ANTICANCER DRUG USE AND OCCURRENCE OF ADVERSE DRUG REACTION IN A TERTIARY HEALTH INSTITUTION IN LAGOS, NIGERIA

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KEY WORDS

Cancer Chemotherapy, Adverse Drug Reactions, Prescribing Pattern

ABSTRACT

This study aims at determining the prescribing pattern for anticancer drugs and the nature and frequency of occurrence of adverse drug reactions in the Lagos University Teaching Hospital Nigeria.

Two hundred and sixty two prescription records from January 1997 to December 2002 were obtained and assessed. Data on the patients' demographics, diagnosis, and patterns of treatment as well as the occurrence of adverse drug reactions were collected and analysed.

Alkylating agents were the most frequently prescribed class of antineosplastics followed by the Cytotoxic Antibiotics, the Antimetabolites, Spindle Poisons and Hormones. The most common drug combinations were: Cyclophoshamide, Methotrexate, 5-Fluorouracil (CMF-, Cyclophoshamide, Doxorubicin, 5-Fluorouracil (CDF-) and Cyclophoshamide, Doxorubicin, Vincristine (CDV-).

The average number of drugs per encounter was 3.4 and percentage of drugs prescribed by generic name was 10.9%. Life threatening ADRs were reported in 79 cases and the most common ones reported were bone marrow depression (28.6%) and severe emesis (21.4%). Death was reported in 24% of the patients; most of which resulted from complications of the disease.
There is a need for an educational intervention aimed at improving the rational use of anticancer agents and effective management of adverse drug reactions

INTRODUCTION

Cancer is one of the major causes of death in developed and some developing countries. In Nigeria it forms a sizeable proportion of mortality in health institutions providing cancer care [1,2].

Less than a quarter of patients will be cured solely by surgery and/or radiotherapy, the remainder will receive systemic chemotherapy.

In a small fraction of patients, chemotherapy will result in a cure or prolonged remission[3], however with early diagnosis and advances in management pattern including combination therapy, the proportion will increase.

Several principles guide the use of combination chemotherapy for malignant disease. Each of the drugs used should have demonstrated activity against the tumor, the drugs should have different mechanisms of action, minimal overlapping toxicities and the maximal optimal doses should be used and scheduled with respect to specific tumor cell kinetics[4].

Cancer chemotherapy, however, presents special dangers to patients because many antineoplastic agents have a narrow therapeutic index and are toxic even at therapeutic dosages[5]. This might result in severe adverse drug reactions (ADRs) especially when they are prescribed in inappropriate combinations.

Previous studies to determine the incidence of antineoplastic related ADRs have reported the high incidence and excessive cost associated with the management of ADRs related to cancer chemotherapy[6,7].

The prescribing, administration and monitoring of these agents therefore require detailed attention to dosage calculations and administration schedules, which can be quite complicated.

Giving the direct association that exists between optimal use of anticancer drugs and increased survival or cure from cancer[8] it becomes imperative to carry out a drug utilization survey with a view to establishing that treatment standards are maintained with minimal occurrence of ADRs. Moreover there is a dearth of studies on anticancer drug use in Nigeria. This study assessed the use of anticancer drugs and the occurrence of their adverse effects in a tertiary health facility located in a Nigerian cosmopolitan city.

METHODS

Setting

The study facility, Lagos University Teaching Hospital Nigeria, has about 600 beds, is government owned and provides secondary and tertiary health care services to the community. As in other government hospitals in Nigeria, patients pay for drugs supplied to them by the hospital pharmacy. The study was carried out at the Oncology unit of the Radiotherapy Department, which records an average weekly attendance of about 30 patients.

Design

This was a retrospective study in which all available prescription records containing anticancer drugs from January 1997 to December 2002 were used, however some records could not be retrieved. The case notes were identified and transcribed on a prescribing encounter form containing the age, sex of patient, name and strength of drug prescribed aa well as working diagnosis. Rational use of prescribed drugs was assessed using some World Health Organization /International Network for Rational Use of Drugs (WHO/INRUD) prescribing indicators[9].

Another form was used to record occurrence of adverse drug reactions, their nature and the interventions that were used to manage the ADRs, including any prophylactic agent given or precautionary measure taken at the begining of therapy.

Data Analysis: All the data were entered, rechecked for accuracy and analyzed using Epi-info 2002. Frequencies were expressed as percentages. The Chi-square test was employed for tests of association at 95% confidence interval. Two-tailed P values less than or equal to 0.05 were considered significant.

