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Pharmacovigilance in Neurosurgery: Analysis of Adverse Drug Reactions at Mohammed V Military Teaching Hospital

Amezouar A[1,2], Bouhlala N[1,2], Belhouari M[1,2], Sabri S[1,2], Elouadghiri B[1,2] and Enneffah W[1,2]*

[1]*Department of Pharmacy, Mohammed V Military Teaching Hospital, Rabat, Morrocco*

[2]*Faculty of Medicine and Pharmacy, Rabat, Morrocco*

Abstract

Introduction: Pharmacovigilance is an essential pillar of medication safety, aiming to detect, assess, understand, and prevent adverse events related to the use of medicines. In the hospital setting, particularly in a specialized department such as neurosurgery, patients are often exposed to complex therapeutic regimens, thereby increasing the risk of adverse drug reactions (ADRs). This study was conducted in the neurosurgery department of Mohammed V Military Teaching Hospital, using the official adverse event reporting form developed by the Moroccan Pharmacovigilance Center. The objective of the present work is to analyze the ADRs that occurred, characterize the drugs involved, and assess their severity, clinical outcome, and the corrective measures implemented.

Materials and Methods: This retrospective descriptive study was conducted in the neurosurgery department of Mohammed V Military Teaching Hospital. It was based on the analysis of adverse drug reaction (ADR) reports collected using the official pharmacovigilance form of the Moroccan Pharmacovigilance Center. Each form provided information on the patient's clinical data, the suspected drugs, the nature of the adverse reactions, their outcome, and the corrective measures implemented. The data were entered into an Excel spreadsheet for descriptive analysis. The objective was to characterize the observed ADRs and assess their clinical impact.

Results and Discussion: The analysis identified 19 cases of adverse drug events (ADEs) reported in the neurosurgery department. Patients were distributed as follows: 52.6% were women and 47.4% were men. The most frequent ADEs were dizziness (15.8%), followed by nausea, vomiting, hypokalemia, and confusion, each accounting for 10.5%. The suspected drugs included sodium valproate (10.5%), empagliflozin (10.5%), carbamazepine, nefopam combined with pregabalin (5.3%), as well as anticoagulants and antibiotics.

Among the 19 events identified, 73.7% were described in the Summary of Product Characteristics (SmPC) of the drugs concerned, whereas 26.3% were not listed. The five reports concerning adverse events not mentioned in the SmPC were forwarded to the local pharmacovigilance officer for further assessment and appropriate follow-up measures. This therapeutic diversity reflects the complexity of neurosurgical care and the risks associated with polypharmacy. The clinical outcome was generally favorable, particularly after discontinuation or substitution of the suspected treatment. These findings highlight the importance of pharmacotherapeutic monitoring and rigorous reporting of ADEs. In this context, the clinical pharmacist plays a key role by identifying ADEs, documenting them, and collaborating with the medical team to ensure safer prescribing. This role is fully integrated into a quality improvement and medication risk prevention approach.

Conclusion: This study highlights the risk associated with adverse drug events and the importance of their reporting. It also emphasizes the role of the clinical pharmacist in their identification, analysis, and management. Hospital pharmacovigilance therefore appears to be an essential tool for securing prescriptions. It contributes to improving the quality and safety of care in the hospital setting.

Keywords: Pharmacovigilance; Adverse drug events; Neurosurgery; Clinical pharmacist

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Correspondence:
Amezouar A, Department of Pharmacy, Mohammed V Military Teaching Hospital, Rabat, Morrocco, E-mail: amezouarabdennabi@gmail.com

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Introduction

Pharmacovigilance is a fundamental component of medication safety. It aims to detect, assess, understand, and prevent adverse effects related to the use of medicines, in accordance with the

approach defined by the World Health Organization [1]. In the hospital setting, adverse drug events represent a major concern, particularly among patients receiving multiple treatments or those managed in specialized departments with high therapeutic complexity, such as neurosurgery [2,3]. In this context, the present study, conducted in the neurosurgery department of Mohammed V Military Teaching Hospital, is based on the official reporting form of the Moroccan Pharmacovigilance Center. Its objective was to analyze the observed adverse drug events, identify the drugs involved, assess their severity and clinical outcome, and describe the corrective measures implemented in order to strengthen the quality and safety of care [4].

Materials and Methods

Study type and setting

This was an observational descriptive study with an analytical purpose, focusing on adverse drug events (ADEs) that occurred among patients hospitalized in the neurosurgery department of Mohammed V Military Teaching Hospital. This type of approach is widely used in hospital pharmacovigilance to characterize the frequency, nature, and severity of adverse events under real-life conditions of medicine use.

Study population

The study population included all patients hospitalized in the department during the study period who experienced at least one reported ADE. Patients of all ages and both sexes receiving one or more drug treatments were included. Patients with incomplete or unusable information were excluded.

Data collection

Data were collected by a clinical pharmacist using the official reporting form of the Moroccan Pharmacovigilance Center. This standardized form ensures complete traceability of ADEs and includes:

- Patient demographic data;
- Clinical characteristics;
- Suspected drugs;
- Description of the adverse event;
- Clinical outcome and management.

Results and Discussion

The analysis identified 19 cases of adverse drug reactions (ADRs) reported in the neurosurgery department. Patients were distributed as follows: 52.6% were female and 47.4% were male.

The most frequent ADRs were dizziness (15.8%), followed by nausea, vomiting, hypokalemia, and confusion, each accounting for 10.5%. The suspected drugs included sodium valproate (10.5%), empagliflozin (10.5%), carbamazepine, nefopam combined with pregabalin (5.3%), as well as anticoagulants and antibiotics.

