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Incidence of Adverse Drug Reactions in Patients on Antiretroviral Therapy: A Study of Pharmaceutical Care in HIV Interventions in A Tertiary Health Facility in Southern Nigeria

Peter Okpe Agada
Pharmacist, University of Calabar Teaching Hospital, Calabar – Nigeria
PO box 1111, Calabar, Nigeria

Abiodun Komomo Eyong
Department of Pharmacy, University Medical Centre, University of Calabar – Nigeria
P O box 1111, Calabar, Nigeria

Eyo Okon Asukwo
Department of Community Medcine, University of Calabar – Nigeria
PO box 1111, Calabar, Nigeria

Chuku Irene
Pharmacist, Department of Pharmacy: University of Calabar Teaching Hospital – Nigeria
PO box 1111, Calabar, Nigeria

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Abstract
Antiretroviral drugs are used to prolong and improve the quality of life for those infected, but this therapy has associated side effects and adverse drug reactions (ADRs) of varying degrees in frequency and severity. A better understanding of adverse effects is of interest not only to the HIV specialists as they try to optimize on therapy but also to the patient who may not be aware of these adverse reactions due to the multiple symptoms associated with the AIDS syndrome. Not much is known about ADRs in Nigeria. The objective of this study was to determine the incidence and management of various ADRs occurring in patients accessing treatment and care at Dr. Lawrence Henshaw Memorial Hospital, Calabar, Nigeria. The study was a Cross-sectional retrospective study conducted by reviewing patient data from the pharmaceutical monthly summary form from May 2012 to-June 2013. Majority of the clients, 73(63%) were males while 43(37%) were females, 116 clients were screen for ADR and out of this number 84(72%) had an adverse drug reaction of various severity grades. The reported incidence of ADR was much higher among male clients 54(74%) than the female clients 30(70%). Interventions were provided for clients who reported ADR and the Number of clients documented for Adverse Drug Reactions (ADRs) interventions were 84(100%), some clients were provided with more than one ADR interventions.
Keywords: ADRs, HIV., Intervention , Antiretroviral drugs

1. Introduction

Patient safety is considered a key element in the overall quality of care of patient accessing antiretroviral therapy. The commencement of Highly Active Antiretroviral Therapy (HAART) has resulted in remarkable decreases in the rate HIV morbidity and mortality in both the developed and developing countries including Nigeria (Palella, et al,2006) and this highly active antiretroviral drugs has been flaunted as one of the greatest advances in the response to the HIV pandemic globally. Encumbrance of toxicity resulting from highly active antiretroviral therapy (HAART) is of public health concern as it constitutes a threat to sustained success of HIV treatment (Dieleman, 2002). Monitoring ADR among patients is important to pharmaceutical care which can be defined as responsible provision of medication-related care designed to achieve definite outcome that improves patient quality of life (ASHP, 1993).

Pharmaceutical care is also aimed at eliminating or reducing drug therapy related problems including ADR. As interventions, HAART regimen may be changed or replaced with another due to drug resistance and HAART may be modified or interrupted as a result of adverse effects or virologic failure (Tayal, Gupta, Nagpal, Kumar, 2010). Studies have shown that adverse effects may in themselves result in virologic failure or disease development as a result of sub optimal dosing or treatment interruption for example in a study by Monforte, d'Arminio, Lepri, Rezza ,Pezzotti, Antinori, &Phillips, (2000) , 21% of those who discontinued therapy did so because of associated toxicity of the drugs . Also In a study carried out in India about ninety percent of all the patients on ART developed an adverse drug reaction and about 618 episodes were recorded in various systems, the abdominal and central nervous systems were the most affected (Tayal, *et al* 2010). Making available data on the types and rates of adverse reactions is important to the success of any HAART program. With limited local

data on adverse reactions and an increase in the availability of HAART services, there is need to report pattern of adverse drug reactions for timely intervention.

2. Research Methodology

2.1 Study Setting

This study was carried out in Dr. Lawrence Henshaw Memorial Hospital (DLHMH),a Hospital owned by the Cross River state Government. It was founded in 1905. The health institution was formerly known as Infectious Disease Hospital (IDH) because it was mainly taking care of people with tuberculosis, leprosy and other infectious disease. It serves people from all the states in South-South and South East. It was renamed DLHMH in 2005. In 2007, it was activated to offer comprehensive ART services under the Global HIV/AIDS Initiative in Nigeria (GHAIN) program. The current Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) program have been supporting the facility immensely after GHAIN. Presently, the facility handles infectious diseases e.g. HIV care/treatment, tuberculosis and Multi-Drug Resistant Tuberculosis (MDR-TB). The ultramodern MDR-TB ward started operation in 2012. It has fourteen (14) bed space. Also there is an ultra-modern MDR-TB Laboratory sponsored by Family Health International (FHI360) in the facility. To ensure the safety and proper care of clients, the hospital is made-up of a male chest ward, female chest ward, general ward and casualty. There are five (5) Medical Practitioners, one (1) Pharmacist, and seven (7) Medical Laboratory Scientists working in the facility.

2.2 Study Design

A Cross-sectional retrospective study was conducted reviewing patient data from the pharmaceutical monthly summary form from May 2012-June 2013

2.3 Data Analysis

Data was analyzed using SPSS version 20and Excel and descriptive statistics was conducted and included frequency distribution of relevant variables. Incidence of ADR was calculated and reported.

