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Pharmacovigilance and patient safety in a Moroccan University hospital.

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 were to calculate the spontaneous reporting rate of ADRs in all patients, to measure their associated mortality rate, to identify their risk factors, and the drug classes involved.

Methods:

This was a descriptive and analytical retrospective study of ADRs reports received by our regional pharmacovigilance center between 2013 and 2018.

Results:

Adverse drug reactions were reported for 140 patients (reporting rate: 47 cases per million inhabitants per year). The mortality rate was 5.7% (n = 8). 66.4% (n=93) of ADRs were classified as serious. Age, sex, and polypharmacy did not appear to be significant risk factors for the occurrence of ADRs (p = 0.835, p = 0.071, and p = 0.055 respectively) or for ADRs related deaths (p = 0.352 for age; p = 0.194 for sex). In total, 327 drugs were used by the patients. Most ADRs were associated with antimicrobials 31.5% (n=103), analgesics and anti-inflammatory drugs 19% (n=62), and cardiovascular drugs 18% (n=59).

Conclusion:

The ADRs reporting rate remains low due to several factors, including insufficient knowledge of pharmacovigilance and the absence of an active reporting system. The role

of polypharmacy in ADRs occurrence is well recognized. Underreporting remains a major issue in our region, despite a notable mortality rate related to adverse drug reactions. Antimicrobial drugs were the most commonly suspected cause of ADRs, reflecting their widespread use.

Keywords: Adverse drug reaction – Reporting – Patient safety - Pharmacovigilance

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 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.

In Morocco, 5% of patients are hospitalized for the ADRs. Since 1989, date of creation of the CAPM 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[2].

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 retrospectively assessed and analyzed all cases of ADRs reported to ourregional pharmacovigilance center between 2013 and 2018.

1 Data collection and analysis

All data were coded and entered into two excel files. The first using ADRs classified according to the << system organ class >> seriousness and evolution of patients.The second analyzing the drugs taken, incriminated drug classes and causality assessment achieved by three methods: WHO, Naranjoand French method. The Imbs [3] method was used to assess the avoidability of deaths.

Computed data was exported into SPSS version 21.0 for analysis. The qualitative variables were expressed in numbers, percentages and the quantitative ones as means and standard deviation or median and quartiles according to the distribution of variable.

A bivariate 1 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.

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.

1 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(table 1).

Of the 140 ADRs reported in this study, the skin and subcutaneous tissue were the most affected (66.4%, n=93), followed by liver disorders and extracardiac vascular system disorders, each accounting for 5% (n=7). Most ADRs reported were classified as serious

66.4%(n=93). ADRs led to hospitalization in 13% (n=12) of cases, extend hospital stay in 48% (n=45), caused permanent disability in 3% (n=3) and were life threatening in 27% (n=25) of cases. 9%of patients (n=8) died as a result of ADRs.

To explore the potential determinants of ADRs seriousness and mortality, a bivariate analysis was conducted. The results are presented in table 2 and 3(table 2 and 3).

According to the WHO method, the causality of 78.3% (n=256) of drugs was assessed as possible and certain in 1.5% (n=5) of cases.Using the Naranjo method, 76.5% (n=250) of drugs were also classified as having possible causality and 0.9% (n=3) were considered certain. According to the French method, the I2 score was the most frequent 31% (n=101) and the I6 score was observed in 4.9%(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, antimicrobials accounted for 31.5% (n=103) of the suspected drugs, followed by anti-inflammatory drugs and analgesics at 19%(n=62). The cardiovascular ones ranked third with 18%(n=59).Among the most frequently suspecteddrugs, amoxicillin ranked first 7.6% (n=25), followed by paracetamol 5.5% (n=18) and allopurinol 3.7% (n=12).

Discussion

Prevalence of ADRs

Several studies have shown that the rate of ADRsvaries between countries. A literature review by Stephanie et al. published in 2011 on theprevalence of ADRsreported a rate of 3.3% in retrospective studies conducted in Germany and 9.65% in prospective studies[4].A study conducted in France by the National Agency for the Safety of Medicines and Health Products showed that more than 20 000 ADRs were reported in 2007, half of which were classified as serious [5].

