ORIGINAL ARTICLE

A Cross-sectional Observational Study of Adverse Drug Reactions among Patients in Nephrology Department at a Tertiary Care Teaching Hospital

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Abstract

Background: The World Health Organization defines adverse drug reaction (ADR) as "A response to a drug, that is noxious and unintended, occurs at doses normally used in humans for the propylaxis, diagnosis, and treatment of disease, for the modifications of physiological function." Clinical pharmacists play an important role in ADR monitoring and reporting, as the majority of serious ADR's occur in a hospital setting and contribute to a significant proportion of hospital admissions. Early detection of the ADR's helps in minimizing and preventing the ADR's by modifying the dose or changing the offending agent. **Aim:** Pharmacovigilance studies are essential in Nephrology and its main aim is to reduce the risk of drug related problems in patients. **Materials and Methods**: This study was Hospital based cross-sectional observational study conducted in Department of Nephrology, Sri Venkateswara Institute of Medical Sciences, South Indian a tertiary care hospital, Tirupati, Andhra Pradesh. This study was approved by the Institutional Research and the Ethics Committee of the hospital. This study used a minimum sample size of 113 participants. **Results:** Out of 113 patients who were treated in nephrology department, 58 (51.32%) patients developed ADRs. Of the 58 patients, 36 (62.06%) are men and 22 (37.93%) are women. Patients of 39–48 (29.31%) age group are mostly affected. Among 58 patients, the causality assessment of 18 patients (31.03) was found to be Possible and the remaining 40 patients (68.96) was found to be Probable. The commonly developed ADRs include "pedal edema, hypokalemia, and maculopapular rash." **Discussion:** ADRs mimic many diseases and result in severe morbidity and mortality, making them a major clinical concern. Adverse medication events are undoubtedly more frequent in hospitalized patients with chronic kidney disease and other comorbidities. **Conclusion:** The present study has generated a useful baseline data regarding ADRs in various categories such as age- and gender-wise distribution of ADRs. By educating the patients about the ADRs, it also contributed to improve the patient's health-related quality of life.

Key words: Adverse drug reactions, chronic kidney disease, comorbidities, hypertension, hypokalemia, nephrology, pharmacovigilance, WHO-UMC, World Health Organization

INTRODUCTION

Adverse drug reactions (ADRs) are a worldwide problem associated with use of drugs for curbing the ailments. ADRs are more susceptible to elderly and hospitalized patients than adult patients.[1] Globally, ADRs are the most important problem representing the one of the leading causes of morbidity and mortality in health-care facilities.[2] Majority of the studies have demonstrated that 0.2–21.7% of hospital admissions occur due to ADR's.[3]

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While the occurrence of ADRs results in a supply of extra economic burden to the patients, their caregivers, and therefore the health-care systems that treat them. The result of drug reaction given for treatment varies from a straightforward inconvenience to permanent incapacity and death. As a results of its health implications, it is become one in every of the main causes of morbidity related to higher hospital admission rates and poor outcomes of treatment.[4]

Evaluation of the incidence and prevalence of ADRs is important to determine the outcomes and impact of their effect on patients. It has been reported that awareness of ADRs can prevent its occurrence or allows for its early identification and treatment, thereby reducing morbidity and mortality due to ADRs.[5] Clinical pharmacists can play a pivotal role in ADR monitoring and reporting, as the majority of serious ADRs occur in a hospital setting and contribute to a significant proportion of hospital admissions.[6] Studies have also reported other mitigation strategies such as computerized physician order entry system in potentially preventing ADRs.[7]

Majority of the drugs and their metabolites are eliminated by the kidney. However, accumulation of the drug or its metabolite can occur in renal impaired patients, resulting in severe and life-threatening adverse events, which can be provoked by comorbid conditions.[8] Although adverse drug events are common in renal compromised patients, most of these adverse drug events can be prevented by validating the renal dose.[9]

MATERIALS AND METHODS

This study was hospital-based cross-sectional observational study conducted in Department of Nephrology, Sri Venkateswara Institute of Medical Sciences, South Indian a tertiary care hospital, Tirupati, Andhra Pradesh. This study was approved by the Institutional Research and the Ethics Committee of the hospital. This study used a minimum sample size of 113 participants.

