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Corresponding Author
Dr. K.N. Saivisveswar ,
Srinivas Institute of Medical Sciences and Research Centre Surathkal, Mangalore, India
saivisveswar@yahoo.com

Author Designation
Assistant Professor

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Assessment of Adverse Drug Reactions in Patients Undergoing Polypharmacy in General Medicine Wards - A Prospective Observational Study

Dr. K.N. Saivisveswar
Srinivas Institute of Medical Sciences and Research Centre Surathkal, Mangalore, India

Abstract
Polypharmacy, or the use of multiple medications, is a major contributor to adverse drug reactions (ADRs). Although it carries potential risks, combining drugs can also provide significant benefits by alleviating symptoms, treating conditions, and preventing complications. However, with the growing availability of over-the-counter drugs and alternative medicines, maintaining a balance between the risks and benefits of polypharmacy has become increasingly challenging. This hospital-based prospective observational study recorded patient data using a structured ADR reporting form. Information collected included baseline parameters, medical history, clinical findings, characteristics of ADRs, and details of both the suspected medications and those used for management. Data analysis was carried out using descriptive statistics with the Statistical Package for the Social Sciences (SPSS) version 25.0 software. During the study, 150 patients meeting the inclusion criteria were enrolled. Among them, 23 developed ADRs after admission. Polypharmacy was identified in 92 patients (61.4%), while 52 patients (38.6%) were not on polypharmacy, showing a statistically significant difference. Polypharmacy is a major contributor to adverse drug reactions (ADRs) due to drug–drug interactions, inappropriate prescribing, and cumulative side effects. Careful review of prescriptions, timely identification, and proper management of ADRs with regular monitoring are essential. Increasing awareness among healthcare professionals and educating patients can help minimize preventable ADRs.

INTRODUCTION

An adverse drug reaction (ADR) is "an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product; adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen, or withdrawal of the product[1]. It is well recognized that ADRs contribute significantly to morbidity and mortality[2]. Drug-related (polypharmacy, dosage, toxicity), patient-related (age, gender, genetics), and societal (smoking, alcoholism, social drug misuse, use of alternative medicinal goods) risk factors are among the many that contribute to adverse drug reactions (ADRs). One of the most prevalent and important causes of adverse drug reactions (ADRs) is polypharmacy, or the use of numerous drugs. To characterize the degree of concurrent drug usage, polypharmacy is categorized as minor (concurrent use of two to four medications) or major (concurrent use of five or more medications). However, this classification does not indicate if the prescription medications are suitable. There are serious repercussions when drugs are misused, which is thought to happen with nearly half of the prescription drugs. When medications are used in combination to treat and reduce symptoms or avoid problems in chronic illnesses, polypharmacy offers several advantages despite possible hazards[3].

Adverse Drug Reactions (ADRs) in hospital patients fall into two main groups: those that result in hospitalization and those that happen to patients after they are admitted to the hospital. ADRs account for about 5% (range 2-20%) of recorded hospitalizations, while 10-20% of hospitalized patients have been reported to experience at least one ADR. An ADR is linked to a nearly twofold higher chance of death, a noticeably longer length of stay, and an increased financial burden. ADRs significantly affect public health by lowering patients' quality of life and placing a heavy financial load on patients and health care systems at a time when many of these systems are already struggling financially. These are a known risk associated with taking medications. While some adverse drug responses (ADRs) are minor and go away without causing any problems, others can lead to death or permanent disability and increase the likelihood of adverse drug reactions, which raises the cost of healthcare[4-6].

MATERIALS AND METHODS

This prospective observational study was conducted in a tertiary care center's internal medicine wards between June and December 2015. Approval from the Institutional Ethics Committee was obtained (IEC/17/2015). The study included all individuals over 12 who were either hospitalized because of an adverse drug reaction (ADR) or who experienced an ADR while in the hospital. All adult participants and the parents/guardians of participants under the age of eighteen provided written informed consent. The study was conducted in compliance with the Helsinki Declaration's ethical guidelines. The study excluded patients who had experienced deliberate or unintentional poisoning, had a history of drug misuse (apart from alcohol), did not take their prescriptions as directed, were in critical care, were pregnant, or were treated in an outpatient department. Demographics, clinical condition, current medication adverse drug reactions, ADR treatment, and results were among the data gathered from case files, charts, nursing notes, and interviews with patients or their families. Each patient was monitored until they were discharged or passed away, and polypharmacy was detected. When additional reasons had been ruled out by proper investigations, causality was established using the WHO-UMC scale[7]. The severity of the ADR was categorized using the Modified Hartwig and Siegel Severity Assessment scale[8]. The Hallas Criteria were used to assess the ADR's avoidability[9]. The Statistical Packages for the Social Sciences (SPSS) program, version 25.0, was used to analyze the data using descriptive statistics.

RESULTS AND DISCUSSIONS

Over the course of the study, 150 patients who met the inclusion criteria were admitted. Of the 150 patients admitted for ADRs, 23 experienced ADRs after being admitted. 92 (61.4%) of the 150 patients who met the study's requirements had polypharmacy, whereas 52 (38.6%) did not. A statistically significant difference was observed. The distribution of the various parameters between patients who received polypharmacy and those who did not was given in Table 1. Individuals with polypharmacy had an average hospital stay of 1 week, compared to 4 days for those without polypharmacy.

