SEXUAL DYSFUNCTION IN PATIENTS TREATED FOR CERVICAL CANCER AT THE CANCER CENTER KENYATTA NATIONAL HOSPITAL

A dissertation submitted in part fulfillment of the requirements for the degree of Master of Medicine (M.MED) in Radiation Oncology of the University of Nairobi

Dr. Kahumburu Susan Wangari

Reg. No. H58/36191/2019

DECLARATION

I hereby declare that this study is my original work and has not been presented for award of degree at any other university.

Dr. Kahumburu Susan Wangari M.Med Student in Radiation Oncology Department of Radiology Registration Number: H58/36191/2019

Elbrojevi

Date: 14/11/2023

SUPERVISOR'S APPROVAL

This dissertation has been submitted for examination with my approval as the university supervisor.

Dr. Catherine Nyongesa

Signed:

Consultant Clinical Radiation Oncologist

Associate lecturer, Department of Radiology

University of Nairobi

Signed:

Date: 15/11/2023

Dr. Callen Onyambu

Chairman, Department of Diagnostic Imaging and Radiation Medicine

Faculty of Health Sciences

University of Nairobi

Signed:

Date: 15/11/23

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ABBREVIATIONS

CIN	CERVICAL INTRAEPITHELIAL NEOPLASIA
СТС	CANCER TREATMENT CENTER
HIV	
HPV	
KNH	
МСН	
NCCN	NATIONAL COMPREHENSIVE CANCER NETWORK
QOL	
WHO	WORLD HEALTH ORGANISATION

ABSTRACT

BACKGROUND: Cervical cancer is the second most common cancer diagnosed in women in Kenya. Majority of the patients are diagnosed with locally advanced cancer which is treated with a combination of concurrent chemotherapy and radiotherapy followed by brachytherapy. With adequate treatment of the disease the survivors are able to have a long disease free and overall survival, and experience the adverse effects of radiation which include fibrosis, vaginal stenosis and dryness. This leads to sexual dysfunction and reduction in the quality of life of the survivors. However despite this changes sexual dysfunction is rarely addressed by the clinicians at the clinic.

OBJECTIVE: To assess the sexual dysfunction in patients treated for cancer of the cervix in the Cancer Treatment Centre, Kenyatta National Hospital.

STUDY DESIGN AND SITE

This is a cross sectional study which will be carried out on the female cervical cancer survivors treated at the Cancer Treatment Centre in the Kenyatta National Hospital, Nairobi Kenya.

PARTICIPANTS AND METHOD

The participants will be recruited from the routine follow up clinics at the cancer treatment centre. The inclusion criteria will be cervical cancer survivors who have been treated with radiotherapy. The exclusion criteria will include patients who have persistent or recurrent disease after radiotherapy and those with stage IV disease including those that have vesicovaginal or rectovaginal fistulas.

DATA MANAGEMENT

A questionnaire will be administered in order to get the sexual history before diagnosis and after treatment of cervical cancer. Information on the side effects of radiotherapy treatment which would affect sexual function will also be determined. The questionnaire will be administered by a trained nurse. Continuous data such as age, duration will be compared using t test or ANOVA as appropriate for normally distributed data and for data that is not normally distributed it will be analysed using non parametric tests such as Chi test for proportions Mannwhitney U test or Kruskal wallis test.

UTILITY OF THE STUDY

The study aims to find out how radiotherapy affects the sexuality and whether the survivors receive counselling or treatment before, during or after radiotherapy. Information emanating from such study will inform policy on introduction of sex education and counseling about the treatment adverse effects in cervical cancer patients. Additionally, this may also lead to improvement in the doctor-patient relationship such that sexual health can be discussed with ease and managed appropriately.

1.0 CHAPTER ONE: INTRODUTION

Cervical cancer is the fourth most frequently diagnosed cancer and the fourth leading cause of cancer death in women worldwide (Globocan 2020). Africa has the highest related incidence and mortality rates, with Swaziland, Malawi, Zimbabwe, Guinea, Burkina Faso and Mali leading in that order (Globocan 2020). In Kenya, cervical cancer is the 2nd most common cancer among women after breast cancer and the leading cause of death among cancer patients (Globocan 2020). 2020).

The incidence and mortality rates of cervical cancer has reduced significantly in many populations worldwide due to early detection as a result of screening in the communities (Akila et al., 2018). Screening detects pre-invasive lesions which can be treated before they become invasive and also early invasive disease that can be treated with a curative intent (Akila et al., 2018).

Integration of routine cervical cancer screening in the Maternal Child Health (MCH) and Human Immunodeficiency Virus (HIV) service delivery points at the comprehensive care clinics in Kenya has resulted in early detection of the invasive disease (Kenya cancer Policy 2019). Increased awareness through the media, health talks in schools, churches and routine outreach activities has led to early detection of pre-invasive and invasive cancer (Kenya cancer Policy 2019). This has subsequently changed the treatment goals of the disease to focus on curative rather than palliative care hence a long disease free and overall survival for the patients.

