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Tolerance profile of therapeutics at the Abidjan Cardiology Institute (CÔTE D'IVOIRE)

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Tolerance of treatments is an important factor in compliance and quality of care for various pathologies. The objective of our study was to evaluate the prevalence of adverse events observed in patients at the Abidjan Cardiology Institute (ACI). This descriptive, observational, cross-sectional study involved 200 patients of all ages who were undergoing drug treatment for cardiovascular diseases or other pathologies. These patients were either outpatients coming for consultations or were hospitalized in the medicine department of the Abidjan Cardiology Institute from February 1 to April 1, 2017, and all agreed to participate in the study after providing informed consent. The average age of the patients was 51.7 years (±18 years), with a predominance of women, resulting in a sex ratio of 0.81. The prevalence of adverse events was 24.5%. The majority of these events were dermatological and neurological, predominantly pruritus (39%) and dizziness (10.2%). Additionally, 79.6% of patients reported experiencing such an event once before. In 85.7% of these cases, the similar episode had occurred several years previously. In 69.4% of cases, the adverse events had resulted in incapacity or disability. Nevertheless, all patients had a favorable outcome with no sequelae. The drugs most frequently suspected of causing adverse events were antimalarial drugs (chloroquine; 37%), antihypertensives (26.5%), and analgesics (14.2%). The frequency of adverse events among patients at the ACI was considerable. Establishing a robust pharmacovigilance system at the ACI and integrating adverse event reporting into patients' therapeutic education would help to better assess this safety profile.

Key words: Cardiology, prevalence, pharmacovigilance, tolerance.

INTRODUCTION

Tolerance to a treatment refers to the body's ability to withstand the administration of chemical substances, including drugs, or treatments with physical agents, without adverse effects (Landry and Rival, 2007). It is a crucial factor in ensuring compliance and quality of care in cardiovascular diseases, particularly in the management of high blood pressure (hypertension), which is currently on the rise and constitutes a serious

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public health problem both in Africa and worldwide (Katchunga et al., 2011; Kearney et al., 2005).

The tolerance profile of treatments is an integral part of pharmacovigilance activities. Before a drug is marketed, knowledge of its side effects is not exhaustive. During clinical trials, drug evaluation is limited to a selected homogeneous population and is subject to sustained monitoring. Under these conditions, rare and potentially serious adverse effects are statistically unlikely to be observed. Therefore, robust pharmacovigilance must estimate the frequency of rare adverse effects, establish the benefit/risk balance of the drug, compare adverse effects with those of other treatments, and advise healthcare professionals and patients on the available treatments to improve patient adherence and compliance (International Society of Drug Bulletins, 2005).

Furthermore, patients at the Abidjan Cardiology Institute (ACI) often present with a precarious pathophysiological condition, having more comorbidities and risk factors, which exposes them to polypharmacy (Yobo-Bi et al., 2020). This potential polypharmacy increases the risk of adverse drug reactions (ADRs) (Trinh-Duc et al., 2007). This study, aimed to raise awareness of the need for national pharmacovigilance activities in hospitals, sought to evaluate the prevalence of adverse effects observed in patients at the ACI.

METHODOLOGY

The study was conducted at the ACI located in the municipality of Treichville, in collaboration with the clinical pharmacology department of the Faculty of Medical Sciences of Bouaké, Côte d'Ivoire. The ACI is a public reference institution specializing in the treatment of cardiovascular diseases at the national level and in the West African sub-region. Operational since January 1977, it includes services for consultation, emergency care, pediatric cardiology, intensive care, medicine, surgery, resuscitation, laboratory work, imaging, and external exploration. Specialized management of cardiovascular diseases in Côte d'Ivoire is provided by the cardiology department at the Bouaké University Hospital and the ACI at the Treichville University Hospital, where this study took place.

