Research Article

Therapy Options Received and Impact of Pharmacist-Led Interventions on Self-Care Management of Adverse Events among Cervical Cancer Patients in a Nigerian Tertiary Hospital

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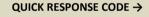[1]Usmanu Danfodiyo University Sokoto, Sokoto State Nigeria.
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ABSTRACT

The available services for the treatment of premalignant and malignant cervical cancer (CC) lesions are grossly inadequate in Nigeria. Drug-oriented self-care education programmes are lacking in our healthcare facilities. Pharmacist interventions as an expert in drug therapy management are needed. This study assessed the therapy options received and impact of pharmacist-led interventions on self-care management of AEs among CC patients in Usmanu Danfodiyo University Teaching Hospital (UDUTH), Sokoto, North-Western Nigeria. The study used a prospective longitudinal design with a 12-week patient follow-up. Instrument used was an interviewer-administered questionnaire, which was developed and pre-tested for reliability. Fifty-six eligible CC patients completed the pre- and post-interventions survey conducted over a period of eight months (From October, 2019 to May, 2020). Data analysis was done with appropriate descriptive (frequencies, percentages, means, and standard deviations) and inferential statistics (Paired sample t-test, Pearson's Chi-square and Correlation) using SPSS Inc., Chicago, IL, USA V. 20 for windows. P< 0.05 was considered statistically significant. The mean age of the patients was 53.8±7.7years and 22(39.2%) have no formal education. Chemoradiation (CRT) and chemotherapy (CT) were the major therapy options received by the 25(44.6%) and 16 (28.6%) of the patients respectively. Before the interventions, the patients scored 57.7±18.7% and 50.8±7.1% overall mean knowledge and practice scores respectively. After the interventions, there was significant increase in the patients' overall mean knowledge and practice, 17.6% and 6.7%, (p<0.05) scores respectively. There were significant association between patients' age and total post-intervention knowledge (r=-0.614, p<0.001), and practice, (r=-0.424, p=0.001) scores. There were significant association between the patients' level of education and total pre- and post-intervention knowledge (r=0.952, p<0.001 and r=0.948, p<0.001) as well as total pre-intervention practice (r=0.626, p<0.001) scores. Pharmacist-led educational interventions improved the CC patients' knowledge and practice of self-care management AEs.

Keywords: Cervical Cancer, Therapy, Self-care Management, Adverse Events.

INTRODUCTION

Cervical cancer is the most common gynecological malignancy[1,2], and the fourth most common cancer among women worldwide. In 2012, Global Cancer Observatory (GLOBOCAN) report showed an estimated 527,624 new cases worldwide, with 27,326 and 14,089 cases from West Africa and Nigeria respectively[3]. According to the National Comprehensive Cancer Network (NCCN) Guidelines, treatment options for cervical cancer include; surgery (cervical cone biopsy, radical hysterectomy, radical trachelectomy, etc.), radiotherapy (pelvic external beam radiation therapy and intracavitary brachytherapy), cisplatin based concurrent chemoradiation, cisplatin or non-cisplatin based chemotherapy with or without surgery [4].

The various therapy options for CC are associated with high incidence of adverse events especially hematological, gastrointestinal, mucocutaneous, renal toxicities etc. as widely described in literatures[5-7]. Despite number of pharmacotherapeutic interventions given to prevent and treat the potential and actual AEs, patients still experience unbearable AEs. Unfortunately, some patients believe that the AEs are unavoidable consequence of therapy. This may explain why AEs were found to be among the major reasons for medication non-adherence[6], treatment interruptions and delays in cancer therapeutics[8] in addition to their negative effects on the patients' QoLs[9-11]. Most of the self-care education provided by other healthcare personnel are more of disease-oriented self-care behaviors. Drug-oriented self-care educational intervention programmes especially on cancer treatments-related AEs are lacking in our healthcare centers. Pharmacist's educational interventions being an expert in drug therapy management is needed to overcome this barrier; educate patients about approaches to management of their treatments-related AEs, and help them feel confident in their use of self-care measures[12]. Williams & Schreier reported that, after an educational intervention, women receiving chemotherapy for breast cancer increased the use of self-care measures to manage fatigue, such as rest, relaxation, and exercise. Borthwick *et*

al., found that patients with lung cancer used exercise, education, attention restoring, and energy conservation to relieve fatigue during RT[12]. These studies assess only patients' knowledge aspect of the self-care managements of AEs. In addition, the studies focus on a particular treatment option (chemo or radiotherapy), although CRT is the gold standard treatment for most CC, especially for the advanced-stage disease. Education programmes for CC patients on knowledge and practice of selfcare management of wider treatments-related AEs are needed.

