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RESEARCH ARTICLE

PHARMACOVIGILANCE AND PATIENT SAFETY IN A MOROCCAN UNIVERSITY HOSPITAL

Mohamed Alem [1,4], Ilyass Derfouf [1], Naima Abda [2], Siham Dikhaye [3,4] and Zayneb Alami [1,4]

1. Department of Pharmacy and Clinical Pharmacology, Mohammed VI University Hospital, Oujda, Morocco.
2. Department of Epidemiology and Public Health, Mohammed First University, Oujda, Morocco.
3. Department of Dermatology, Mohammed VI University Hospital, Oujda, Morocco.
4. Medicine and Pharmacy school, Mohammed First University, Oujda, Morocco.

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Abstract

Background: Adverse drug reactions (ADRs) are a major cause of morbidity and mortality. They carry considerable clinical and economic burdens, as they often lead to hospital admissions, prolonged hospital stays, disability, or even death.The aim of this study wasto calculate the spontaneous reporting rate of ADRs among all patients, to determine the associated mortality rate, and to identify the risk factors and drug classes involved.

Methods: We conducted a retrospective descriptive and analytical study based on adverse drug reaction (ADR) reports submitted to our regional pharmacovigilance center between 2013 and 2018.

Results: Adverse drug reactions were reported in 140 patients, corresponding to a reporting rate of 47 cases per million inhabitants per year. The mortality rate was 5.7% (n = 8), and 66.4% of ADRs (n = 93) were classified as serious.No significant association was found between the occurrence of ADRs and patient characteristics, including age (p = 0.835), sex (p = 0.071), or polypharmacy (p = 0.055). Similarly, no significant association was observed between ADR-related mortality and age (p = 0.352) or sex (p = 0.194). A total of 327 drugs were reported. ADRs were most frequently associated with antimicrobials (31.5%, n = 103), followed by analgesics and anti-inflammatory drugs (19%, n = 62) and cardiovascular drugs (18%, n = 59).

Conclusion: In conclusion, the reporting rate of ADRs is low and ADR-related mortality is considerable. Antimicrobial drugs were the most frequently implicated and patient characteristics did not show sign ificant associations with ADR occurrence or ADR-related mortality.

Introduction:-

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and mortality. It is estimated that around 2.9–5.6% of all hospital admissions are due to ADRs and as many as 35% of hospitalized patients experience an

Corresponding Author: Mohamed Alem
Address:-Department of Pharmacy and Clinical Pharmacology, Mohammed VI University Hospital, Oujda, Morocco. 4. Medicine and Pharmacy school, Mohammed First University, Oujda, Morocco.

ADRs during their hospitalization [1].ADRs carry significant economic and clinical burdens,as they often result in hospital admission, extended hospital stay, disability or even death.Health care systems can use data on the frequency, seriousness, causality and avoidability of ADRs to identify medications that should be targeted to improve patient safety and ultimately reduce ADRs related expenditures. According to a study conducted in a university hospitalin Morocco, 4.2% of patients are hospitalized due to ADRs [2]. Since 1988, date of creation of the CAPM (National Poison Control and Pharmacovigilance Center) based in Rabat, capital of Morocco, becoming a WHO collaborating center in 2011, new regulatory and scientific processes are being developed to strengthen national pharmacovigilance system especially regionalization[3]. In 2013, and in order to improve patient safety in the eastern region of Morocco, the regional pharmacovigilance center was created in Oujda. Identifying serious ADRs and their analysis could have a significant impact on reducing the avoidable ones. The aims of this study were to calculate reporting rate of ADRs in all patients, to measure their mortality rate and to describe the several factors that influence their occurrence and the incriminated therapeutic classes.

Material and Methods:-

Study design:

We conducted a retrospective study of all ADRs reports submitted to the Regional Pharmacovigilance Center between January 2013 and December 2018. The study population consisted of all ADRs reported from the different departments of the university hospital and recorded in the pharmacovigilance database during the study period. All types of suspected ADRs were considered. Reports containing sufficient clinical and drug-related information to allow assessment of the suspected ADR were included in the analysis. Reports with incomplete or missing essential data were excluded.