An additional challenge is that the incidence of ADRs cannot be accurately measured using pharmacovigilance data, as 1 the number of patients who experienced an ADRs

and the number of patients exposedto the drug during a specific period areunknown. Spontaneous reporting remains the main source of pharmacovigilance data. However, at regional, national and international levels, pharmacovigilance systems face a major challenge: underreporting.

A study published in 2006 in Drug Safety, which analyzed 37 studies from 12 different countries estimated that the rate ofunderreporting is higherthan 98%[6].

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[7].

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[8].

The 47 ADRs case reports per million inhabitants per year recorded in the city of Oujda, Morocco confirms underreporting by health professionals with the exceptionof the dermatology department, which reported the highest number of cases. In contrast, in the M-G study byGuédat et al. (2012), the internal medicine department accounted for the majority of reports 70%[9].

Factors influencing ADRs

The bivariateanalysisindicatesthat age, sex and polypharmacy are notstatisticallysignificant factors in the occurrence of serious ADRs ormortalityrelated to ADRs. This couldbeexplained by the small sample size.

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 [10].

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)[11]. A Dutch studyinvestigating ADRs in consumers of selective serotonin reuptake inhibitors drugs confirms theseresults[12].

An American studypublished in 2016, based on an analysisof thefood and drug administrationdatabaserevealedthatamong 20 of the mostcommonlyused treatmentprotocols in the United States, 307 drugs showed sex differences in the occurrence of ADRs[13].

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[14]. This can be partly explained by pharmacokinetic and pharmacodynamic differencesbetween the two sexes [15].

Otherfactorscontributing to this sex differencesincludedvariations in body mass, hormonal levels, drugconsumption patterns, frequency of hospitalvisits, and also the higher adherence to medical prescriptions among women [16].

However, according to a meta-analysis of observationalstudies published in2016, which analyzeddatafromFebruary 2002 to July 2013, no significant difference was observed[17].

Polypharmacy was common: 43% (n=60) of patients were on monotherapy, while 57% (n=80) were taking more than one drug, which agrees with the study by M. von Euler et al (2006) which showed that ADRs occurred more frequently inpatientstaking an average of 8.3 medications. Another study involving 2185 elderly patients onpolypharmacy found that this group was more likely to develop ADRs[18].

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[19].

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 ourseries. 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 byS. Schneeweiss et al (2002) [20].

In2000, an analysis of American studiespublishedsince 1992 reported a mortality rate of 2.7% among all hospitalized patients[21]. An Ethiopian study from 2018 reported a death rate of 1.5%[22]. In four South African hospitals, the rate was 16%[23].In the United States, hepatic ADRs are the leading cause of liverfailure, far surpassing viral and other causes[24].

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.

On the 8 recorded death cases, 3 (37.5%) were related to allopurinol (cases 1, 6 and 7) a drug commonlyprescribed for symptomatic hyperuricemia and the treatment of gout. Allopurinol isknown to be the leading cause of severebullousreactions in Europe including stevens-johnson syndrom (SJS), toxic epidermal necrolysis (TEN) and Lyell's syndrome. It is also one of the main causes of drug rash with eosinophilia and systemic symptoms (DRESS syndrome).Allopurinol should only be prescribed when clearly indicated.It must not beinitiated in cases of asymptomatichyperuricemia. Treatment should be started at a low dose and be increased gradually. Patients shouldbeadvised to stop allopurinol [2] immediately if a rash or itching occurs.

In order to limit the risk of serious bullous reactions, the starting dose of allopurinolshould not exceed 100mg per day andshouldbegraduallyincreasedevery 1-2 months.

Renal function must beassessed prior to prescription, especially in older adults. Allopurinol and its active metabolite are eliminated by renal excretion.In patients with advanced kidney disease, drug accumulation may lead to prolonged half-life.Therefore, the dose of Allopurinol must beadjustedaccording to creatinine clearance [25].