According to the WHO-UMC scale, the causality was "certain" in three cases involving polypharmacy and "probable" in the remaining cases. It was found that 32% of all polypharmacy patients had diabetes. Glimepiride was responsible for 22.5% of all ADRs, making metabolic ADRs the most prevalent type. In cases involving polypharmacy, approximately 10% of all ADRs were determined to be "definitely avoidable," 50% "probably avoidable," and 40% "unavoidable." Those without polypharmacy were found to fall into similar categories at 9%, 45%, and 46%. All categories showed similar results, with the exception of mortality,

Table 1: Comparison of various parameters between patients with polypharmacy and those without polypharmacy

Variable	Number of Patients (n=150)	Percentage (%)	p-value
Total patients admitted (met inclusion criteria)	150	100	–
Patients who experienced ADRs after admission	23	15.3	–
Patients with polypharmacy	92	61.4	< 0.05
Patients without polypharmacy	52	38.6	< 0.05

Table 2: Comparison of ADR Characteristics Between Polypharmacy and Non-Polypharmacy Groups

Parameter	Polypharmacy Group	Non-Polypharmacy Group
WHO-UMC Causality	Certain: 3 casesProbable: Remaining cases	–
Comorbidity (Diabetes)	32%	–
Most common drug responsible for ADRs	Glimepiride (22.5% of ADRs)	–
Most common ADR type	Metabolic ADRs	–
Preventability (WHO criteria)	Definitely avoidable: 10%Probably avoidable: 50%Unavoidable: 40%	Definitely avoidable: 9%Probably avoidable: 45%Unavoidable: 46%
Mortality	3%	9%
Severity distribution (by gender)	Similar in both genders	Similar in both genders
Severity distribution (by age group)	Minor variations among age groups	Minor variations among age groups

where the polypharmacy group reported 3% and the non-polypharmacy group recorded 9%. Although the severity distribution was similar for both genders, there were a few variations among the different age groups (Table 2).

In the age range of 60 to 80 years, polypharmacy was observed in approximately 69% of all ADRs. The prevalence of neurological symptoms was highest among those under 18, hepatic and vascular symptoms were highest among those between 25 and 58, and metabolic symptoms were highest among those over 65. All individuals with polypharmacy who were under 18 years old reported "severe" adverse drug reactions. But in every other age category, the number of "severe" adverse drug reactions (ADRs) in the non-polypharmacy patients was at least as high as in the polypharmacy cases. It is noteworthy that across all age categories, more adverse drug reactions (ADRs) in polypharmacy cases were categorized as "possibly avoidable" than in those without, but more ADRs in the non-polypharmacy group were determined to be "unavoidable."

Polypharmacy was found to be present in more than half of all patients admitted with ADRs, suggesting that it may be a significant risk factor for the occurrence of ADRs. Although polypharmacy is more prevalent in the elderly population, people aged 40 and under accounted for a larger proportion of those admitted with ADRs, both with and without polypharmacy. However, in every instance involving a patient older than 20, the non-polypharmacy group's ADR severity was found to be comparatively higher. Although the exact cause is unknown, one possible explanation is that people who take several medications may report their symptoms earlier since they see doctors more frequently and are more aware of the warning indications.

ADRs are not strictly reported, particularly when polypharmacy prevents an appropriate cause relationship. Despite having a longer average hospital stay, a higher percentage of patients in the polypharmacy group had recovered by the time the data was assessed, suggesting a better outcome in that group. It's also important to remember that, in comparison to the non-polypharmacy group, fewer cases in the polypharmacy group were deemed "unavoidable." This study demonstrates that polypharmacy is a significant contributor to adverse drug reactions (ADRs), underscoring the need of avoiding or reducing the use of numerous medications at the same time. This study and other research have revealed a number of approaches to enhance results for individuals requiring polypharmacy:

The establishment of an interdisciplinary team at the hospital, national, and international levels to evaluate common regimens with newly identified ADRs and recommend new or revised regimens, a clear display of all drugs taken by the patient, a standardized reporting system for all ADRs and strict adherence to it, a routine medication review to identify any unnecessary drugs, especially OTC drugs taken by the patient[10]. A comprehensive record of all medications taken by the patient, along with a standardized system for reporting adverse drug reactions (ADRs) and strict adherence to it, is essential[11]. The establishment of interdisciplinary teams at hospital, national, and international levels can help in evaluating commonly used regimens, identifying newly emerging ADRs, and recommending modifications or alternative therapeutic approaches[12]. Greater application of Beer's Criteria can further minimize inappropriate prescribing[13], while expanding the role of pharmacists in patient counselling and medication monitoring is particularly important in the context of polypharmacy[14].

CONCLUSION

Polypharmacy has emerged as one of the leading contributors to adverse drug reactions (ADRs) among

inpatients. The simultaneous use of multiple medications increases the risk of drug-drug interactions, inappropriate prescribing, and cumulative side effects, all of which can compromise patient safety. Therefore, prescriptions involving several drugs should be carefully reviewed, and any ADRs should be promptly identified, documented, and managed with regular monitoring and follow-up. Enhancing awareness among healthcare professionals about the risks associated with polypharmacy, together with patient education, can play a vital role in minimizing preventable ADRs. Furthermore, implementing standardized protocols for the detection, reporting, and analysis of ADRs-particularly those related to polypharmacy-can significantly improve patient outcomes, optimize therapeutic effectiveness, and strengthen overall pharmacovigilance practices.

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