Treatment of cervical cancer is done using hysterectomy, concurrent chemotherapy, radiotherapy and brachytherapy which results in cure rates of between 80% and 90% in stage I – II and 60% in stage III patients (Petignant et al., 2007). As patients survive longer they experience the long term toxicities associated with the treatment which impact negatively on their quality of life. This, therefore, is an important clinical concern. One of the toxicities affecting quality of life of the survivors is sexual dysfunction which can occur after surgery or radiotherapy (Petignant et al., 2007). According to Maslow's hierarchy of needs, sexual activity is an important aspect of life. Therefore, sexual dysfunction may cause immense distress in patients.

Sexual dysfunction includes the persistent or recurrent difficulty with sexual response, desire, orgasm or pain during coitus (MayoClininc.org 2020). Sexuality and sex is described as one of the central aspect of human lives by the World Health Organisation (WHO). A cancer diagnosis causes a reduction in the quality of life of the patient and hence affecting sexuality (Holy et al., 2016). Cervical cancer treatment aggravates the sexual dysfunction due to various adverse effects it has on the reproductive system. Shankar et al. (2017) reported that up to 50% of women treated for cancer of the cervix had sexual dysfunction as they recover and become cancer survivors.

Radiotherapy-induced effects on the normal tissues during and after treatment result in impaired sexual function and decreased quality of life (Jensen et al., 2015). Acute effects of radiation include desquamation and mucositis whereas the chronic effects which occur after 3 months cause fibrosis with subsequent shortening and tightening of the vagina (Jensen et al., 2015). In addition, loss of ovarian function secondary to radiation of the ovaries causes menopausal changes in the premenopausal women which further aggravates the mucosal changes (Jensen et al., 2015). The effects on the bladder and rectum such as urgency, cystitis, feacal incontinence, proctitis may lead to ulceration, necrosis and fistula formation which also impair sexual activity (Andreyev HJ. et al., 2007).

In Morocco, a study done on the sexuality among cervical cancer survivors reported that 54% were sexually active while 34% were inactive. Some of the reasons given for lack of sexual

interest were fear of relapse, fatigue and pain (Khalil et al., 2015). In addition, majority of the survivors who had been informed of the side effects of the treatment resumed sexual activity earlier compared to the ones who had not been informed (Khalil et al., 2015). Iavazzo et al. (2015) also reported that majority of the survivors would have liked to be informed of the complications of the cancer treatment before they begun the treatment. Counseling about cancer specific issues and sexual education at the inception of care and throughout during treatment is therefore imperative.

Cervical cancer mainly affects women between 35 and 50 years (Ngune et al 2020). This is the age at which sexual function is associated with the overall wellbeing of the premenopausal women (Holy et al., 2016). Therefore, majority female patients who happen to be in this age group not only suffer the effects of the disease but also the effects of post-treatment sexual dysfunction. However, healthcare workers rarely inquire about it or treat it. This is partly due a paucity of information on the impact of cancer treatment on sexual health.

This study aims to find out how radiotherapy affects the sexuality of the survivors and whether any treatment is offered to them before, during or after treatment.

2.0 CHAPTER TWO: LITERATURE REVIEW

The cervix is the lower part of the uterus that connects to the vagina. Cancer of the cervix usually starts at the junction of the cervix and endocervical canal where there is transformation of squamous to columnar epithelium (Akila 2018). Initially there is dysplasia of the cells with cervical intraepithelial neoplasia (CIN) type 1 and CIN2 associated with a 60% 40% regression rate, respectively, whereas higher levels of dysplasia progress to cancer especially in the presence of smoking or impaired immunity such as HIV -related immunosuppression (Akila 2018). In women with normal immune systems progression to neoplasia takes 15 to 20 years but in those with immunosuppression, especially HIV patients, it may only take 5 to 10 years (WHO 2019).

Cancer of the cervix is considered a vaccine-preventable neoplasm owing to availability of an effective vaccine against Human Papilloma Virus (HPV) 16 and 18 which are associated with transformation of their host normal cells and normal cells to malignant cells. It is also considered a curable cancer when diagnosed early or in the pre-invasive stage. When cancer evolves, treatment options are surgery and radiation therapy, with or without chemotherapy, and brachytherapy. However, the side effects and morbidity caused by these therapies often affect women's sex lives, even several years after the treatment (Rafaella et al, 2020).

Treatment of cervical cancer is dependent on the FIGO stage of the disease (Fig. 1).