RESULTS

Demographics

A total of 244 case notes were assessed. The number of male patients was 56(23%) and female patients 188(77%). The age range was 1 to 82 years with a mean age of 41.2
The age group with the highest number of cancer patients was 41-50 years with 67 (27%) patients. This age group also accounted for the highest number of breast cancer (31.9%), cervical cancer (36.6%) and thyroid cancer (37.5%) patients. Furthermore, 85% of the patients in this age group were females. The 51-60 years age group followed closely with 56 (23%) patients. The 21-30 year and 71-82 year age groups had the least number of cancer patients with 13 (5%) and 9 (3.6%) respectively. (Table I)

Diagnosis

Breast cancer accounted for the highest proportion of cases (37.3%) followed by cervical cancer (16.8%). (Table II) Some (4.9%) patients had retinoblastoma, (most of them in the <20 age group), 8 (3.3%) had thyroid cancer while the remaining (37.7%) had other forms of cancer including Adenocarcinoma, Leukaemia, Hodgkins disease, Wilms tumor, colon cancer, rhabdomyosarcoma, protate cancer and various lymphomas.

Management

This consisted of chemotherapy, radiotherapy and surgery. Chemotherapy alone accounted for 40.1% of cases, radiotherapy alone, 28.6% of cases while radiotherapy plus chemotherapy accounted for 24.4% of cases. A combination of these three modes of treatment in patients accounted for only 4.6% of cases.

Alkylating agents were the most frequently prescribed class of antineosplastics (54.5%) followed by the Cytotoxic Antibiotics (27.5%), Antimetabolites (24.5%), Spindle Poisons (17.2%) and Hormones (12.3%) (Table III) The most commonly prescribed antineoplastic drug combinations were Cyclophosphamide, Methotrexate, 5-Fluorouracil (CMF-21.4%), Cyclophoshamide, Doxorubicin, 5-Fluorouracil (CDF-18.8%) and Cyclophoshamide, Doxorubicin, Vincristine (CDV-17.6%). Cyclophoshamide was the most frequently prescribed antineoplastic agent, occurring in 52.5% of prescriptions.

Average number of drugs per encounter was 3.4. Percentage of drugs prescribed by generic name was 10.9% and 63.6% of drugs prescribed where from the Essential Drugs List (EDL).

Life threatening ADRs were reported in 79 (32%) cases the most common being bone marrow depression (28.6%), severe emesis (21.4%) and anorexia (9%). Other ADRs included general body weakness (7.1%), pruritus (1.5%), stomatitis (7.1%) and emergence of second malignancy (2.6%) (Figure I).

Death resulting from complications of the disease was reported in 24% of patients.

DISCUSSION

The findings of this study showed a direct association between age and cancer incidence from age 21 up to age 50 and then an inverse association from age 51 upwards among adult patients The same trend could be observed in patients with breast cancer, which was the most frequently diagnosed malignancy. Studies have shown that although cancer of the breast is rare in a female who is less than 25yrs of age the incidence increases beyond the age of 25 years, with the peak occurring in women who are approximately 50 years of age (or coincident with the onset of menopause)[4]. Our findings agree with these studies and also with the findings that post menopausal women continue to be at a higher risk of developing breast cancer than younger women. However as they age further, the risk decreases[4]. Retinoblastoma though a childhood tumor, was observed in 3 adult patients. From our findings most of the prescriptions contained appropriate combinations of anticancer agents the most common of which were CMF and CDF. These two combinations are modifications of a succesful 5-drug combination consisting of Cyclophoshamide, Methotrexate, 5-Fluorouracil Vincristine and Prednisolone CMFVP which was found to provide an unprecedented response rate of 90% in 60 hormone-resistant breast cancer patients[10]. The classical treatment for Hodgkins disease (MOPP)[11] was utilized appropriately. Studies have shown that combination chemotherapy is superior to single-agent

chemotherapy[10,11] The rationale for combination therapy is that several effective agents with different mechanisms of action are more likely to destroy different subpopulations of cancer cells and reduce the potential for development of drug resistance. Furthermore the minimal doses used are expected to reduce incidence of ADRs. However polypharmacy (as much as 8 drugs per prescription) was observed in some prescriptions, which could cause adverse drug events arising from overlapping toxicities and drug interactions As in previous studies[6,7] a high incidence of ADRs (32%) was reported When using drugs with moderate selectivity, like anticancer drugs, adequate facilities must be available to provide vigorous supportive therapies including platelet transfusion, powerful antiemetic agents e.g. Ondansetron, a 5HT3 antagonists, broad spectrum antibiotics and haematopoeitic growth factors amongst others[3]. These are additional cost, which the patient must bear to improve therapeutic effectiveness and minimize address.