Case 2 involved a newborn whoreceivedvitamin D supplementation for rickets prevention.Sterogyl 15 "H"® 600,000 IU/1.5 ml is indicated for the treatment and prophylaxis of vitamin D deficiency in adults. It is contraindicated in children due to its high vitamin D content [26].

In cases 3 and 4, the respiratory distress syndrome caused by Interstitiallungdisease isaknown ADR of Docetaxel[27].Corticosteroid therapy appears to reduce the incidence of this effect and/or delay its onset[28].

Case 5 presented with pulmonary-renal syndrome, characterized by alveolar hemorrhage and glomerulonephritis. The patient was receiving a daily dose of 2g of amoxicillin/ clavulanic acid, whichshouldhave been reduced to 1.5g and subsequently adjusted according to renal function[29].

Regarding case 8, the patient was a man in his sixties who developed anaphylaxis immediately after receiving rituximab for the first time for the treatment of MALT (mucosa-associated lymphoid tissue) Lymphoma.

Table 6 provides an overview of all cases of death associated with reported ADRs(Table 6):

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. [30], 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 are among the leading causes of morbidity and mortality worldwide. The aim 1 of this study was to analyze all reports received by our regional pharmacovigilance center between 2013 and 2018. Several observations were made, and factors influencing the occurrence of ADRs were studied.Age, sex and polypharmacydo not appear to predispose patients to serious ADRs ormortalityresulting from ADRs. However, a larger sample is needed to better study these factors.

Prospective studies and surveys are necessary to detect and quantify the occurrence of ADRs, and where possible, to reduce healthcare costs associated with ADRs.

Conflicts of interest

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

Acknowledgments

Special acknowledgments to all the staff of Dermatology Department for reporting adverse drug reactions to the regional Pharmacovigilance center, ensuring a culture of patient safety.

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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 1 : Descriptive characteristics of ADRs reports

Factors

Serious ADRs

P

No

Yes

Age

0.835

Adult

6 (35.3%)

11 (64.7%)

Extremes

37 (32.7%)

76 (67.3%)

Sex

0.585

Female

26 (35.1%)

48 (64.9%)

Male

20 (30.8%)

45 (69.2%)

Polypharmacy

0.679

Yes

28(35%)

52(65%)

No

19(32%)

41(68%)

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

Factors

No – Death

Death

P

N(%)

N(%)

Age

0.352

Adult

44 (88%)

6 (12%)

Extremes

7 (78%)

2 (22%)

Sex

0.194

F

34 (92%)

3 (8%)

M

22 (81.5%)

5 (18.5%)

Seriousness of ADRs

0.071

Yes

39 (83%)

8 (17%)

No

17 (100%)

0 (0%)

Polypharmacy

0.572

Yes

30 (88.2%)

4 (11.8%)

No

26 (86.7%)

4 (13.3%)

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

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 4: Causality assessment results

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 5: Avoidability of deaths assessment

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

45 days

21 days

21 days

15 days

Hyperuricémia/ Bladder cancer

Prescription

2

[0-3] months / M

Vitamine D (S)

600 000 UI

Renal failure

/néphrocalcinosis

21 days

Rickets prophylaxis

Prescription

3

[35-39] years / F

Docetaxel (S)

100mg/m2

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)

2g

500mg

DRESS

13 days

Pulmonary renal syndrom with lower limbpurpuric lymphoma

Prescription

6

[30-34] years / M

Allopurinol (S)

Amoxicillin+Clavulanic acid (C)

Oméprazole (C)

Dompéridone (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)

Méthylprednisolone (C)

700mg

Anaphylaxis

Immediately

-

Prescription

Table 6 : Description of deaths

Sources

1	https://pmc.ncbi.nlm.nih.gov/articles/PMC9949640/ INTERNET 2%
2	https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f3bd5852-8e43-6b5d-e053-2995a90a194f INTERNET <1%
3	https://www.journalofhospitalinfection.com/article/S0195-6701(21)00188-2/fulltext INTERNET <1%

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