NCO	Co CN Ca	tional mprehensive NCCN Guidelines Version 1.2021 <u>Table of Contents</u> ncer twork® Cervical Cancer <u>Discussion</u>
able Stage		ational Federation of Gynecology and Obstetrics (FIGO) Surgical Staging of Cancer of the Cervix Uteri (2018) Description
Jiaye		The carcinoma is strictly confined to the cervix (extension to the corpus should be disregarded).
IA		Invasive carcinoma that can be diagnosed only by microscopy with maximum depth of invasion ≤5 mm ^a
	IA1	Measured stromal invasion ≤3 mm in depth
	IA2	Measured stromal invasion >3 mm and 55 mm in depth
IB		Invasive carcinoma with measured deepest invasion >5 mm (greater than stage IA); lesion limited to the cervix uteri with size measured by maximum tumor diameter ^b
	IB1	Invasive carcinoma >5 mm depth of stromal invasion and ≤2 cm in greatest dimension
	IB2	Invasive carcinoma >2 cm and ≤4 cm in greatest dimension
	IB3	Invasive carcinoma >4 cm in greatest dimension
		The cervical carcinoma invades beyond the uterus, but has not extended onto the lower third of the vagina or to the pelvic wall
IIA		Involvement limited to the upper two-thirds of the vagina without parametrial invasion
	IIA1	IIA1 Invasive carcinoma ≤4 cm in greatest dimension
	IIA2	Invasive carcinoma >4 cm in greatest dimension
IIE		With parametrial invasion but not up to the pelvic wall
III		The carcinoma involves the lower third of the vagina and/or extends to the pelvic wall and/or causes hydronephrosis or non-functioning kidney and/or involves pelvic and/or paraaortic lymph nodes
III	Ą	Carcinoma involves lower third of the vagina, with no extension to the pelvic wall
111	3	Extension to the pelvic wall and/or hydronephrosis or non-functioning kidney (unless known to be due to another cause)
1110	2	Involvement of pelvic and/or paraaortic lymph nodes (including micrometastases) ^c , irrespective of tumor size and extent (with r and p notations).
	IIIC1	Pelvic lymph node metastasis only
	IIIC2	Paraaortic lymph node metastasis
IV		The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum. A bullous edema, as such, does not permit a case to be allotted to stage IV
IV	4	Spread of the growth to adjacent organs
IV	В	Spread to distant organs
	g and path findings.	tology can be used, when available, to supplement clinical findings with respect to tumor size and extent, in all stages. Pathological findings supercede imaging and

Figure 1: FIGO staging Adopted from NCCN Guidelines

Early stage 1A is treated with surgery while 1B can be treated with either surgery of concurrent chemoradiotherapy then brachytherapy. Stage IIA, IIB, IIIA, IIIB, IIIC, IVA are treated with chemoradiation with brachytherapy. Stage IVB disease is treated with palliative chemotherapy with or without palliative radiotherapy (NCCN 2020).

Radiotherapy-induced effects on the normal tissues during and after treatment result in impaired sexual function and decreased quality of life. Acute effects of radiation including vaginal erythema, moist desquamation, and a confluent mucositis occur within 3 months of radiation whereas the chronic effects occur after 3 months. These include loss of capillaries leading to impaired circulation and mucosal atrophy, dilatation of the capillaries with resultant telangiectasia and easy bleeding, increased collagen production with fibrosis with subsequent shortening, tightening and stenosis of the vagina. In addition, loss of ovarian function secondary

to radiation of the ovaries causes menopausal changes in the premenopausal women which further aggravates the mucosal changes (Jensen et al., 2015). The effects on the bladder and rectum such as urgency, cystitis, feacal incontinence, proctitis and may lead to ulceration, necrosis and fistula formation may also impair sexual activity (Andreyev HJ. et al 2007).

Painful intercourse is the most common sexual dysfunction reported by cancer patients after surgery and chemoradiation and may persist long after radiotherapy treatment is completed (Jensen et al., 2004). Majority of the patients who experience deep dyspareunia after radiotherapy have impaired vaginal elasticity (Stinesen et al., 2015). In addition, women who experience sexual dysfunction after chemoradiation complain of reduced vaginal lubrication, bleeding after coitus, fatigue, lack of sexual arousal, fear that the intercourse will cause health injury or that the cancer might recur (Dariusz et al. 2016; Flay et al., 1995). Patients treated with external beam radiotherapy (EBRT) with concurrent chemotherapy and brachytherapy experienced stenosis as the main complication followed by vaginal dryness (Kpoghomou et al.,2021). Patients who underwent surgery and then radiotherapy had a higher risk of sexual dysfunction compared to those who underwent one modality of treatment (Shankar et al., 2017). This demonstrates that surgery and radiation both negatively affect the sexual life of the patient after treatment and should therefore be addressed before, during and after treatment. Accordint to Jensen et al. (2015), sexual functioning was one of the most important aspects of quality of life (QOL) in long-term survivors whereas Schover et al. (1989) reported that survivors who developed sexual dysfunction were less likely to resume several other daily life activities. This indicates that sexual dysfunction is a major sequelae cervical cancer treatment that needs to be

diagnosed and treated.