METHODS

Study design and setting

The study used a prospective longitudinal design with a 12-week patient follow-up at the Radiotherapy and Oncology department of Usmanu Danfodiyo University Teaching Hospital (UDUTH), Sokoto, North-Western Nigeria.

Study participants and eligibility requirements

CC patients who were receiving chemotherapy, radiotherapy or both, with or without surgery were included in the study. Those patients who were treated with surgical intervention alone were excluded from the study. Patients who were clinically stable and could respond to interviews were included in the study. Those who could not respond to interviews due to severity of their illnesses were excluded. Patient participation in the study was voluntary, patients who declined the written inform consent were excluded from the study.

Sampling technique

All the eligible CC patients who came to the hospital clinics during the 12-week recruitment period (between 5th October and 25th December, 2019) were surveyed.

Study instruments

A Cancer patients' knowledge and practice of self-care management of adverse events Questionnaire was developed, pre-tested and deployed for the study. The Questionnaire consisted of three sections, two of which encompassed items pertaining to knowledge and practice, in addition to a section on socio-demographics and clinical characteristics. It was designed as an interviewer-administered Questionnaire, according to standard protocols for questionnaire design and testing. A panel of 14 experts comprising four consultants Radiation and Clinical Oncologists, four Radiation and Clinical Oncology Ward Nurses and six Clinical Pharmacists Academics assessed the content validity of the Questionnaire. The reliability of the Questionnaire was tested using 31 CC patients between August and September, 2019. A predefined Cronbach's alpha coefficient, ≥ 0.70[13] was set to be considered acceptable. After the psychometric analysis, the Cronbach's alpha coefficients of the knowledge and practice question items were 0.956 and 0.913 respectively, thus, the Questionnaire was considered reliable. The domains, concepts covered, and response options in the Questionnaire are presented in Table 1 below.

Table 1: Domains, concepts covered, and response options of the knowledge and practice questionnaire

Section	No. of items	Concepts measured	Response options
Socio-demographics and clinical characteristics	8	Age, tribe, level of education, marital status, average monthly income, diagnosis/clinical staging, comorbidities and therapy option received	Closed-ended, multiple-choice
Knowledge	69	What to do, how to do, what to avoid	Yes/No/Not sure; 1=correct answer 0=wrong/Not sure
Practice	48	AE(s) experience, practice of the dos and don'ts	Yes/No; No= AE not experienced Yes=AE experienced For Yes; 0=Never, 1=Rarely, 2=Occasionally, 3=Frequently, 4=Almost constantly

AE = Adverse Event

Study procedure

Pre-intervention survey

The pre-educational intervention data of all the eligible CC patients were collected between October and December, 2019. CC patients were met during the traditional "health-talks" sessions that take place every Mondays, Wednesdays, and Fridays of the week at the Radiotherapy and Oncology department of the hospital. Patients who had met the study eligibility criteria were interviewed by the investigating clinical pharmacist or the trained research assistant.

The Intervention

The patients received 3 sessions of grouped educational intervention at 2 weeks interval between January and February, 2020. Each session lasted for an average of 1-hour including questions and answers, after which clinics start. A colored pictorial "Cancer patients' education on self-care management of adverse events Flyer" was designed and printed for distribution to the patients during the educational intervention programme sessions. This was to ease understanding and remembrance even after the session. The educators (the principal investigator and a trained research assistant nurse) stood before the patients with their own copies of the flyers and educated them on AEs of CC treatments; possibilities of occurrence, symptoms to be observed when they occurred and approaches to manage or ameliorate them if they occurred.

Post-intervention survey

The post-educational intervention data of the patients were collected using the same Questionnaire between March and May, 2020 as the patients came for follow-up visits. The CC patients who had completed the three sessions of the grouped educational intervention programme were interviewed by the investigating clinical pharmacist or the research assistant.