Data collection and analysis:

All relevant data were extracted from the pharmacovigilance reports and coded prior to analysis. The collected information was entered into two Microsoft Excel databases. The first database included variables related to ADRs, classified according to the System Organ Class, as well as the seriousness of the reactions and patient outcomes. The second database contained information on the drugs involved, including the suspected medications, therapeutic classes, and causality assessment. Causality was evaluated using three established methods: the WHO–UMC method, the Naranjo algorithm, and the French causality assessment method.These complementary approaches were used to improve the robustness of causality evaluation, as each method applies different criteria and levels of standardization. The use of multiple assessment tools allowed a more comprehensive evaluation of the relationship between the suspected drug and the reported ADRs.

The avoidability of deaths was assessed using the Imbs method [4]. Computed data were exported to SPSS version 21.0 for statistical analysis. Qualitative variables were expressed as frequencies and percentages. Quantitative variables were summarized as means and standard deviations for normally distributed data, or as medians and interquartile ranges for non-normally distributed data. A bivariate analysis was performed using the Chi 2 test or fisher's exact test to compare the qualitative variables. Any $p<0.05$ was considered to be statistically significant. Results were presented with 95% confidence intervals (95% CI). The study was approved by our institution administration. An authorization to conduct the study in accordance with relevant guidelines and regulations was obtained. Anonymity and confidentiality were respected.

Results:-

A total of 140 cases were reported,with an average of 23cases per yearand a reporting rate of 47per million inhabitants per year. Table1summarizes the descriptive characteristics of the patients who experienced ADRs. Of the 140 ADRs reported in this study, the most frequently affected organ system was the skin and subcutaneous tissue (66.4%, n=93), followed by liver disorders (5%, n=7) and extracardiac vascular system disorders (5%, n=7). Regarding ADR seriousness, 66.4% (n=93) of the ADRs were classified as serious. Among these serious ADRs, outcomes included hospitalization in 13% of cases (n=12), prolonged hospital stay in 48% (n=45), permanent disability in 3% (n=3), life-threatening reactions in 27% (n=25) and death in 9% (n=8). Percentages for ADRs seriousness are expressed relative to the total number of reported ADRs (n=140), while percentages for outcomes are expressed relative to the number of serious ADRs (n=93). To explore the potential determinants of ADRs seriousness and mortality, a bivariate analysis was conducted. The results are presented in table 2 and 3.

Causality assessment was performed using three established methods. According to the WHO–UMC method, 78.3% of drugs (n=256) were classified as having a possible causal relationship with the reported ADR, while 1.5% (n=5)

were considered certain. Using the Naranjo algorithm, 76.5% (n=250) of drugs were also classified as possible and 0.9% (n=3) as certain. The French method indicated that the I2 score, representing a likely causal relationship was the most frequent (31.0%, n=101), while the I6 score, indicating a definite causal relationship was observed in 4.9% of cases (n=16) (Table 4). Regarding the avoidability of deaths, the assessment using Imbs method revealed the following results: (Table 5).

Of the 327 medications involved in the reported ADRs, antimicrobials were the most frequently suspected accounting for 31.5% (n=103) of drugs, followed by anti-inflammatory drugs and analgesics (19%, n=62), and cardiovascular drugs (18%, n=59). Drug classification was performed according to the Anatomical Therapeutic Chemical (ATC) classification system. Among the most frequently suspected individual drugs, amoxicillin was the most common (7.6%, n=25), followed by paracetamol (5.5%, n=18) and allopurinol (3.7%, n=12).

Table 1 : Descriptive characteristics of ADRs reports

Characteristics	N (%)
Patients	140
Age (Years) (Average±SD)	42 ± 20
Adults (More than 11 and less than 65 years)	113 (86.9%)
Extreme Ages (0-11 years and>65years)	17 (13.1%)
Sex	
Female	75 (53.5%)
Male	65 (46.8%)
Medical prescription/self medication	
Medical Prescription	124 (88.5%)
Self medication	16 (11.5%)
Drug intake (number)	
1 drug	60 (43%)
2 drugs or more	80 (57%)
Nature of ADRs	
Skin and subcutaneous tissue disorders	93 (66.4%)
Liver disorders	7 (5%)
Extracardiac vascular system disorders	7 (5%)
Seriousness of ADRs	
Serious	93 (66.4%)
Non serious	47 (33.6%)
Seriousness criteria	
Death	8 (9%)
Life threatening	25 (27%)
Permanent disability	3 (3%)
Hospitalization	12 (13%)
Hospital stay extension	45 (48%)
Evolution	
Favorable	56 (87.5%)
Death	8 (12.5%)