Khalil et al., (2015) studied sexual activity among cervical cancer survivors in Morocco and reported that 54% of them were sexually active at the time of the interview but the remaining 34% who were sexually inactive giving lack of interest, fear of relapse or infection and fatigue as some of the reasons for not engaging in sexual activity. In addition, majority of the survivors who had been informed of the side effects of the treatment resumed sexual activity earlier compared to the ones who had not been informed. Iavazzo et al. (2015) also reported that majority of the survivors would have liked to be informed of the complications of the cancer treatment before they begun the treatment. Counseling about cancer specific issues and sexual education at the inception of care and throughout during treatment is therefore imperative.

A study at Kenyatta National Hospital reported that 13.8% of respondents diagnosed and treated for cancer of the cervix by radiotherapy were interested in coitus (Kamau et al., 2007). Majority of these survivors who expressed interest in sexual activity were less than 50 years old and some of them were still sexually active. This study suggested that sex was subtle but was significantly affected by age more in survivors less than 50 years old. Some respondents reported that diagnosis and treatment of cervical cancer had affected their sexual life thus their relationship with their spouse resulting in a decrease in their quality of life. Counselling on quality of life in order to enable the survivors cope with the sequalae of the treatment and the disease was therefore recommended.

Zhou et al (2016) recommended that survivors should be educated on sexual dysfunction and active treatment of the complications initiated by the medical care givers, in order to improve the quality of life (QOL) of the cervical cancer survivors. At the Christie Hospital in London, a Gynaecological Advice Clinic offers support to patients who have sexual dysfunction post their treatment. Various treatment options including local estrogen, aqueous cream, lubrication,

tibolone, massage to areas of discomfort, use of vaginal dilators are offered to the survivors and pelvic floor exercises and vulval care are explained (Khalil et al., 2015). As a result, the clinic has assisted many survivors and helped them restore their sexual function.

JUSTIFICATION

Majority of the cervical cancer patients in Kenya present with locally advanced disease and require radiation as part of their treatment. Most of these patients are treated in the Cancer Treatment Centre at the Kenyatta National Hospital as this was the only public hospital offering radiotherapy services in the country until 2020. For instance, in the year 2020, a total of 675 newly diagnosed patients with cancer of the cervix were treated in the cancer treatment center and are now on routine follow up. The survivors are likely to develop side effects related to the treatment which include sexual dysfunction. In spite of this, sexual dysfunction is rarely diagnosed, managed or researched and therefore the survivors suffer in silence. No study has addressed the issue of sexuality after treatment for cervical cancer in the country. It is therefore imperative to find assess the common side effects associated with sexual dysfunction and the gaps in the treatment of these adverse effects among the cervical cancer survivors treated in the Centre.

Information emanating from such study will inform policy on introduction of sex education and counseling about the treatment adverse effects cervical cancer patients in the clinic. Additionally, this may also lead to improvement in the doctor-patient relationship such that sexual health can be discussed with ease and managed appropriately.

RESEARCH QUESTIONS

- 1. What is the prevalence of sexual dysfunction in patients treated for cancer of the cervix at the Cancer Treatment Centre, in Kenyatta National Hospital?
- 2. What is the most common adverse effect related to sexual dysfunction that is experienced by the cervical cancer survivors?
- 3. Is there any treatment for sexual dysfunction that has been initiated before or after treatment of cervical cancer in the hospital?

PROBLEM STATEMENT

Sexual dysfunction is an important sequelae of treatment of cancer of the cervix which negatively affects the quality of life of the survivors. It is often associated with the treatment of the cancer or the psychological effects the cancer has on the patient. In spite of this, the survivors rarely discuss about these effects and no treatment is offered. This is mainly due to lack of awareness about the problem by patients and health care workers.

HYPOTHESIS

• There is no association between sexual dysfunction and treatment of cancer of the cervix among patients treated in the Cancer Treatment Centre at the Kenyatta National Hospital.

OBJECTIVES

GENERAL OBJECTIVE

To assess the prevalence of sexual dysfunction in patients treated for cancer of the cervix at the

Kenyatta National Hospital, Cancer Treatment Centre

SPECIFIC OBJECTIVES

1. To determine the prevalence of sexual dysfunction after treatment of cervical cancer.

2. To determine most common adverse effect related to sexual dysfunction that is experienced by the cervical cancer survivors.

3. To establish whether the cervical cancer survivors have received any form of treatment (psychotherapy or medication) for sexual dysfunction before during or after treatment.

3. METHODOLOGY

STUDY AREA

The present study will be carried out in Kenyatta National Hospital which is located in Nairobi, Kenya, located approximately 5km from the Nairobi Central Business District in Upper Hill Area. It has a 1,900 bed capacity and attends to approximately six hundred out-patients daily. The hospital is a public hospital and its catchment is mainly the middle to low income socioeconomic groups.