Inclusion and exclusion criteria

Patients in the age group of 18 and above of both gender (male and female) were included in the study. Patients with hypertension, acute renal injury and chronic kidney diseases (CKDs) and co-morbidities attending both outpatient and inpatient department of nephrology were included in the study. Patients below the age group of 18 were excluded. The patients were recruited for the study based on the inclusion and exclusion criteria after obtaining the written informed consent form, from the patients or their guardians. A predesigned data collection form was utilized to collect the information about the type of ADR induced and the suspected agent and documented in ADR reporting form. Patient demographic data (age, gender, weight, diagnosis, prescription patterns, comorbid conditions, family history, medical history, social history) was obtained from all the patients participated in the study. Data were collected by interviewing the patients, patient's medical records and laboratory investigations. Collected data entered in ADR reporting form. Causality of ADRs was assessed using the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) Scale. The collected data were entered in MS Excel work sheets and will be analyzed using Statistical Package for the Social Sciences Version 26.0 V. The categorical data were expressed in numbers and percentage.

Methods

A cross-sectional observational study was conducted to assess the ADRs in nephrology patients. It was conducted in the Department of Nephrology, Sri Venkateswara Institute of Medical Sciences South Indian tertiary care teaching hospital, Tirupati, Andhra Pradesh. A predesigned data collection form was utilized to collect the information about the type of ADR induced and the suspected agent and documented in ADR reporting form. Causality of ADRs was assessed using WHO-UMC Scale.

RESULTS

Out of 113 patients who were treated in nephrology department, 58 (51.32%) patients developed ADRs. Of the 58 patients, 36 (62.06%) are men and 22 (37.93%) are women. Patients of 39–48 (29.31%) age group are mostly affected. Among 58 patients, the causality assessment of 18 patients (31.03) was found to be possible and the remaining 40 patients (68.96) were found to be probable. The commonly developed ADRs include "pedal edema, hypokalemia, and maculopapular rash" and it is shown in Table 1.

Frequency of gender distribution

A total of 58 patients were included in the final analysis. There are 36 (62.06%) males and 22 (37.93%) females.

Frequency of age distribution

Among 58 patients, 8 (13.79%) patients fall in the age group of 18–28 years, 5 (8.62%) patients in the age group of 29–38 years, 17 (29.31%) patients in the age group of 39–48 years, 6 (10.34%) patients in the age group of 49–58 years, 13 (22.41%) patients in the age group of 59–68 years, and 9 (15.51%) patients in the age group of 69–78 years. The data were analyzed for age distribution, maximum age was observed in adults, and it is shown in Table 2.

Frequency of causality assessment

Among 58 patients, the causality assessment of 18 patients (31.03%) was found to be possible and the remaining 40 patients (68.96%) were found to be probable, and it is shown in Table 3.

Frequency of suspected drugs

Considering individual drugs, the most frequently reported drugs causing ADRs were Lasix, Wysolone, Amlodipine, and Minipress. Among the 58 ADRs, 8 (13.79%) ADRs were developed by Lasix, 7 (12.06%) ADRs were developed by Wysolone, 5 (8.62%) ADRs were developed by Amlodipine, 4 (6.89%) ADRs were developed by Minipress, and it is shown in Table 4.