Death was reported in 24% of patients most of which resulted from complications of the disease. Interview with some of the prescribers at the Oncology unit showed that non-adherence to prescribed regimens might be a major contributing factor, as many of the patients could not afford the high cost of a complete regimen. Further more many of these drugs were prescribed using specific brand names which are much more expensive than their generic equivalents Subsidy on anticancer drugs by government and non-governmental organizations will increase access to these drugs and therefore improve adherence, minimize complications and consequently improve therapeutic outcomes.

Fatigue and reduced appetite were among the commonly occuring ADRs reported.

They have been shown along with constipation and drowsiness to impact negatively on patients well being[12] It is therefore important to ensure that patients are taught to recognize these ADRs so that treatment can be modified accordingly[5] Indeed the benefits of this on the patients quality of life has been reported[12]. There is a need for additional studies on the quality of life associated with many treatments and whether transitions from curative treatments to end-of-life care (i.e., use of supportive agents [such as pain medication] only) are occurring appropriately."

The prescribing indicators used in this study gave an insight into the prescribing pattern for antineoplastics. However the study did not compare prescriptions/management with standard clinical oncology practice guidelines[13] including the availability of the chemotherapy order form, which ensures completeness in prescription information .

Conclusions: This study has shown that although appropriate combinations of antineoplastics were prescribed, their was minimal use of generic products. There is a need for an educational intervention for prescribers aimed at improving rational use of antineoplastics and more effective management of ADRs.

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Table I: Relationship between Age Groups and Sex of Patients attending the Oncology Clinic, LUTH

AGE GROUP	FEMALE (%)	MALE (%)	TOTAL (%)
<20	18 (78.3)	5 (21.7)	23 (9.4)
21-30	8 (61.5)	5(38.5)	13 (5.3)
31-40	31(70.5)	13(29.5)	44(18)
41-50	57(85.1)	10(14.9)	67(27.5)
51-60	45(80.4)	11(19.6)	56(23)
61-70	24(75.0)	8(25.0)	32(13.1)
71-82	5(55.6)	4(44.4)	9(3.7)
TOTAL	188(77.0)	56(23.0)	244 (100)

N = 244 P = 0.0000 df = 6

Table II Relationship between Age group and Diagnosis of patients attending the Oncology Clinic, LUTH

	DIAGNOSIS (%)					
AGEGRP	BREAST CANCER	CERVICAL CANCER	RETINO. BLASTOMA	THYROID	OTHERS	TOTAL %
<20	1(1.1)	0(0.0)	9(75.0)	0(0)	13(14.1)	9.4
21-30	3(3.3)	1(2.4)	1(8.3)	0(0)	8(8.7)	5.3
31-40	21(23.1)	5(12.2)	2(16.7)	2(25)	14(15.2)	18.0
41-50	29(31.9)	15(36.6)	0(0)	3(37.5)	20(21.7)	27.5
51-60	22(24.2)	12(29.3)	0(0)	2(25.0)	20(21.7)	23.0
61-70	12(13.2)	6(14.6)	0(0)	1(12.5)	13(14.1)	13.1
71-82	12(13.2)	2(4.9)	0(0)	0(0)	4(4.3)	3.7
TOTAL	91(37.3)	41(16.8)	12(4.9)	8(3.3)	92(37.7)	244

N = 244 P = 0.000 df = 24

Table III - Prescribing Pattern showing the different groups of Antineoplastic Agents at the Oncology Unit, LUTH

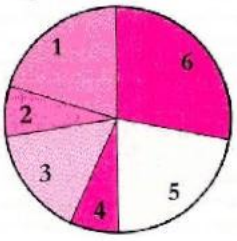
Pharmacological Class	Drug	Frequency	Total
Alkylating Agent	Cylophosphamide	128	133(40.1)
	Cisplatin	5	
Antibiotics	Adriamycin	44	67(20.2)
	Actinomycin	16	
	Bleomycin	7	
Antimetabolites	5Fluorouracil	45	60(18.1)
	Metotrexate	15	
Hormones	Tamoxifen	30	30(9.0)
Spindle Poisons	Vincristine	42	42(12.7)

Table IV - Prescribing Pattern showing most common Cancer Drug combination

Combination	Percentage
CMF	21.4%
CAF	18.8%
CAV	17.6%

CMF = Cylophosphamide, Metotrexate and 5Fluorouracil; **CAF** = Cyclophosphamide, Adriamycin and 5Florouracil; **CAV** = Cylophosphamide, Adriamycin and Vincristine

Figure I - Prevalence of Adverse Drug Reactions at the Oncology Unit, LUTH



1. Others 20%
2. Stomatitis 7%
3. Anorexia 16%
4. Weakness 7%
6. Emesis 21%
5. BMD 29%

non-participation. Lack of time was given as the major reason for not participating.