In the Cancer Treatment Centre the patients are usually referred from peripheral hospitals from all over the country. There are four main clinics in the cancer centre and one ward with a 30 bed capacity. The clinics include, new patients' clinic for first visit patients which attends to about 60 patients per week, follow up clinic where 200 patients are reviewed after the first visit and after completion of treatment, chemotherapy clinic where about 150 patients who are on chemotherapy treatment are reviewed during their cycles of treatment, and the treatment follow up clinic where 200 patients on radiotherapy are seen at least once per week. At the Cancer Treatment Centre patients are initially attended to by medical officers or registrars where they are clerked and sent for the relevant staging investigations. They are also reviewed by counsellors who counsel them on the diagnosis and different modalities of treatment. On the second visit the patients are reviewed based on the results of the investigations in the follow up clinic and a decision is made on the plan of management which could include chemoradiotherapy/radiotherapy and brachytherapy.

STUDY POPULATION

The study population will be patients who have successfully completed treatment for cervical cancer more than 3 months before and are on regular follow up at the Cancer Treatment Centre.

STUDY DESIGN

The present study is cross-sectional in nature where patients who have been treated for cervical cancer and are on follow up will be given a questionnaire to fill about their current and previous sexual history.

SAMPLE SIZE CALCULATION

The sample size of the patients to be enrolled into the study was calculated using Fisher's formula (Naing, 2006) as follows;

 $n = \{Z^2P(1-P)\}/d^2$

Where, n=sample size Z=confidence interval

P=known prevalence according to literature (In this case we will use 38.4% based on a study done at National cancer Institute, Mohamed V University, Rabat, Morocco (Khalil et al., 2015).

d=precision (in proportion of one; if 5%, d=0.05

therefore,

 $n = (1.96)^2 \times 0.384(0.616)/0.05^2 = 363$ or 365 patients

INCLUSION CRITERIA

i. Patients treated for cancer of the cervix with radiotherapy at the cancer treatment centre

EXCLUSION CRITERIA

- i. Survivors with stage IV disease including those with Rectovaginal or Vesicovaginal fistula.
- ii. Patient with persistent or recurrent disease

DATA COLLECTION

The data will be collected using a questionnaire adapted from the European Organization for Research and Treatment of Cancer Quality of life Questionnaire cervical Module 24 (EORTC QLQ Cx24). It will be modified in order to include the patient demographics and stage of the disease. The data to be collected will include sexual history before diagnosis and after treatment of cervical cancer. Information on the side effects of radiotherapy treatment which would affect sexual function will also be determined. The questionnaire will be given to the participants to fill in but a research assistant who will be a trained nurse will be available to clarify and assist the participants. The questionnaire will be pretested in order to ensure quality control.

DATA ANALYSIS

Data will be entered into Excel spreadsheet and then transferred into statistical software (Stata version 15) for statistical analysis. Continuous data such as age, duration will be compared using t test or ANOVA as appropriate for normally distributed data and for data that is not normally distributed it will be analysed using non parametric tests such as Chi test for proportions Mannwhitney U test or Kruskal wallis test. A statistician will be enganged for the analysis of the data.

ETHICAL CONSIDERATION

Approval will be sought from the University of Nairobi/ KNH ethical and research committee. Individual patient consent will be obtained. Patient confidentiality will be maintained at all times. Data will be stripped of all personal identifiers and only study identity numbers will be used. The questionnaires will be assigned numerical identities and will be kept under lock and key when not in use.

Knowledge generated from the study will be disseminated to the KNH/UoN Ethics and Research Committee and academic forum. It is hoped that recipients will use the knowledge to enhance their diagnostic and management practices for the benefit of the patients treated at the Cancer Treatment Centre.

LIMITATIONS

There may be respondents who do not complete the questionnaire.

RESEARCH TIMELINES

The research will run for six months that is data collection in the clinical area and analysis.

RESULTS

The study assessed the prevalence of sexual dysfunction in patients treated for cancer of the cervix at the Kenyatta National Hospital, Cancer Treatment Centre. A total of 365 patients treated for cancer of the cervix with radiotherapy at the cancer treatment centre were recruited into the study. All the questionnaires were completed and returned for analysis representing 100% response rate.

Demographic characteristics of patients treated for cancer of the cervix at the Kenyatta National Hospital, Cancer Treatment Centre.

The average age of the study respondents was $44.8(\text{SD}\pm8.3\text{years})$ with majority, 63.3% (n =231) aged between 35 and 49 years. In investigating level of education, 37.5%(n =137) had tertiary level education. Further, the findings showed that 38.1%(n =139) were self employed and 74%(n =270) had partners/husbands as shown in Table 1.

	Frequency	Percent
Age (Mean, SD)	44.8±8.3	
\leq 34 years	37	10.1
35 - 49 years	231	63.3
$\geq =50$ years	97	26.6
Education level		
Primary or lower	116	31.8
Secondary	112	30.7
Tertiary	137	37.5
Employment status		
Employed	113	31.0
Unemployed	100	27.4
Self employed	139	38.1
Retired	13	3.6
Status of living		
Alone	95	26.0
Partner/husband	270	74.0

Table 1: Demographic characteristics of patients treated for cancer of the cervix at the
Kenyatta National Hospital, Cancer Treatment Centre.