Table 2: Factors related to the occurrence of serious ADRs according to a bivariate analysis

Factors	Serious ADRs		*P*
	No	Yes	
Age			
Adult	6 (35.3%)	11 (64.7%)	*0.835*
Extremes	37 (32.7%)	76 (67.3%)	
Sex			
Female	26 (35.1%)	48 (64.9%)	*0.585*
Male	20 (30.8%)	45 (69.2%)	
Polypharmacy			
Yes	28(35%)	52(65%)	*0.679*
No	19(32%)	41(68%)	

Table 3: Factors related to the occurrence of deaths according to a bivariate analysis

Factors	No – Death	Death	*P*
	N(%)	N(%)	
Age			
Adult	44 (88%)	6 (12%)	*0.352*
Extremes	7 (78%)	2 (22%)	
Sex			
Female	34 (92%)	3 (8%)	*0.194*
Male	22 (81.5%)	5 (18.5%)	
Seriousness of ADRs			
Yes	39 (83%)	8 (17%)	*0.071*
No	17 (100%)	0 (0%)	
Polypharmacy			
Yes	30 (88.2%)	4 (11.8%)	*0.572*
No	26 (86.7%)	4 (13.3%)	

Table 4: Causality assessment results

Causality assessment	
WHO Method	
Possible	256 (78,3%)
Unlikely	40 (12,2%)
Likely	26 (8%)
Certain	5 (1,5%)
Naranjo Method	
Possible	250 (76,5%)
Likely	61 (18,7%)
Unlikely	7 (2,1%)

Doubtful	6 (1,8%)
Certain	3 (0,9%)
French Method	
I0	5 (1,5%)
I1	77 (23,5%)
I2	101 (30,9%)
I3	76 (23,3%)
I4	9 (2,8%)
I5	43 (13,1%)
I6	16 (4,9%)

Table 5: Avoidability of deaths assessment

Case	Avoidability
1	Potentially avoidable
2	Absolutely avoidable
3	Absolutely unavoidable
4	Absolutely unavoidable
5	Absolutely unavoidable
6	Absolutely avoidable
7	Potentially avoidable
8	Absolutely unavoidable

Table 6 : Fatal ADRs description

Case	Age Range and Sex	Suspected drug (S) and Concomitant use (C)	Daily dose	ADRs	Time to onset	Observation	Prescription Or Self medication
1	[55-59] year / M	Allopurinol (S) Ramipril (C) Bisoprolol (C) Aspirine (C)	400mg 5mg 1.25mg 160mg	DRESS syndrom	45 days 21 days 21 days 15 days	Hyperuricemia/ Bladder cancer	Prescription
2	[0-3] months / M	Vitamine D (S)	600 000 UI	Renal failure /nephrocalcinosis	21 days	Rickets prophylaxis	Prescription
3	[35-39] years / F	Docetaxel (S)	100mg/m^2	Acute respiratory distress syndrome (ARDS)	11 days	-	Prescription
4	[40-44] years / F	Docetaxel (S)	600mg	ARDS	15 days	Comorbidity: hypertension treated by calcium channel blockers	Prescription

5	[50-54] years / M	Amoxicillin+Clavulanic acid (S), Ciprofloxacine (C)	2000 mg 500mg	DRESS	13 days	Pulmonary renal syndrom with lower limbpurpuric lymphoma	Prescription
6	[30-34] years / M	Allopurinol (S) Amoxicillin+Clavulanic acid (C) Omeprazole (C) Domperidone (C)	200mg	Lyell Syndrome	10 days	Diabetes, pre terminalrenalfailure (Clearance 10ml/min) Sicklecellanemia	Prescription
7	[80-84] years / F	Allopurinol (S)	300mg	Lyell Syndrome	6 days	Comorbidity : Diabetes with insulin, hypertension	Prescription
8	[65-69] years / M	Rituximab (S) Paracetamol (C) Ondansetron (C) Methylprednisolone (C)	700mg	Anaphylaxis	Immediately	-	Prescription