Outcomes measures

The mean domain scores, overall mean percentage scores as well as outcome grades of the patients' knowledge and practice of self-care management of AEs, pre-and post-interventions were measured. The impact of the patients' socio-demographic and clinical characteristics on knowledge and practice of self-care management of AEs, pre- and post-interventions was also measured.

Data management and analysis

The data obtained was sorted, coded and entered into SPSS Inc., Chicago, IL, USA V. 20 for windows and subsequently analyzed. Pearson's Chi-square was used to compare proportions. Paired sample *t*-test was used to test for mean differences of the domains and overall knowledge and practice scores before and after the interventions. Pearson's Correlation was used to test for association between the patients' socio-demographic and clinical characteristics and total pre- and post-intervention knowledge and practice scores. The patients' knowledge scores were categorized as; Poor (<70.0%) and Good (≥70.0%), while the practice scores were categorized as; Poor (<55.0%) and Good (≥55.0%). The categorizations were based on the distributions of the patients scores before and after the interventions. *P*<0.05 was considered statistically significant throughout.

Ethics approval

Ethical approval was obtained from the Health Research Ethics Committee of UDUTH (UDUTH/HREC/2018/No.731) before the commencement of the data collection. The confidentiality and anonymity of the patients were maintained during and after the study.

RESULTS AND DISCUSSION

A total of 61 patients were recruited during the pre-intervention survey, however, 56(91.8%) completed the pre-and post-intervention surveys. Five patients were dropped out due to loss on follow-up. The mean age of the patient was 53.8±7.7years; this was similarly reported in previous studies[14-16]. A rise in CC was seen with increasing age, parity and early and prolonged sexual period[15]. Majority were married, 48(85.6%), Hausa/Fulani, 41 (73.2%) and have no formal education, 22(39.2%). This was not unexpected as the patients' population comprised adult of marriageable age group. Hausa/Fulani were the predominant tribe in the North-Western Nigeria. A low education level and illiteracy have been shown to increase the risk of invasive CC[14]. A total of 20(35.7%) patients each reported earning ₦50,000-100,000 and >₦100,000.

A study conducted in Abuja revealed that the direct cost of RT for CC is ₦600,000 per course of teletherapy plus approximately ₦150,000 for pre-treatment evaluation in the FCT[17]. This showed how affordability would be a greatest challenge to majority of CC patients in Nigeria. Most of the patients, 20(35.7%), presented with a baseline clinical stage III, which is consistent with previous studies conducted in Nigeria[18,19]. In contrast, a study showed that in United Kingdom, only 21.9% of women present with the advanced-stage disease[20]. Majority of the patients, 25(44.6%) received CRT and 16(28.6%) were prescribed CT. A study conducted to provide comprehensive treatment given to CC patients showed that, majority (97%) of the patients received external beam radiation, 84% brachytherapy, and only 4% received concomitant chemotherapy[21]. Kumar *et al.,* reported that radical hysterectomy was the most common treatment modality followed by Wertheims Hysterectomy and Radio-chemotherapy[22]. Details of the socio-demographic, clinical characteristics and therapy options received by the patients can be seen in Table 2 below.

The mean overall knowledge scores before and after the interventions were 57.7±18.7 and 75.2±17.4, *p*<0.001 respectively. The mean overall practice scores before and after the interventions were 50.8±7.1, 57.5±4.8, *p*<0.001 respectively. After the interventions, the patients' mean overall knowledge and practice scores increased by 17.6% and 6.7% respectively. After the intervention, patients' knowledge scores of self-care management of 'low blood counts', 'skin rashes, itching or burns from radiation', and 'sexuality problems' were the most to have been significantly increased by 1.4, 1.3 and 1.3, *p<0.05* respectively. There were significant increases in the patients' practices of self-care management of 'constipation' (before, 5.9±1.5 scores and after, 8.4±1.2 scores, *p*=0.001), 'sexuality problems' (before, 5.3±2.7 scores and after, 7.2±1.2 scores *p*<0.001) and 'mouth or throat sores' (before, 5.3±1.1 scores and after, 7.1±0.3 scores, *p*<0.001). A total of 14(24.1%) and 34(58.6%)

patients, *p*=0.001 had "Good" knowledge before and after the interventions respectively. On the other hand, 22(37.9%) and 39(67.2%), *p*<0.001 had "Good" practice before and after the interventions respectively.