This cross-sectional observational study, with a descriptive aim, focused on patients under drug treatment for cardiovascular conditions (such as essential hypertension, hypertensive or ischemic heart disease, thromboembolic diseases, etc.) or other conditions. It included both hospitalized patients and outpatients who came for consultation at the ACI from February 1 to April 1, 2017 (2 months). Conscious patients, regardless of sex or age, who came for outpatient consultation or were hospitalized in the ACI medicine department during the study period and who provided informed consent were included. Patients who refused to participate and patients or parents of patients facing language barriers without an interpreter were not included. Sampling was random among patients in the outpatient and inpatient medicine departments of the ACI. The sample size will be calculated according to the Schwartz formula:

$$N = t^2 p (1 - p) / i^2,$$

where N: minimum sample size necessary, t: threshold value read in the reduced deviation table for a significance threshold α at 5% = 1.96, p: estimated prevalence = 88% and i: desired precision = 5%, N= 162.26 or 162.

Considering the refusal rate, the sample was estimated at 200 patients to maintain acceptable power. Data were collected using the national pharmacovigilance form and were obtained from interviews, patient files, patient follow-up diaries, and consultation forms. Investigators filled out the survey form through face-to-face interviews with the patient or the patient's family. Given that pharmacovigilance is not a widely practiced activity at the ACI, the interview process included informing patients about the concept and objectives of pharmacovigilance and the study to obtain their consent to participate.

The parameters studied included sociodemographic data (age, sex, weight) and pharmacovigilance data (prevalence of adverse effects, frequency, nature, clinical type, severity, evolution, and suspected drugs). Data were processed using the Epi Info 7 software. In the statistical analysis, proportions and percentages were estimated from qualitative variables, while quantitative variables were used to calculate averages with standard deviation and extremes.

Authorization from the Medical and Scientific Directorate of the ACI was obtained (No. 001-2017 of February 3, 2017). Patients' opinions, anonymity, and confidentiality were respected throughout the data collection and processing period.

RESULTS

Socio-demographics

The average age of the patients interviewed was 51.7 ± 18 years, with age extremes ranging from 1 to 88 years, and a predominance of the age group from 1 to 64 years. Females represented 55% of the general population, with a sex ratio (M/F) of 0.81. The average weight was 69 ± 18 kg. The average age of patients experiencing drug-related adverse effects was 52 ± 11 years, with a female predominance (65.3%) (Table 1).

Pharmacovigilance

The prevalence of adverse events was calculated according to the formula:

$$P\ (\%) = \frac{\text{Number of cases of adverse events}}{\text{Number of patients exposed during the study period}} \times 100$$

Among the 200 patients included in the study, 49 had experienced at least one adverse event, representing a prevalence of 24.5%. These were all clinical adverse events. The majority of these events were dermatological and neurological signs, predominantly pruritus (39%) and dizziness (10.2%) (Table 2). In 79.6% of cases, patients had experienced the adverse events once, with these events occurring several years prior in 85.7% of cases. In 69.4% of cases, the adverse events had resulted in incapacity or disability. However, all patients had a favorable outcome with no sequelae (Table 3). The suspected drugs were mainly antimalarials (chloroquine; 37%), antihypertensives (26.5%), and analgesics (14.2%)

Table 1. Sociodemographic characteristics of the general population.

Sociodemographic	N=200	Percent
Age classification		
01-64 years old	148	74
≥65 years old	52	26
Average age ±SD	51.7± 18	
Sex		
Female	110	55
Male	90	44
Ratio (M/F)		0.81
Average weight (kg)	69 ±18	
Drug iatrogenic	**N=49**	
Age group		
36-64 years old	42	85.7
≥65 years old	7	14.3
Average age ±SD	52 ±11 years	
Sex		
Female	32	65.3
Male	17	34.7

SD: Standard deviation.

Table 2. Distribution of patients according to clinical type of adverse event.