Disease specific characteristics patients treated for cancer of the cervix at the Kenyatta National Hospital, Cancer Treatment Centre

The findings showed that 81.1%(n = 296) of the respondents had sexual partners, 58.1%(n = 212) were stage II based on FIGO staging. Further, 75.1%(n = 274) were premenopausal while 4.1%(n = 15) underwent hormonal replacement therapy as shown in Table 2.

	Frequency	Percent
Have sexual partner		
Yes	296	81.1
No	69	18.9
FIGO staging		
Stage I	12	3.3
Stage II	212	58.1
Stage III	141	38.6
Menopausal status		
Premenopausal	274	75.1
Postmenopausal	91	24.9
Hormonal replacement therapy		
Yes	15	4.1
No	346	94.8
Unknown	4	1.1

Table 2: Disease specific characteristics of patients treated for cancer of the cervix at the Kenyatta National Hospital, Cancer Treatment Centre

The prevalence of sexual dysfunction in patients treated for cancer of the cervix at the Kenyatta National Hospital, Cancer Treatment Centre

The findings showed that 53.2% (n =194) of the patients had sexual dysfunction with a confidence interval (CI), 95%CI: 47.9% - 58.4% as shown in Figure 1.

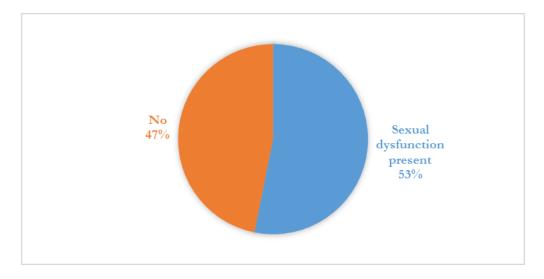


Figure 1: The prevalence of sexual dysfunction after treatment of cervical cancer

Most common adverse effect related to sexual dysfunction that is experienced by the cervical cancer survivors

The common adverse effects related to sexual dysfunction after treatment of cervical cancer were investigated as shown in Table 3. The findings established that sexual worry was the most commonly occurring adverse effect, 67.4% (n =246) followed by body image 61.9% (n =226), pain during sexual activity 53.4% (n =195), symptoms experienced 52.6% (n =192) and sexual/vaginal functioning 47.7% (n =174).

	Frequency	Percent
Symptoms experienced	192	52.6
Body image	226	61.9
Sexual/vaginal dryness	174	47.7
Lymphoedema	39	10.7
Peripheral neuropathy	75	20.5
Menopausal symptoms	116	31.8
Sexual worry	246	67.4
Sexual activity pain	195	53.4
Sexual enjoyment	112	30.7

Table 3: Most common adverse effect related to sexual dysfunction that is experienced by the cervical cancer survivors

Treatment approaches for patients treated for cancer of the cervix at the Kenyatta National Hospital, Cancer Treatment Centre

A total of 365 patients who had undergone radiotherapy were recruited into the study. Of these 155 (42.5%) were also treated with brachytherapy and 4 (1.1%) had previously undergone surgery.

Factors associated with sexual dysfunction in patients treated for cancer of the cervix at the Kenyatta National Hospital, Cancer Treatment Centre

The findings from bivariable analysis showed that age (\leq 34 years), education level, menopausal status and treatment approach were significantly associated with sexual dysfunction as shown in Table 4. Those who were aged \leq 34 years were 0.74 times less likely to have sexual dysfunction compared to those aged \geq 50 years (COR =0.26, 95%CI:0.11 – 0.60, p =0.002). Those who had secondary level education were 2 times more likely to have sexual dysfunction (COR =2.15, 95%CI:1.29 – 3.57, p =0.003), those who had tertiary level education were 0.49 times less to have sexual dysfunction compared to those who had primary level education (COR =0.49, 95%CI:0.29 – 0.83, p =0.008). Those who were premenapausal were 2.7 times more likely to have sexual dysfunction (COR =2.67, 95%CI:1.63 - 4.37, p<0.001). Those who were additionally managed using branchytherapy were 2 times more likely to have sexual dysfunction compared to those who had surgery as an addition (COR =2.11, 95%CI:1.35 – 3.29, p=0.001).