Table 2: Socio-demographic, clinical characteristics and therapy options received by the patients

Socio-Demographic & Clinical Data (N=56)	n(%)
Mean Age (Years)=53.8±7.7	
Marital Status	
Single, n(%)	2(3.6)
Married, n(%)	48(85.6)
Divorced, n(%)	3(5.4)
Widow	3(5.4)
Tribe	
Hausa/Fulani, n(%)	41(73.2)
Yoruba, n(%)	3(5.4)
Igbo, n(%)	3(5.4)
Others, n(%)	9(16.0)
Level of Education	
Non Formal, n(%)	22(39.2)
Primary, n(%)	3(5.4)
Secondary, n(%)	16(28.6)
Tertiary, n(%)	15(26.8)
Average Monthly Income	
<₦50,000, n(%)	16(28.6)
₦50,000-100,000, n(%)	20(35.7)
>₦100,000, n(%)	20(35.7)
Clinical Stage	
I, n(%)	7(12.5)
II, n(%)	19(33.9)
III, n(%)	20(35.7)
IV, n(%)	7(12.5)
Recurrent/Metastatic, n(%)	3(5.4)
Therapy Option Received	
Chemotherapy	16(28.6)
Chemoradiation therapy	25(44.6)
Chemotherapy and surgery	5(8.9)
Radiation therapy and surgery	3(5.4)
Chemoradiation and surgery	7(12.5)

It can be seen that, the patients have the knowledge of some of the self-care management approaches that are more of general healthcare knowledge such as personal hygiene, reporting to healthcare personnel, taking prescribed drugs to treat symptoms etc., and thus might have been practicing them even before the interventions. Williams & Schreier reported that, after an educational intervention, women receiving chemotherapy for breast cancer increased the use of self-care measures to manage fatigue, such as rest, relaxation, and exercise. However, Yates *et al.,* reported that these measures did not translate into actual self-reported decreases in fatigue. Borthwick *et al.,* found that patients with lung cancer used exercise, education, attention restoring, and energy conservation to relieve fatigue during RT. Lundberg and Rattanasuwan showed that, a group of Thai Buddhist patients undergoing RT reported relieving fatigue by getting moral support from family and friends, through religion and meditation practices, and consulting with doctors and nurses[12]. Details of the mean domain scores, overall mean percentage scores, and outcome grades of the patients' knowledge and practice of self-care of management AEs pre-and post-intervention can be seen in Table 3 below.

There were significant negative associations between the patients' age and total pre- (*r*=-0.612, *p*<0.001) and post-intervention knowledge (*r*=-0.614, *p*<0.001), as well as total pre- (*r*=-0.518, *p*<0.001) and post-intervention (*r*=-0.424, *p*=0.001) practice. On the other hand, there was significant positive association between the patients' level of education and total pre- and post-intervention knowledge. This might be due to the fact that even though the flyer was pictorial, older patients and those who are not literate might have find it difficult to read and understand the contents independently and especially after the grouped educational intervention sessions. There was also significant positive association between average monthly income and total pre- and post-intervention knowledge. This could have been so because, some of the practice items require additional financial commitment from the patients, hence those with financial constraints might have find it difficult. There was a significant positive association between the patients' level of education (*r*=0.360, *p*=0.006), average monthly income (*r*=0.626, *p*<0.001) and total pre-intervention practice. However, no association exists between the patients' level of education, average monthly income and total post-intervention practice, see Table 4 below.

CONCLUSION

Pharmacist-led educational interventions improved the cervical cancer patients' knowledge and practice of self-care management of AEs.   More studies should be conducted to determine the association between patients' knowledge and practice of self-care management of AEs and other outcomes especially clinical and humanistic.

Table 3: Mean domain scores, overall mean percentage scores, and outcome grades of the patients' self-care knowledge and practice of approaches to treatment related AEs pre- and post-intervention