The results of our study show that dizziness was the most commonly reported ADR, representing 15.8% of cases, followed by nausea, vomiting, hypokalemia, and confusion, each observed in 10.5% of cases. This predominance of neurological and gastrointestinal manifestations is consistent with hospital literature data, in which nausea, vomiting, dizziness, drowsiness, and neurocognitive disorders are among the most frequently reported adverse reactions,

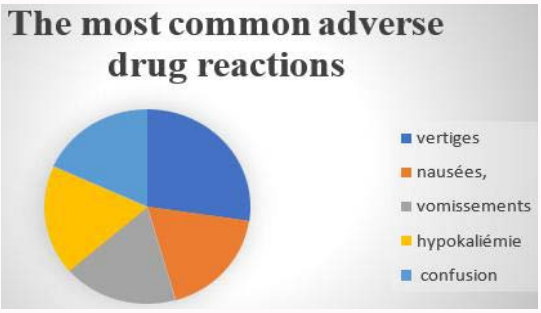

Figure 1: The most common adverse drug reactions.

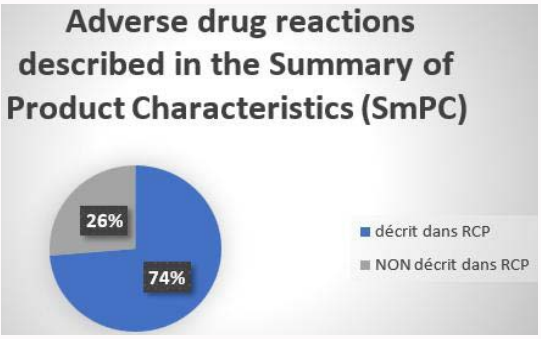

Figure 2: Adverse drug reactions described in the Summary of Product Characteristics (SmPC).

particularly with analgesics, antiepileptic drugs, antibiotics, and treatments used in neurological or neurosurgical patients. Smith et al. reported that nausea and vomiting were among the most frequently observed ADRs in hospitalized patients [5].

The frequency of dizziness and confusion may be explained by the profile of neurosurgical patients, who are often exposed to drugs acting on the central nervous system, including antiepileptic drugs, opioids, sedatives, and certain antibiotics. Several studies have reported that antiepileptic drugs may cause dose-dependent neurological adverse effects such as dizziness, drowsiness, fatigue, cognitive impairment, confusion, nausea, and vomiting [6].

The hypokalemia observed in our series may be related to certain treatments frequently used in the hospital setting, particularly diuretics, corticosteroids, beta-2 agonists, or clinical situations associated with gastrointestinal losses. The literature emphasizes that drug-induced hypokalemia is a frequent and potentially serious electrolyte disorder requiring regular laboratory monitoring, especially in hospitalized or frail patients [7].

Thus, the distribution of ADRs found in our study appears consistent with published data. It highlights the need for close clinical and laboratory monitoring in neurosurgery, particularly among patients receiving neurotropic drugs, analgesics, antiepileptic drugs, or corticosteroids.

Among the 19 events identified, 73.7% were described in the Summary of Product Characteristics (SmPC) of the drugs concerned, whereas 26.3% were not listed. The five reports related to adverse events not mentioned in the SmPC were forwarded to the local pharmacovigilance officer for in-depth assessment and appropriate follow-up measures.

Our results show that 74% of the observed ADRs were already

described in the SmPC, compared with 26% that were not described. This predominance of expected ADRs suggests that most reported events corresponded to the already known safety profile of the drugs used. This finding is consistent with the literature, where adverse reactions reported in hospital settings are often already mentioned in official product information, particularly when they involve common neurological, gastrointestinal, or metabolic effects [8].

However, the presence of 26% of ADRs not described in the SmPC remains significant. These cases should be carefully considered, as an adverse reaction not mentioned in the Summary of Product Characteristics may represent a potential pharmacovigilance signal, especially if it is serious, recurrent, or clinically unexpected. International recommendations define an ADR as "unexpected" when its nature, severity, or outcome is not consistent with the information available in the SmPC [9].

This finding therefore emphasizes the importance of systematic ADR reporting in neurosurgery. Even when an adverse reaction is already known, reporting it helps assess its frequency and severity in real-life clinical practice. Conversely, undescribed ADRs may contribute to enriching drug safety data and, ultimately, to updating SmPCs.

This therapeutic diversity reflects the complexity of neurosurgical care, where polypharmacy increases the risk of drug interactions and adverse drug reactions [10]. The clinical outcome was generally favorable, particularly after discontinuation, dose adjustment, or substitution of the suspected treatment.

These findings confirm the value of close pharmacotherapeutic monitoring, especially in patients receiving several drug classes. The literature shows that pharmaceutical interventions contribute to reducing adverse drug events and improving prescription safety [11].

In this context, the clinical pharmacist plays a central role in the identification, documentation, and reporting of ADRs [12]. Collaboration with the medical team enables early adjustment of the therapeutic strategy. Thus, the pharmacist's role is fully integrated into a quality improvement, prevention, and medication-use safety approach [13].

Conclusion

This study highlights the importance of pharmacovigilance in neurosurgery, where therapeutic diversity and polypharmacy expose patients to an increased risk of adverse drug reactions.

Most of the observed adverse reactions had a favorable outcome after discontinuation, dose adjustment, or substitution of the suspected drug, emphasizing the value of early clinical monitoring.

The findings also confirm the need for rigorous ADR reporting in order to improve knowledge of the safety profile of medicines used in real-life clinical practice.

In this context, the clinical pharmacist plays a central role in identifying, analyzing, documenting, and preventing medication-related risks.

Thus, strengthening pharmacotherapeutic monitoring and promoting a culture of reporting constitute essential levers for improving the quality and safety of care.

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