Discussion:-

Prevalence of ADRs:

The prevalence of adverse drug reactions (ADRs) varies considerably across countries and study designs. A literature review by Stephanie et al. reported ADR rates ranging from 3.3% in retrospective studies conducted in Germany to 9.65% in prospective studies [5].Similarly, data from the French National Agency for the Safety of Medicines and Health Products indicated that more than 20 000 ADRs were reported in 2007, half of which were classified as serious. These variations may be explained by differences in pharmacovigilance systems, reporting practices, and study methodologies[6]. One of the main methodological limitations of our study is the reliance on spontaneous reporting data. Pharmacovigilance databases do not provide the exact number of patients exposed to a given drug or the total number of patients experiencing ADRs during a specific period. As a result, the true incidence of ADRs cannot be accurately estimated. Furthermore, spontaneous reporting systems are known to be affected by underreporting, which remains a major challenge at regional, national, and international levels. Consequently, the number of ADR cases identified in our study may underestimate the actual occurrence of ADRs. A study published in 2006 in Drug Safety, which analyzed 37 studies from 12 different countries estimated that the rate ofunderreporting is higher than 98% [7].

A study conducted in 2011 on ADRs caused by antimalarial drugs between 1968 and 2008 reported a notification rate of 1.2% in developing countries [8]. Another study conducted in Denmark in 2012 using data fromVigibase(the international database of ADRs)covering the period from 2000 to 2009, showed that reporting rates varied widely across countries from less than 1 per million inhabitants per year in Russia and Tanzania to 2 in Ukraine, 3 in Saudi Arabia, 38 in Chile, 99 in Morocco, 233 in the United Kingdom,261in Cuba, 300 in Switzerland, 302 in Australia, 333 in Sweden and up to 613 in New Zealand[9]. The 47 ADR case reports per million inhabitants per year recorded in the city of Oujda, Morocco, suggest a relatively low reporting rate, which may reflect underreporting by healthcare professionals. In our study, the dermatology department accounted for the highest number of reports. In contrast, in the M-G study by Guedat et al. (2012), the majority of reports originated from the internal medicine department (70%)[10].These differences may be explained by variations in hospital organization, clinical practices, and the level of awareness or involvement of different medical departments in pharmacovigilance activities. In addition, differences in healthcare systems and reporting structures between settings may influence which departments are more actively engaged in ADR reporting.

Causality assessment:

The majority of ADRs were classified as having a possible rather than certain causal relationship, regardless of the assessment method used. This suggests that while a link between the drugs and the reported ADRs is plausible, definitive attribution remains limited, highlighting the inherent uncertainty in pharmacovigilance causality assessment.

Factors influencing ADRs:
The bivariate analysis showed that age, sex and polypharmacy were not statistically associated with the occurrence of serious ADRs or ADR-related mortality in our study. Although the limited sample size may have reduced the statistical power to detect significant associations, other factors may also explain these findings. For instance, differences in patient characteristics, patterns of drug use, and reporting practices may influence the observed relationships. In addition, the use of spontaneous pharmacovigilance data may introduce variability due to underreporting or incomplete clinical information. In ourstudy, adults aged between 11 and 65 years were also affected by ADRs with a meanage of 42 years. This contrasts withother studiesthat highlight the vulnerability of older populations with an average age of 76 years (Pirmohamed et al ,2004) and 72 years old [11]. The sex ratio for ADRs was 1.14 in favor of females, which agrees with the findings of L.Aagaard et al (2012) who reported that 60% of ADRs occurred in women and N. Moore et al (1998)[12].

A Swedishstudy conductedbetween 2005 and 2012 on ADRs related to antihypertensive drugs showed a high prevalence of reports among womenin 6 out of 10 groups[13]. This can be partly explained by pharmacokinetic and pharmacodynamic differencesbetween the two sexes [14]. Otherfactorscontributing to this sex differencesincludedvariations in body mass, hormonal levels, drugconsumption patterns, frequency of hospital visits and also the higher adherence to medical prescriptions among women [15]. However, according to a meta-analysis of observationalstudies published in2016, which analyzeddatafromFebruary 2002 to July 2013, no significant difference was observed [16]. Polypharmacy was also common in our study with 57% of patients receiving more than one medicationwich agrees with the study by M. von Euler et al (2006).