3.0 Findings/Result

Majority of the clients, 73(63%) were males while 43(37%) were females, 116 clients were screen for ADR and out of this number 84(72%) had an adverse drug reaction, while 34 (23%) had never had an adverse drug reaction. The reported incidence of ADR was much higher among male clients 54(74%) than the female clients 30(70%). The reported ADR included; dry mouth 31(14.4%), malaise 20(9.3%), abdominal pain 16(7.4%), Anemia 12(5.5%) (Table 1). Adverse drug reactions studied in the reported data indicated that Nausea / Vomiting, was more frequent in males (Table 2). Interventions were provided for clients who reported ADR and the Number of clients documented for Adverse Drug Reactions (ADRs) interventions were 84(100%), some clients were provided with more than one ADR interventions. Interventions provided includes; Referred to prescriber / other HCWs/facility for ADR management (71), Patient counseled on how to manage ADR (84), Drug therapy initiated/ changed (58).

Table1. Frequency distribution of documented ADR

ADR Description	Frequency/Percent
Nausea / Vomiting	14(6.5)
Abdominal pain	16(7.4)
Fever	4(1.8)
Gastritis	3(1.3)
Conjunctivitis	1(0.4)
Anorexia (loss of appetite)	15(6.9)
Depression	2(0.9)
Dizziness	5(2.3)
Dry mouth	31(14.4)
Headache	12(5.5)
Insomnia	9(4.1)
Nightmares	3(1.3)
Pain, tingling or numbness in hands or feet	2(0.9)
Visual disturbances (blurred vision etc)	2(0.9)
Chest pain / Chest discomfort	3(1.3)
Tinnitus	6(2.7)
Oedema	3(1.3)
Palpitation	13(6.0)
Pruritus (Itching)	3(1.3)
Hypoglycemia	2(0.9)
Dehydration	1(0.4)
Atropy on injection site	1(0.4)
Polyuria (Increased micturition)	4(1.8)
Arthralgia	4(1.8)
Myopathy	6(2.7)
Muscle Pain (Myalgia)	4(1.8)
Anaemia	12(5.5)
Fatigue/weakness	5(2.3)
Malaise	20(9.3)
Psychosis	4(1.8)
Neurological complications	5(2.3)

Table 2. Distribution of documented ADR by sex

ADR Description	Male	Female
Nausea / Vomiting	14	0
Abdominal pain	11	5
Fever	4	0
Gastritis	3	0
Conjunctivitis	0	1
Anorexia (loss of appetite)	11	4
Depression	2	0
Dizziness	4	1
Dry mouth	19	12
Headache	8	4
Insomnia	8	1
Nightmares	2	1
Pain, tingling or numbness in hands or feet	2	0
Visual disturbances (blurred vision etc)	2	0
Chest pain / Chest discomfort	2	1
Tinnitus	5	1
Oedema	2	1
Palpitation	12	1
Pruritus (Itching)	2	1
Hypoglycemia	0	2
Dehydration	0	1
Atropy on injection site	1	0
Polyuria (Increased micturition)	4	0
Arthralgia	4	0
Myopathy	3	3
Muscle Pain (Myalgia)	2	2
Anaemia	8	4
Fatigue/weakness	3	2
Malaise	11	9
Psychosis	3	1
Neurological complications	5	0

4. DISCUSSION

The gamut of adverse drug reaction is wide and varied, and the exact cause may be difficult to identify however a wide range of group and individual adverse drug reaction effect have been documented and described. Research have shown that the impact of HAART on the natural history of HIV infection is undeniably positive in terms of overall improved health and clinical outcomes, but it is quite worrisome that in spite of this, the occurrence of adverse reactions to HAART may negatively impact quality of life and adherence to treatment, limiting its efficacy (Teodor, Teodor & Luca,2004). Most adverse effects can be determined by appropriate clinical examination for specific symptoms and signs, including fatigue with conjunctiva pallor anemia, neuropsychiatric problems, peripherial wasting, rash etc (Subbaraman, Chaguturu, Mayer, Flanigan TP, &Kumarasamy, 2007). Dry mouth constituted the highest ADR reported among the ART patients followed by, malaise 20(9.3%), abdominal pain 16(7.4%), and Anorexia (loss of appetite). There were no reported cases of Skin rashes this contradict previous research findings that skin rash and peripheral neuropathy were common ADRs in ART patients (Olowookere, Fatiregun , Akinyemi, Bamgboye, Osagbemi ,2013).

The study findings showed very low occurrence of fever, conjunctivitis, dehydration, atrophy, hypoglycemia, blurred vision, pain, tingling or numbness in hands or feet and depression compared to previous study findings by Olowookere *et* al. (2013) . The reported prevalence of ADR was much higher among male than the female clients 30(70%), compared to a previous study finding (Singh, Dulhani, Tiwari, Singh &Sinha, 2009). The majority of the actions taken to treat ADRs were not indicated. Interventions that were provided included referral to prescriber / other HCWs/facility for ADR management, counseling of patient on how to manage ADR, change of Drug therapy initiated. The study provided the data on the incidence of suspected ADRs in patients on ART in DLHMH, Calabar. It also shows that active surveillance for ADRs in HIV-positive patients on ART is feasible in resource-constrained health facilities using pharmaceutical care in HIV interventions. However, the study excluded ADRs caused by other drug related problems such as medication

errors and therapeutic failures. Inadequate pharmacy personnel and high patient load were the major barriers to achieving active surveillance for ADRs, thus some ADRs cases in patients may have been missed.

5.CONCLUSION:

The study reveals a significant incidence of adverse drug reactions occurring in patients on HAART requiring case specific interventions. Pharmaceutical care/Pharmacovigilance is therefore recommended for these patients to enhance positive treatment outcomes.

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