Clinical type	Symptoms/clinical signs	N	Percent
Dermatological 24 (49%)	Pruritus	19	38.8
	Urticaria	5	10.2
Neurological 10 (20.4%)	Vertigo	5	10.2
	Headache	2	4.1
	Insomnia	1	2
	Lipothymia	1	2
	Migraine	1	2
Allergic 3 (6.1%)	Facial puffiness	1	2
	Macroglossia	1	2
	Sneeze	1	2
Muscular 3 (6.1%)	Cramp	1	2
	Adynamia	1	2
	Heaviness	1	2
General 2 (4.1%)	Edema	1	2
	Asthenia	1	2
Cardiovascular 2 (4.1%)	State of shock	1	2
	Palpitation	1	2
Urological 2 (4.1%)	Polyuria	2	4.1
Ophthalmological 2%	Visual blur	1	2
Pulmonary 2%	Cough	1	2
Digestive 2%	Hypersalivation	1	2
Total		49	100

Table 3. Distribution of patients according to the characteristics of the adverse event.

Adverse events	N=49	Percent
Frequency of occurrence		
Once	39	79.6
Twice	3	6.1
Thrice	0	0
Four times and more	7	14.3
Period of occurrence		
Week	1	2
Month	6	12.2
Year	42	85.7
Nature		
Clinical	49	100
Biological	0	0
Severity		
Minor	34	69.4
Moderate	14	28.6
Severe	1	2
Evolution		
Healing without sequelae	49	100
Patient not yet restored	0	0

(Table 4). The drugs were primarily in tablet form and administered orally (93.8%). Only 6.2% were injectable solutions administered intravenously (metopimazine; 2.06% and penicillin; 2.06%) and subcutaneously (SAT; 2.06%). Chloroquine, cotrimoxazole, and codeine were responsible for pruritus, urticaria, and dizziness, respectively (Table 5).

DISCUSSION

Limitations of the study

In the study, the general population was relatively young, with an average age of 50 years, and predominantly female. The frequency of drug iatrogenicity was high, with dermatological signs predominantly dominated by pruritus, for which chloroquine was responsible. Difficulties were encountered, including cases of refusal to participate and reluctance during questioning, which could potentially introduce recruitment bias. However, the number of cases seemed significant. The survey involved direct interrogation for some patients, and the form presented questions with multiple-choice answers, possibly leading to unnatural or non-enhancing responses from patients and/or fear of the practitioner.

To address this, an information session was held prior to the survey to obtain verbal consent. Additionally, imputation, which would have allowed assessment of the causal link between the occurrence of the event and the taking of the medication, was not conducted. Drug interactions were also not investigated in this study. Another limitation was the inclusion of the pediatric age group, where only adverse effects visible to parents or the attending physician would have been reported, considering the differences in pharmacokinetics of medications between pediatric and adult populations.

Strong points

Despite the encountered difficulties, this study shed light on the prevalence of adverse events in the cardiology department and emphasized its significance in the reporting system to enhance data quality. It specifically highlighted the role of antihypertensive drugs and their frequency in the occurrence of these adverse events.

Socio-demographics

The study population at the Abidjan Cardiology Institute (ACI) consisted mainly of adults in their fifties, with a predominant age group between 01 and 69 years,

Table 4. Distribution of suspected drugs during adverse events.

Families	INN	N=49	Percent
Antimalarials 18 (37%)	Chloroquine	18	37
Antihypertensives 13 (26.4%)	Captopril	5	10.2
	Amlodipine	4	8.2
	Amiloride	1	2
	Furosemide	1	2
	Spironolactone	1	2
	Telmisartan	1	2
Analgesics 7 (14.3%)	Paracetamol, Codeine	7	14.3
Antibiotics 5 (10.1%)	Cotrimoxazole	3	6.1
	Amoxicillin	1	2
	Amoxicillin, Clavulanic acid	1	2
NSAIDs 4 (8.1%)	Acetylsalicylic acid	3	6.1
	Aceclofenac	1	2
Antiemetics 1 (2%)	Metopimazine	1	2
Anti-tetanus 1 (2%)	Anti-tetanus serum (SAT)	1	2

INN: International Non-proprietary Name; NSAIDs: Nonsteroidal Anti-inflammatory Drugs.

