pharmacovigilance Program (NPP) on 1st January 2005 which was further revived in July 2010. This program is overseen by the Central Drugs Standard Control Organization (CDSCO), New Delhi (Vikas et al, Amrita and Singh).[2] Under-reporting is a major concern

in NPP, especially those dependent on spontaneous reporting. So there is a need to study ADRs seriously to create awareness about ADRs among patients to motivate health care professionals in the hospital to report ADRs to minimize the risk. Early detection, evaluation and monitoring of ADR are essential to reduce harm to patients and thus improve public health (Pirmohamed and Brecken, 1998).[3] Hence the following study is conducted.

According to WHO, Adverse drug event is defined as: "Any injury resulting from medication use, including physical harm, mental harm or loss of function is stated to be adverse drug events."

Objective

- To evaluate the proportion of adverse drug event among patients visiting SRM health care centers in urban and rural areas.
- To describe the pattern and distribution of these adverse drug events.

METHODS

Study population

All patients attending the health centers in urban and rural areas.

Study design

Cross sectional study.

Data collection

- On reviewing of the studies, we planned to have a interview base questionnaire type study.
- The samples are collected accordingly from the patients coming to op, any adverse drug events in this are only reported
- This questionnaire would also help us to know, that the patient suffered adverse drug event at present drug administration or at past
- The exact duration of occurrence of ADE after administration of drug.
- What kind of adverse reaction the patient suffering from, will be observed.

Study duration

The time duration taken for study was from 15th March 2016 to 16th May 2016 (2 Months).

Inclusion and exclusion criteria

The samples are collected accordingly from the patients coming to OP, any adverse drug events in this are only reported.

Inclusion criteria

All patients who have been treated for any condition in the past six months.

Exclusion criteria

Individuals who are not willing to participate in the study.

Consent

Oral consent obtained.

Sample size calculation

The sample size are calculated based on the formula

$(4*p*q)/d*d=248.2$
(~250)

p - Prevalence = 19.2%
q - (100-p) = 80.8%
d – error = 5%

Sample size

At present the sample size is calculated and estimated as 250- Urapakkam- 125 cases**,** M. M. Nagar- 125 cases.

In M. M. Nagar, the number of cases that come per day are 18-20, out of these the cases of ADE are rare

Similarly for Urapakkam, per day we get on average 15-18 cases.

Statistical analysis

The study of proportion and pattern of adverse drug events among patients coming to health centers in urban and rural areas was determined by statistical analysis of age group, gender, frequently used drugs, common adverse drug events and duration of onset of adverse drug events. The statistical tool used to analyze the data was the mean study.

RESULTS

In this study, 250 patients were assessed from both the urban and rural health centre's in 2 months duration, if any experience for adverse drug events.

Age

The patients who came to urban and rural health centre's are categorized according to the age groups. Patients less than and equal to 20 years were 14.4% in both urban and rural centre, 21-50 years were 47.2% in urban centre and 44.8% in rural centre, >50 years were 38.4% in urban centre and 50% in rural centre.

Table 1: Age of population on urban and rural area.

Age	Urban	Rural
1-10	6	5
11-20	12	13
21-30	21	17
31-40	16	22
41-50	22	17
51-60	22	18
61-70	12	19
>70	14	13

Gender

The patients who came to urban and rural health centre's are categorized according to the gender. 51 (40.8%) patients were males who came to urban health centre and 74 (59.2%) were females. 49 (39.2%) patients were males who came to rural centre and 76 (60.8%) were females. In total 100 were males and 150 were females.

Health educational status

The health educational status among the urban and rural population who came to health centre were assessed to know the awareness about adverse drug events. 88 (70.4%) patients who came to urban health centre were educated and 37 (29.6%) were uneducated. 90 (72%) patients who came to rural centre were educated and 35 (28%) were uneducated. In total 178 were aware of adverse drug events and 72 were unaware.

Reason for admission

The commonest reasons for admission as outpatient in urban and rural health centre's were myalgia (urban-25.6%, rural-20%), urinary tract infection(urban-12%, rural-8.8%), hypertension (urban-6.4%, rural-13.6%), trauma (urban-4.8%, rural-10.4%), rashes (urban-3.2%, rural-2.4%), abdominal pain (urban-2.4%, rural-10.4%), diabetis mellitus (urban-5.6%, rural-4%) and others like headache, fever, cough, sinusitis (urban-40%, rural-30.4%).