Table 4: Factors associated with sexual dysfunction in	patients treated for cancer of the cervix at the
Kenyatta National Hospital, Cancer Treatment Centre	:

	Sexual dysfunc	tion		
	Present	Absent		P-
	n(%)	n(%)	cOR (95%CI)	value
Age			· · · ·	
≤34 years	28(14.4)	9(5.3)	0.26(0.11 - 0.60)	0.002
35 - 49 years	123(63.4)	108(63.2)	0.70(0.43 - 1.13)	0.141
\geq 50 years	43(22.2)	54(31.6)	Ref	
Education level				
Primary or lower	41(21.1)	75(43.9)	Ref	
Secondary	79(40.7)	33(19.3)	2.15(1.29 - 3.57)	0.003
Tertiary	74(38.1)	63(36.8)	0.49(0.29 - 0.83)	0.008
Employment status				
Employed	69(35.6)	44(25.7)	0.74(0.24 - 2.36)	0.615
Unemployed	41(21.1)	59(34.5)	1.68(0.53 - 5.36)	0.382
Self employed	77(39.7)	62(36.3)	0.94(0.30 - 2.94)	0.382
Retired	7(3.6)	6(3.5)	Ref	
Living status				
Alone	52(26.8)	43(25.1)	1.09(0.68 - 1.74)	0.811
Partner/husband	142(73.2)	128(74.9)	Ref	
Have sexual partner				
Yes	154(79.4)	142(83.0)	0.79(0.46 - 1.34)	0.422
No	40(20.6)	29(17.0)	Ref	
FIGO stage		~ /		
Stage I	5(2.6)	7(4.1)	Ref	
Stage II	115(59.3)	· · ·	1.55(0.47 - 5.11)	0.474

Stage III	74(38.1)	67(39.2)	0.93(0.61 - 1.43)	0.745
Menopausal status			· · · · ·	
Premenopausal	162(83.5)	112(65.5)	2.67(1.63 - 4.37)	< 0.001
Postmenopausal	32(16.5)	59(34.5)	Ref	
Hormonal replacement therapy				
Yes	11(5.7)	4(2.3)	2.51(0.78 - 8.03)	0.112
No	181(93.3)	165(96.5)	Ref	
Treatment				
Surgery + radiochemotherapy	3(1.5)	1(0.6)	Ref	
Radiotherapy	29(14.9)	11(6.4)	0.50(0.05 - 4.92)	0.552
Radio-chemotherapy	69(35.6)	97(56.7)	0.57(0.27 - 1.22)	0.148
Brachytherapy+	93(47.9)	62(36.3)		
radiochemotherapy			2.11(1.35 - 3.29)	0.001

Multivariable analysis of factors associated with sexual dysfunction in patients treated for cancer of the cervix at the Kenyatta National Hospital, Cancer Treatment Centre

Multivariable analysis revealed that respondents who were aged between ≤ 34 years were 4 times more likely to have sexual dysfunction compared to those aged ≥ 50 years, aOR = 3.87, 95%CI:1.40 – 10.66, p =0.009. Level of education analysis established that those who had secondary level education were 2 times more likely to have sexual dysfunction, aOR =1.81, 95%CI:1.01 – 3.26, p =0.047, those who had tertiary level education were 52% less likely to have sexual dysfunction compared to those who had primary level education, aOR =0.48, 95%CI:0.27 – 0.84, p =0.010. Those who had premenopausal status were 6 times more likely to have sexual dysfunction, aOR =5.68, 95%CI:2.05 – 15.77, p<0.001. Those who were managed using brachytherapy were 2 times more likely to have sexual dysfunction compared to those who had surgery, COR =1.97, 95%CI:1.23 – 3.17, p=0.005.

Table 5: Multivariable analysis of factors associated with sexual dysfunction in patients treated for cancer of the cervix at the Kenyatta National Hospital, Cancer Treatment Centre

aOR(95%CI)	P-value

Age 20 - 34 years	3.87(1.40 - 10.66)	0.009
35 - 49 years	1.62(0.46 - 5.68)	0.455
≥50 years	Ref	
Education level		
Primary or lower	Ref	
Secondary	1.81(1.01 - 3.26)	0.047
Tertiary	0.48(0.27 - 0.84)	0.010
Menopausal status		
Premenopausal	5.68(2.05 - 15.77)	0.001
Postmenopausal	Ref	
Treatment		
Surgery	Ref	
Chemotherapy	0.31(0.03 - 3.70)	0.353
Radio-chemotherapy	0.52(0.22 - 1.22)	0.133
Brachytherapy	1.97(1.23 - 3.17)	0.005

DISCUSSION

Cervical cancer contributes approximately 12% of all cancer cases diagnosed in Kenya, and is the leading cause of all cancer deaths, with over 3,200 deaths in 2020 (sung et al 2020). Mortality rates of cervical cancer has reduced significantly in many populations worldwide due to early detection as a result of screening in the communities (Akila et al., 2018). Treatment of cancerof the cervix includes surgery, chemoradiation, brachytherapy or a combination of these modalities.