Table 5. Distribution of medications according to adverse events observed.

Adverse events	INN	N=49	Percent
Pruritus	Chloroquine (18); Amoxicillin (1)	19	38.8
Urticaria	Cotrimoxazole (2); SAT (1); Codeine (1); ASA (1)	5	10.2
Dizziness	Codeine (3); Spironolactone (1); ASA+Codeine+Caffeine (1)	5	10.2
Headache	Codeine (1); Captopril (1)	2	4.1
Polyuria	Amlodipine (1); Perindopril+Indapamide (1)	2	4.1
Insomnia	ASA	1	2
Lipothymia	Metopimazine	1	2
Migraine	Captopril	1	2
Face puffiness	Captopril	1	2
Macroglossia	Aceclofenac	1	2
Sneeze	Amlodipine	1	2
Cramp	Amiloride hydrochloride + Hydrochlorothiazide (1)	1	2
Adynamia	Paracetamol + Codeine	1	2
Heaviness	Cotrimoxazole	1	2
Edema	Telmisartan	1	2
Asthenia	Amlodipine	1	2
State of shock	Penicillin	1	2
Palpitation	Captopril	1	2
Visual blur	Codeine	1	2
Cough	Captopril	1	2
Hypersalivation	Methyldopa	1	2

ASA: Acetyl salicylic acid.

reflecting similar findings from Ivorian studies at the ACI where the average age ranged between 50 and 60 years (Konin et al., 2007; N'goran et al., 2015). This average age aligns closely with that of other African populations,

which typically range from 44.5 to 61 years (Sagui, 2007; Coulibaly et al., 2010). In contrast, cardiovascular pathologies predominantly affect individuals' aged 80 to 89 in European populations (Bamba-Kamagate et al., 2016). The early onset of cardiovascular disease in Africa could be attributed to non-compliance with hygienic-dietary measures due to poverty and illiteracy, which affect 56.1% of the population (National Institute of Statistics, 2014).

While adverse reactions can occur in any patient, certain characteristics of the elderly, such as co-morbidities (e.g., heart disease, renal failure) and polypragmatism, render them more susceptible. Age-related changes in pharmacodynamics and pharmacokinetics further increase the risk of adverse effects (Snezana et al., 2015; Ruscin et al., 2021). In our study, there was a predominance of females, with a sex ratio of 0.81. This female predominance has been previously observed at the ACI, with rates around 56 to 57% (Adoubi et al., 2006; N'goran et al., 2015). However, Cowppli-bony et al. (2007) found a male predominance in the occurrence of cardiovascular pathologies at the Bouaké University Hospital. Indeed, prevalence varies according to sex in the African literature (Sagui, 2007).

Notification

Drug-related adverse reactions appeared to be significant, with a prevalence of adverse drug events estimated at 24.5% over a 2-month period. This figure underscores the substantial impact of adverse drug events in terms of morbidity. Our results were comparable to those of Snezana et al. (2015) who found a 34% prevalence of adverse drug reactions among 200 cardiac patients hospitalized at the Montenegro cardiology center. However, it is worth noting that our results likely underestimate the true prevalence of adverse events due to the absence of an operational pharmacovigilance system in Côte d'Ivoire, particularly at the ACI. This is especially pertinent for patients with chronic illnesses requiring prolonged medication use. Healthcare professionals may perceive pharmacovigilance as an additional unpaid workload, leading to low reporting rates (Yobo-Bi et al., 2020; Kamagate et al., 2016).

Establishing a telephone hotline accessible to outpatients could facilitate remote management of minor cases and improve the assessment of drug tolerance profiles. Integrating adverse drug reaction monitoring into the key parameters of clinico-biological monitoring during external consultations or inpatient visits could also enhance reporting rates. Recent work in Nigeria showed an 18.1% prevalence of adverse effects (Olowofela and Isah, 2017), while the study by Millogo et al. (2018) found an overall prevalence of 60.1% over a 3-month period. Comparing their study to ours, which focused solely on outpatient-treated patients, we observe either good treatment tolerance among ACI patients or under-notification.