Table 2: Main causes for admission as outpatient.

Reason	Urban	Rural	Total
Myalgia/LBA	32	25	57
URI	15	11	26
HTN	8	17	25
Trauma	6	13	19
Rashes	4	3	7
Abdominal pain/gastritis	3	13	16
DM	7	5	12
Others	50	38	88

Prescribed by

To know whether the patients who came to urban and rural health centre had taken any drugs on their own or prescribed by the Doctors six months prior to their visit to health centre. The patients who took drug on their own in urban centre were 20.8% and in rural centre were 24%. The patients who took drugs prescribed by the Doctors in both urban centre and rural centre were 72%. The patients who had not taken any drug six months prior to their visit to the health centre.

Table 3: Medications prescribed by doctors/self-prescribed/not taken any drugs.

Prescribed by	Urban	Rural	Total
Self	26	30	56
Doctor	90	90	180
Others	9	5	14

No previous history of any drug intake

To know the patients who had never taken drugs before for any cause among the patient who had not taken any drugs for past 6 months prior to their visit to the health centre. 0.8% patients (1/9) in urban centre and 1.6% patients (2/5) in rural centre.

Table 4: No previous history of drug intake.

No h/o drug intake	Urban	Rural	Total
Past 6 months	8	3	11
Never taken	1	2	3

Drugs taken

The drugs taken by the patients prior to their visit to health centre's are diclofenac (urban-9.6%, rural-7.2%), paracetamol (urban-39.2, rural-36%), CPM/amoxicillin (urban-6.4%, rural-2.4%), pantoprazole (urban-12%, rural-13.6%), amlodipine (urban-12.8%, rural-9.6%), others like hydrocholrthiazides, telmesartan (urban-20%, rural-31.2%).

Table 5: The drugs taken by the patients.

Drugs	Urban	Rural	Total
Diclofenac	12	9	21
Paracetamol	49	45	94
Cpm/amoxicillin	8	3	11
Pantaprazole	15	17	32
Amlodipine	16	12	28
Others	25	39	64

Patients with ADE

Among the total number of patients who came to health centre's, those with adverse drug events were 3.2% in urban centre and 4% in rural centre. Out of this, 0.8% were females patients and 2.4% were males patients who came to urban centre. 2.4% were female patients and 1.6% were male patients who came to rural centre.

Adverse drug events

The commonest adverse drug events presented in the patients who came to the health Centre's were edema (urban-2.4%, rural-2.4%), rashes (urban-0%, rural-0.8%), giddiness (urban-0.8%, rural-0%), diabetes mellitus (urban-0%, rural-0.8%), vomiting (urban-0%, rural-0%), skin changes (urban-0%, rural-0%), any other events or new events (urban-0%, rural-0%).

Table 6: Common ADE presenting in population.

Events	Urban	Rural
Edema	3	3
Rashes	0	1
Giddiness	1	0
DM	0	1
Vomiting	0	0
Skin changes	0	0
Others	0	0

Drugs causing ADE

The commonest drugs which caused adverse drug events in patients are amlodipine (urban-1.6%, rural-0.8%), amoxicillin (urban-0.8%, rural-0.8%), diclofenac (urban-0.8%, rural-1.6%), hydrochlorothiazide (urban-0.8%, rural-0%).

Table 7: Drugs causing ADE.

Drugs	Urban	Rural	Total
Amlodipine	1	2	3
Amoxycillin	1	1	2
Diclofenac	2	1	3
Hydrochlorthiazide	0	1	1

Duration of onset

The duration of onset of adverse drug events from the time of consuming the drugs were within 6 hours (urban-1.6%, rural-1.6%), within 1 day (urban-0.8%, rural-0.8%), within 1 week (urban-0.8%, rural-0.8%), within 1 month (urban-0.8%, rural-0%).

Table 8: Duration of onset.