S/N	Domain	Knowledge			Practice			P-Values	
		Pre-I (Mean±SD)	Post-I (Mean±SD)	MD^d±SD	Pre-I (Mean±SD)	Post-I (Mean±SD)	MD^d±SD	Knowledge	Practice
1	Problem of taste or loss of appetite	4.1±1.5	4.9±1.3	0.8±0.4	6.6±0.9	7.4±0.7	0.7±0.9	<0.001	<0.001
2	Nausea or vomiting	3.6±1.1	4.5±1.2	0.8±0.4	10.8±2.0	11.7±1.5	0.9±1.1	<0.001	<0.001
3	Tiredness	3.2±1.0	4.3±1.5	1.0±0.7	6.6±2.2	6.9±0.9	0.3±1.9	<0.001	0.187
4	Hair loss	3.8±1.2	4.9±0.8	1.1±0.6	10.3±1.1	11.2±1.6	0.9±1.0	<0.001	<0.001
5	Low blood counts	3.4±1.2	4.8±0.8	1.4±0.5	12.1±2.6	12.9±1.8	0.8±0.9	<0.001	<0.001
6	Mouth or throat sores	3.2±1.0	4.4±1.2	1.2±0.4	5.3±1.1	7.1±0.3	1.8±0.9	<0.001	<0.001
7	Diarrhea	3.9±0.8	4.8±0.8	1.0±0.1	7.3±0.9	8.4±1.6	1.1±1.1	<0.001	<0.001
8	Constipation	3.9±0.8	4.6±0.6	0.8±0.4	5.9±1.5	8.4±1.2	2.6±1.6	<0.001	0.001
9	Urinary problems	2.3±1.2	3.4±1.2	1.0±0.2	6.0±1.0	7.4±0.7	1.4±0.9	<0.001	<0.001
10	Swelling of the legs	2.0±0.7	2.8±0.8	0.8±0.4	11.5±1.1	12.0±0.5	0.5±0.8	<0.001	0.001
11	Skin rashes, itching or burns from radiation	3.4±1.2	4.7±0.8	1.3±0.6	8.1±2.1	8.9±2.2	0.8±1.3	<0.001	<0.001
12	Sexuality problems (low libido, vaginal shortening, or vaginal dryness)	4.0±0.9	5.3±0.6	1.3±0.6	5.3±2.7	7.2±1.2	1.9±2.2	<0.001	<0.001
	Overall Mean % Correct Score (±SD)	57.7±18.7	75.2±17.4	17.6±2.1	50.8±7.1	57.5±4.8	6.7±5.9	<0.001	<0.001
	Outcome Grades								
	Poor, n(%)	42(72.4)	22(37.9)		34(58.6)	17(29.3)			
	Good, n(%)	14(24.1)	34(58.6)		22(37.9)	39(67.2)		0.001	<0.001

Pre-I=Pre-Intervention, Post-I=Post-Intervention, SD=Standard Deviation, MD^d=Mean Difference.

Table 4: Associations between socio-demographic and clinical characteristics of the patients and total pre- and post-interventions knowledge and practice of self-care management of AEs

Variables		Total Pre-I knowledge score	Total Post-I knowledge score	Total Pre-I practice score	Total Post-I practice score	Age of the respondent	Level of education	Average monthly income	Clinical stage of the cancer
Total pre-intervention knowledge score	Corr. Coef.	1.000							
	P-value	.							
Total post-intervention knowledge score	Corr. Coef.	0.974**	1.000						
	P-value	<0.001	.						
Total pre-intervention practice score	Corr. Coef.	0.643**	0.694**	1.000					
	P-value	<0.001	<0.001	.					
Total post-intervention practice score	Corr. Coef.	0.274*	0.284*	0.651**	1.000				
	P-value	0.041	0.034	<0.001	.				
Age of the respondent	Corr. Coef.	-0.612**	-0.614**	-0.518**	-0.424**	1.000			
	P-value	<0.001	<0.001	<0.001	0.001	.			
Level of education	Corr. Coef.	0.952**	0.948**	0.626**	0.168	-0.486**	1.000		
	P-value	<0.001	<0.001	<0.001	0.215	<0.001	.		
Average monthly income	Corr. Coef.	0.449**	0.459**	0.360**	0.021	-0.084	0.403**	1.000	
	P-value	0.001	<0.001	0.006	0.880	0.538	0.002	.	
Clinical stage of the cancer	Corr. Coef.	0.042	0.064	0.232	0.161	0.074	0.063	-0.195	1.000
	P-value	0.758	0.637	0.085	0.237	0.356	0.643	0.150	.

Pre-I=Pre-Intervention, Post-I=Post-Intervention; **. Correlation is significant at the 0.01 level (2-tailed), *. Correlation is significant at the 0.05 level (2-tailed).

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