DISCUSSION

ADRs can results in higher health expenses, more doctor visits, a lower quality of life, hospital stays, and even fatalities. Investigating a medication's side effects profile requires the recording and reporting of ADRs. A comprehensive drug safety monitoring program is the only thing that makes it feasible. While it's important to keep an eye on previously reported and well known ADRs, as their patterns may change over time.[10]

ADRs mimic many diseases and result in severe morbidity and mortality, making them a major clinical concern.[11]

Table 1: Frequency of gender distribution

Gender	No. of patients (*n*=58)	Percentage
Males	36	62.06
Females	22	37.93

Table 2: Frequency of age distribution

Age group (in years)	No. of. patients	Percentage
18–28	8	13.79
29–38	5	8.62
39–48	17	29.31
49–58	6	10.34
59–68	13	22.41
69–78	9	15.51
Total	58	100.0

Table 3: Frequency of causality assessment

Causality assessment	No. of. patients (*n*=58)	Percentage
Possible	18	31.03
Probable	40	68.96

Adverse medication events are undoubtedly more frequent in hospitalized patients with CKD and other comorbidities.[12] The frequency of ADRs is 3–10 times higher in elderly adults with renal impairment than in those with normal kidneys.[13]

The reason for this could be because most medications and their metabolites, which are removed by the kidneys, are accumulated by people with reduced renal function.[14] Moreover, patients with renal illness are more susceptible to developing ADRs due to changed pharmacokinetics and polypharmacy.[15] Furthermore, changes in drug distribution,

Table 4: Frequency of suspected drugs

Drug	Cases (*n*=58)	Percentage
Rosuvastatin	1	1.72
Wysolone	7	12.06
Sartel	2	3.44
Prozosin	1	1.72
Amlodipine	5	8.62
Lasix	8	13.79
Tolvaptan	1	1.72
Minipress	4	6.89
Seloken	1	1.72
Olmezest	1	1.72
Streptokinase	1	1.72
Encicarb	2	3.44
Azoran	1	1.72
Telmasartan	2	3.44
Moxifloxacin	1	1.72
Etoricoxib	1	1.72
Dabigatra	1	1.72
Piptaz	1	1.72
Clopidogrel	1	1.72
Endokan	1	1.72
Torsest	1	1.72
Carnitor	2	3.44
Levocarnitor	1	1.72
Tigcycline	1	1.72
Nefidipine	1	1.72
Metaprolol	1	1.72
Ceftriaxone	1	1.72
Calci	1	1.72
Nitroglycerine	1	1.72
Terlipressin	1	1.72
Dytor plus	1	1.72
Piptal	1	1.72
Vancomycin	1	1.72
Buscopin	1	1.72
Total	58	100

protein binding, abnormalities in metabolism, or a decrease in the drug's or its toxic metabolites' rate of elimination can all cause ADRs in patients with renal insufficiency.[16] An Indian study revealed that a number of ADRs features are significantly impacted by renal impairment.

Of the 113 patients treated in the nephrology department, 58 (51.32%) experienced an ADRs. Based on the study's demographic profile, it was discovered that a higher percentage of men (62.06%) than women (37.33%) had ADRs. Nonetheless, it is impossible to completely rule out the possibility that the higher frequency of ADRs in men may be caused by the fact that more men than women are admitted for nephrology care in this study. Overall, reports indicate that older persons and elderly adults have a much higher frequency of ADRs than other age groups.

According to our research, patients receiving treatment for CKD who also had hypertension had the highest frequency of ADRSs (56.89%). The most frequent ADRs seen in our study were hypokalemia, nausea, and vomiting. According to observations, the most frequently prescribed medications that induce ADRs in patients are prednisolone (12.6%) and anti-hypertensives (39.65%).

CONCLUSION

The present study has generated a useful baseline data regarding ADRs in various categories such as age- and gender-wise distribution of ADRs. By educating the patients about the ADRs, it also contributed to improve the patient's health-related quality of life.

ADRs are becoming a major worry for medical professionals, particularly when treating patients with impaired renal function. Every day, there are more and more ADRs, particularly among adults. Recognizing the ADR that can prevent life threatening causes at an early stage. Pharmacovigilance is the crucial instrument that may be used to regularly monitor clinical and laboratory results in order to ascertain the ADRS of the nephrology department. Timely identification of ADR is crucial in reducing morbidity and death rates.

This current study can also serve as a baseline for ADRs across different demographics, such as age and gender distribution of ADRs, among others. Patient's quality of life with regard to their health was also enhanced by teaching them about hazardous drug responses.

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