Survey Instrument

A questionnaire was employed in the study. The questionnaire was constructed on a 5- point response scale. It consisted of four sections made up of the personal data section and sections A to C. Items included in the instrument covered different aspects of hypertension management such as diagnostic measures adopted by community pharmacists, drug therapy associated problems encountered and involvement of community pharmacists in lifestyle modification.

The questionnaire was validated after pretest of survey instrument on a sample of 20 community pharmacists.

Analysis of Data

The retrieved completed questionnaires were analysed with SPSS (Statistical Package for Social Sciences, version 10). Data analysis was carried out by simple percentage and mean. The respondents were rated on a 5-point scale, "5"
representing the highest mean score and "1" representing the lowest mean score. Mean values greater or equal to 3 suggested a slightly satisfactory performance. All mean values were reported with standard deviation.

RESULTS

The survey questionnaire response rate was 78%. The personal data of community pharmacists that participated in the survey and their basis for diagnosing hypertension are shown in Table 1. Majority of the community pharmacists in FCT, Abuja are males; between the age bracket of 30 to 39 and have practised for between 1 to 5 years. More than one-third of these respondents have seen greater than 69 hypertensive cases in the last one year and about 64% indicated that their basis of recognizing hypertension was when BP was above 140/90 mmHg.

Table 2 shows that community pharmacists rarely diagnose their patients of hypertension on routine examination for other ailments since that is usually carried out by medical doctors. Regularly, they have been able to identify hypertension on routine check of patient's blood pressure in absence of any ailment, on clinical manifestation of the disease and by studying the prescription presented by the patients.

As shown in Table 3, sexual dysfunction (mean score of 3.06) and poor patients compliance (mean score of 3.28) were the most widely drug associated problems met by community pharmacists in Abuja city. Drug interactions, high or low drug dosage and wrong choice of drugs are rarely encountered.

Using 8-item measures (Table 4), community pharmacists rarely placed their hypertensive patients on exercise as well as adopting measures that will improve individual hypertensive insulin sensitivity. Urging patients to check their BP regularly, discouraging smoking, nutritional counseling, encouraging the obese to lose weight and discouraging alcohol intake formed their regular activities.

DISCUSSION

The results of this survey revealed that community pharmacists in FCT, Abuja provide some level of pharmaceutical care to hypertensive patients. A good number of community pharmacists (63.9%) recognised hypertension based on blood pressure reading consistently above 140/90 as specified by JNC 7. Community pharmacists in FCT, Abuja had satisfactory performance in their ability to identify hypertensive patients in the course of their daily professional activity. A 3.2 mean score in routine check of patient's blood pressure in absence of ailment revealed a good level of pharmaceutical care outlook. There was some level of pharmacovigilance as they were able to detect some medication related problems especially sexual dysfunction (mean score of 3.06) and poor patients compliance (mean score of 3.28). Hypertension treatment/management guidelines also stress on patient lifestyle changes. A mean score of 4.36 in urging patients to check their BP regularly indicated that community pharmacists in FCT, Abuja participate actively in patient lifestyle modification. They also scored very high in persuading hypertensive individuals not to smoke (4.21), give nutritional counsel (4.06), encourage obese patients to lose weight (4.10), discourage alcohol intake (4.21) and encourage hypertensives to moderate sodium intake (4.23).

The result from this survey is impressive compared to other studies of this nature that have been carried out in Nigeria. A couple of surveys of Nigerian community pharmacists' involvement in various PHC programmes have been conducted. A survey carried out in Lagos showed that community pharmacists have not been adequately integrated into PHC programmes[7]. With particular reference to hypertension, Oparah and Arigbe-Osula[5] carried out a study in Benin to evaluate the involvement of community pharmacists' in PHC. The study indicated that community pharmacists' in Benin scored a mean average of 2.65 on 5 point scale (35% performance) on screening of hypertension. They rarely treat or take part in managing hypertension (mean score, 2.55).