Seriousness of adverse effects:
Among the 140 reported cases, 66.4% (n=93) were classified as serious, reflecting both: the frequency of serious ADRs and the tendency of healthcare professionals to underreport non-serious ones [17]. A total of 22.2% (n=3) of patients at extreme ages died. Althoughmortality appears to be higher in the extreme age group, the difference is not statistically significant. To confirm this difference statistically, a larger dataset would be required.

Deaths analysis:
Deaths caused bydrug-induced iatrogenesisare important in our series. Among the 140 ADRs reported, 5.7% were fatal (n=8).However,theyrepresent 12.5% of the cases for which outcomes were known.ADRs are therefore a major cause of death in this population. This percentage exceeds the 1.7% reported in the study by S. Schneeweiss et al (2002) [18]. In2000, an analysis of American studiespublishedsince 1992 reported a mortality rate of 2.7% among all hospitalized patients[19]. An Ethiopian study from 2018 reported a death rate of 1.5% [20]. In four South African hospitals, the rate was 16% [21].In the United States, hepatic ADRs are the leading cause of liverfailure, far surpassing viral and other causes[22]. In ourstudy, women were moreaffected by the occurrence of ADRs, but men had a higher risk of death. Patients with serious ADRs had a highermortality rate thanthose with non-seriousones. Approximately half of the death cases involvedcutaneous eruptions,followed by respiratorydistress syndrome. All medicationswere prescribed, ruling out the role of self-medication. Deaths occurred across all age groups. Among the eight recorded deaths, three cases (37.5%) were related to allopurinol.

This drug, commonly used in the treatment of gout and symptomatic hyperuricemia, is well known for its association with severe cutaneous adverse reactions, including Stevens–Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS). The occurrence of fatal cases in our study highlights the importance of careful prescribing and appropriate patient monitoring when initiating allopurinol therapy, particularly in patients with risk factors such as renal impairment [23]. The fatal ADR cases identified in this study illustrate several mechanisms underlying severe drug-related outcomes. Some cases were related to inappropriate drug use or prescribing practices. For example, case 2 involved the administration of a high-dose vitamin D formulation that is contraindicated in children [24]. Other cases corresponded to known severe adverse reactions associated with specific drugs. In cases 3 and 4, respiratory distress due to interstitial lung disease is a recognized adverse reaction of docetaxel [25]. In case 5, the dose of amoxicillin/clavulanic acid was not adequately adjusted according to the patient's renal function, which may have contributed to the pulmonary renal syndrome observed [26].

In case 8, the patient developed an immediate anaphylactic reaction following the first administration of rituximab. Overall, these cases highlight different mechanisms leading to fatal ADRs, including inappropriate drug use, dose adjustment issues, and unpredictable severe hypersensitivity reactions. Table 6 summarizes the characteristics of all fatal ADR cases reported in this study:

Avoidability of deaths assessment: 50% (n=4) of deaths were judged to be absolutely or potentially avoidable, highlighting the importance of integrating pharmacovigilance principles into daily clinical practice to improve patient safety.

Incriminated therapeutic classes:31.5% of suspected drugs belong to the antimicrobial class, which is consistentwith the study by Rajan A et al. [27], where antimicrobialsrankedsecondafter various vaccines, with a rate of 7.5%.This highlights both, the potential risk of this drug class to causeADRs and theirhigher use.

Conclusion:-

ADRs remain a significant cause of morbidity and mortality worldwide, highlighting the importance of effective pharmacovigilance. Our study provides an overview of ADR reports received by the regional pharmacovigilance center between 2013 and 2018, emphasizing the diversity of drugs and patient profiles involved. Although age, sex, and polypharmacy were not significantly associated with serious ADRs or ADR-related mortality in this sample. Careful monitoring and adherence to prescribing guidelines remain essential to prevent severe outcomes. These findings underscore the need for continued pharmacovigilance efforts and larger studies to better identify risk factors and improve patient safety.

Conflicts of interest:
The authors state that they have no conflicts of interest to declare.

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