Duration of onset	Urban	Rural	Total
Within 6 hours	2	2	4
Within 1 day	1	1	2
Within 1 week	1	1	2
Within 1 month	0	1	1

Hospital admission due to ADE

To know the hospital admissions among the patients who came to the health centre's with adverse drug events. Hospital admission for the patients with the events were 3.2% (rural-2.4%, urban-0.8%). Patients having events without any hospital admission were 4% (rural-1.6%, urban- 2.4%).

Table 9: Hospital admission due to ADE.

Hospital admission	Urban	Rural	Total
Admission	1	3	4
No admission	3	2	5

DISCUSSION

There are many studies done in peripheral health care centres regarding ADE in India. In our study, out of 250 patients, 125 were from urban and 125 were from rural. Among the 125 patients from urban centre, 3.2% (4 cases) of adverse drug events were reported. Among the 125 patients from rural centre 4% (5 cases) of adverse drug events were reported. The adverse drug events reported in the patients who came to heath centre were amlodipine causing edema in 1.2% patients, diclofenac causing lid edema in 1.2% patients, Amoxicillin causing rashes in 0.8% patients, hydrochlorthiazide causing diabetis mellitus in 0.4% patients.

Table 10: Result (total no. of events in urban and rural population).

Drugs	Events	Number of events
Amlodipine	Edema	3
Diclofenac	Lid edema	3
Amoxicillin	Rashes	2
Hydrochlorothiazide	Diabetes	1

Most of the studies in the past had explored and reported knowledge and perception toward ADE among health-care professionals, pharmacists, and medical students as study population; but studies on awareness among patients are limited.[4-6] This study was conducted to find out awareness of ADE among the patients who actually experienced the same. Majority of respondents belonged to rural areas. This study showed that majority study patients understood ADEs as side effects that can occur after taking any medicine. Study conducted by Jha et al had also showed similar results.[6] 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 in Malaysia showed same results.[7] 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. Lack of awareness among them is also one of the reasons responsible for underreporting of ADE. 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.[8] Spontaneous reporting of ADE can be significantly increased if the patients are aware of ADE and its reporting system. It is, therefore, important to give adequate and sufficient information about their medications and to inform the patient about the Figure 1, respondents' awareness, whether medicines can cause side effect. Figure 2, respondents' awareness as per education level whether medicines can cause side effect. Table 1, respondents' opinion about the person qualified to report an ADR In your opinion who is qualified to report ADE? Response medical practitioner 128 (85.33%), nurses 2 (1.33%), pharmacist 1 (0.67%), patient/consumer 7 (4.67%) and all of the above 12 (8%) Table 2, respondents' perception about the purpose of ADE reporting. According to you what could be the purpose of ADE reporting? Response to strengthen patient safety 84 (56%), to prevent recurrence of ADE in the same person 58 (39%) just for requirements to help the doctor for easy diagnosis 8 (5%). Table 3: Respondents' perception about the best way to educate patients regarding ADE reporting According to you, what is the best way to educate patients regarding ADE reporting? Response Awareness campaign 105 (70%) By reading packet insert 1 (0.67%) Published articles regarding ADE in newspapers 4 (2.67%). Knowledge and perception toward ADE among patient 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 ADE reporting can improve patient safety and prevent recurrence of ADE. The common view shared by most of (96%) respondents that reporting of ADE is beneficial for people whereas a study conducted in Nepal also showed similar results regarding this.[6] 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 ADE 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.[6] 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 and Palaian et al in Malaysia have shown the need for developing a separate ADE reporting form for consumers.[9,10] ADE reporting form for consumers is available in India since August 2014, but educating consumers about the significance and importance of ADE reporting is required.[11] They should be encouraged to fill consumer ADE 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 ADE. This view is being supported by a review of published literature and international experience.[12] 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.[13] Greater awareness among consumers will reduce the harmful effects and suffering caused by medicines.[14] Consumer reporting can promote consumer rights and equity.[15] The Yellow Card Scheme is the UK system for collecting information on suspected ADEs to medicines. The scheme allows the safety of the medicines and vaccines that are on the market to be monitored.[16] Basically two main domains should be covered in the process of educating patients: 1. Patients should be aware of ADE 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.

CONCLUSION

This study provides a baseline idea about the knowledge and perception toward ADEs among patients visiting an outpatient department at urban and rural hospital in India. Respondents were unaware about the process of reporting ADEs, 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 ADE reporting.

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