All over the globe, community pharmacy-based hypertension management model is being encouraged, with the goal of improving hypertension control at community level through a more active involvement of pharmacists in the prevention, detection and management of hypertension. A community pharmacist is a highly trained professional who can be seen without prior arrangement, in a familiar setting which is often regarded to be part of an every day shopping occurrence. Pharmacists are therefore the most highly accessible members of the primary health care team. Community pharmacies are visited by both people who are sick and people who are in good health and as such have a potential for health promotion and disease prevention. A regular visit of a person with hypertension for prescribed drug therapy puts the patient in a regular contact with the pharmacist and provides opportunities for intervention.[8] Numerous studies have been carried out to ascertain the level of community pharmacists'

involvement in the management of hypertension. Sookaneknun et al were able to establish that hypertensive patients who received pharmacist input achieved a significantly greater benefit in BP reduction, BP control, and improvement in adherence rate and lifestyle modification.[9] Carter in his study to evaluate the pharmacists' collaborative role in the management of hypertension showed that the expanded role of clinical pharmacists in programs for evaluating, monitoring, and treating patients with hypertension can result in improved adherence to therapy and established guidelines.[6] In Canada, the effect of a pharmaceutical intervention program on blood pressure (BP) and factors affecting BP was explored. Compared with the control group, the pharmacy program resulted in significant systolic BP reduction (7.8 vs. 0.5 mm Hg; p = 0.01) and an increase in the proportion of controlled patients only for those with high incomes. In the high-income group, the program also had a positive impact on physical activity, self-reported adherence, health concerns, and information transmitted. The low-income group did not appear to benefit from the program.[10] Carter et al suggests that when community pharmacists in a clinic setting are trained and included as members of the primary care team in a clinic setting, significant improvements in blood pressure control, quality of life, and patient satisfaction can be achieved.[11] These and many other studies have demonstrated that when pharmacists are included as members of health care teams, control rates for hypertension increase.[12]

CONCLUSION

Community pharmacists in FCT, Abuja are involved in the pharmaceutical care of hypertensive patients. Nevertheless, there is still room for improvement. Implementation of some sets of interventions seems necessary. Development and implementation of standardized health information systems and sustenance of the mandatory continuing professional development program (MCPD) for pharmacists are steps in the right direction. More studies are necessary in this area so as to establish through objective measures, the effect of pharmacist participating in management of different diseases. With such facts, coupled with advocacy efforts, pharmacy intervention programs on different health issues can be instituted as practice standards.

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Table 1: Personal data of community pharmacists in FCT, Abuja and basis of recognizing hypertension in patients (n = 180)

		Frequency/Percentage
Sex	Male	124 (68.9%)
	Female	56 (31.1%)
Age	20-29	39 (21.7%)
	30-39	94 (52.2%)
	40-49	21(11.7%)
	50 and above	1 (0.6%)
	No response	25 (13.9%)
Duration of Practice	<1 year	25 (13.9%)
	1-5 years	104 (57.8%)
	6-10 years	23 (12.8%)
	>10 years	19 (10.6%)
	No response	6 (3.3%)
Number of hypertensive cases seen in the last one year	<10	11 (6.1%)
	11-50	63 (35%)
	51-90	31 (17.2%)
	>90	69 (38.4%)
Basis of recognising hypertension	No response	6 (3.3%)
	Above 130/85	25%
	Above 140/90	63.9%
	Above 165/105	7.8%
	Above 185/115	3.3%

Table 2: Diagnostic measures adopted by community pharmacists (n = 180)

		Mean	Standard deviation
1	Routine examination for other ailments	2.66	1.02
2	Routine check of patients blood pressure in absence of ailment	3.2	1.24
3	Clinical manifestation	3.49	1.16
4	Prescription study	3.69	1.33

Table 3: Drug therapy associated problems encountered (n = 180)

		Mean	Standard deviation
1	Wrong drug prescribed for patients	2.51	1.20
2	Prescribed dose too low to be effective	2.19	1.00
3	Prescribed dose too high to be safe	2.33	0.95
4	Unfavorable drug interactions	2.69	1.00
5	Drug affecting sexual function	3.06	1.20
6	Drugs affecting social function	2.19	1.67
7	Poor patient compliance	3.28	1.26

Table 4: Involvement of Community pharmacists in lifestyle modification (n = 180)

		Mean	Standard deviation
1	Urging patients to check their BP regularly	4.36	0.91
2	Persuading hypertensive individual not to smoke	4.21	1.04
3	Giving nutritional counseling (low fat and high fibre intake)	4.06	1.23
4	Putting individual hypertensive on regular exercise	2.99	1.44
5	Encouraging the obese to lose weight	4.10	1.07
6	Discouraging alcohol intake by hypertensive	4.21	0.99
7	Encouraging individual hypertensive about moderate sodium intake	4.23	1.08
8	Adopting measures that will improve individual hypertensives' insulin sensitivity	2.68	1.08