These ADRs were predominantly clinical in nature, with dermatological signs comprising 49% and neurological signs 20.4%. Immuno-allergic effects represented a small proportion at 6.1%. However, it's important to note that this low frequency may not account for iatrogenic cutaneous drug reactions such as pruritus and urticaria, which often have an immuno-allergic mechanism (Olivier et al., 2001). Consequently, the number of drug allergies in this study is likely higher. Despite this, no serious cutaneous reactions such as toxidermia were observed, despite their occurrence affecting 2 to 3% of hospitalized patients in France (Veyrac and Jolliet, 2006).

A significant proportion of patients (79.6%) had previously experienced a similar episode, with most occurrences dating back several years (85.7%). This long latency phase before the appearance of a new adverse event episode could be a source of concern for patients or their relatives, prompting them to report to the doctor, which could explain the high notification rate observed. The majority of adverse events were minor (69.4%) or moderate (28.6%). These ADRs were attributed to antimalarial drugs (chloroquine; 37%), antihypertensives (26.4%), and analgesics (14.3%). The widespread availability of smuggling markets in Côte d'Ivoire and certain medicines, such as paracetamol, being sold over the counter in pharmacies, could contribute to the high use of these products. Additionally, inappropriate self-medication and the low level of knowledge among street drug sellers may be linked to the over-consumption of chloroquine.

Chloroquine, previously utilized in the treatment and prevention of malaria, was abandoned due to the emergence of chloroquine-resistant strains of *Plasmodium falciparum*. However, these drugs (chloroquine and hydroxychloroquine) remain among the oldest drugs used in rheumatology (Alina et al., 2021). Hydroxychloroquine is the standard treatment for systemic lupus erythematosus (SLE), and the latest European guidelines recommend its use in all patients without contraindications or adverse effects (Alina et al., 2021).

For several decades, chloroquine has demonstrated its efficacy in vitro by inhibiting the replication of numerous viruses (Nessaibia et al., 2021). These in vitro antiviral effects have sparked hope for the repositioning of this old and inexpensive drug for the treatment of various viral infections. This is particularly significant in cases where specific treatments are either non-existent or not widely available, especially in countries with limited resources (Nessaibia et al., 2021; Bhagteshwar et al., 2021).

However, the use of chloroquine is limited by numerous side effects. Among these effects, common ones include pruritus, rash, blurred vision, retinopathy, and myocardiotoxicity, which may manifest as QT interval

abnormalities (Nessaibia et al., 2021; Bhagteshwar et al., 2021). This toxicity can be attributed to the drug's very long half-life and large volume of distribution. Additionally, other psychiatric side effects, sometimes neuromuscular, have been associated with the use of chloroquine and its derivatives (Nessaibia et al., 2021).

Most of the adverse events associated with these medications were already known. However, symptoms such as heaviness, insomnia, visual blurring, polyuria under amlodipine, and hypersalivation appeared to be previously undescribed. Apart from chloroquine-related adverse effects, the results are comparable to those of Olowofela and Isah (2017). Other drugs implicated in the occurrence of adverse drug reactions included captopril, amlodipine, and analgesics, especially paracetamol and codeine.

Conclusion

In this study, the frequency of adverse events among patients at the ACI was considerable, with dermatological and allergic reactions being predominant, particularly pruritus and urticaria. While these events were primarily minor, they were known and expected. Chloroquine, previously indicated for the treatment of malaria, was the most frequently implicated molecule. Combatting contraband markets could help limit the frequency of ADRs associated with medications, especially those with a high risk of toxicity. Therefore, establishing an operational pharmacovigilance system at the ACI and integrating notification into therapeutic patient education would aid in better assessing this tolerance profile.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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