Item	Unit cost (KES.)	Quanti	ty	Total (KES.)	Total (US\$)
Ethical review fee	2,000.00	1	once	2,000.00	45.87
Research assistant allowance	1,500.00	120	days	180,000.00	1641.38
Stationery	10,000.00	1	once	10,000.00	91.74
Laptop computer	60,000.00	1	pc	60,000.00	550.46
Printing plus binding charges	40,000.00	3700 pages	@10sh p/p	40,000.00	367
Publication charges	20,000.00	1	pc	20,000.00	183.49
Statistician (consultation) fee	45,000.00	1	once	45,000.00	412.84
Total				357,000.00	3292.78

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APPENDICES

APPENDIX 1: INFORMED CONSENT DOCUMENTS STUDY ON SEXUAL DYSFUNCTION IN PATIENTS TREATED FOR CERVICAL CANCER AT THE CANCER TREATMENT CENTRE KENYATTA NATIONAL HOSPITAL

PART A.

Introduction

My name is Susan Kahumburu, a Master's student at the University of Nairobi, department of a diagnostic and radiation medicine. I am conducting a study on the sexual dysfunction in patients treated for cervical cancer at the Kenyatta national hospital.

Cervical carcinoma is the development of abnormal cells along the lining of the cervix at the neck of the womb. It is the second commonest cancer in women in the developing world after breast cancer. The treatment includes surgery, chemoradiation and brachytherapy with the majority of the patients being treated with radiation. Unfortunately, the treatment is associated with adverse effects including bleeding, shortening and narrowing of the vagina which affect the sexual function of the survivor. Sexuality is an important indicator of quality of life in premenopausal women especially those aged between 35 and 50 years. It therefore cannot be overemphasized the importance of diagnosing and treating sexual dysfunction.

Purpose of the study

The study aims to identify gaps in the treatment of sexual dysfunction in cervical cancer survivors. It is hoped that the study will inform management of survivors with sexual dysfunction. The information obtained is also important for the attainment of a Masters Degree in Radiation Oncology for the principal investigator.

Study procedure

The information required from you is in the data collection tool. The study will not in any way affect your treatment or follow-up schedule.

Risks and benefits to the participant.

No risks are directly related to the study. The benefit will be participation in a study that will identify treatment related complications in the survivors and how best they can be managed in order to improve their quality of life.

Study costs

If you take part in this study, there will be no payment from you or to you. No added investigations will be required from you.

Confidentiality

The data collection chart is strictly confidential. Your name will not appear in it and your hospital number is for follow-up purposes only. If you so wish, you shall be given a copy of this consent form.

Participant information.

Your participation in this study is voluntary and failure to participate or withdrawal from the study will not affect your management in any way or stage.

Contacts and questions

The researcher conducting this study is Dr. Susan Kahumburu. You may ask any questions you may have now or if you do have questions later, you are encouraged to contact her through the mobile number +254724503973 or email <u>kahumbs@gmail.com</u> or Dr. Catherine Nyongesa mobile no 0723698888.

If you have questions or concerns regarding the study and would like to talk to someone other than the researcher you are encouraged to contact the following:

The Director, KNH/University of Nairobi- ethical review committee

Telephone 726300-9 or (254-020) 2726300 Ext 44102

PART B

PARTICIPANT CONSENT FORM

I have understood the above information which has been fully explained to me by the investigator and I voluntarily consent to participate.

Signature

Or participants thumb print.

Date.....

Witness signature

BARUA YA IDHINI (SWAHILI TRANSLATION)

UTAFITI KUHUSU MATATIZO YA KINGONO KATI Y A WAGONJWA WALIOTIBIWA SARATANI YA MLANGO WA KIZAZI KATIKA HOSPITALI KUU YA KENYATTA SEHEMU YA KWANZA

UTANGULIZI

Jina langu ni Susan kahumburu. Mimi mi mwanafunzi wa uzamili (Masters Student) katika chuo kikuu cha Nairobi, idara ya matibabu ya seratani. Kwa wakati huu, ninaendeleza utafiti kuhusu matatizo ya kingono kati ya wagonjwa wa saratani ya mlango wa kizazi waliotibiwa katika hospitali kuu ya Kenyatta.

Katika mataifa yanayostawi, saratani ya mlango wa kizazi ni ya pili kwa wingi baada ya saratani ya matiti. Satani hii hutibiwa kwa upasuaji ama matibabu ya mionzi (radiation therapy). Wengi wa wagonjwa hawa hutibiwa kwa matibabu ya mionzi. Licha ya matibabu haya kuwa na faida zake, yana madahara pia. Kati ya madhara haya kwa sehemu ya siri ni kuvuja damu, kufupika na kuwa nyembamba, matokeo yake ni kuadhirika kwa uhusiano wa kingono kati ya walioadhirika na kutibiwa ugonjwa huu.

UMUHIMU WA UTAFITI HUU

Utafiti huu unanuia kufichua mianya katika matibabu ya walioadhirika kingono kufuatia matibabu ya saratani ya mlango wa kizazi.

Ni muhimu kuelewa kuwa hautapokea malipo yoyote kwa kushiriki utafiti huu. Ujumbe wote utakaopeana utawekwa siri, na jina lako halitatumiwa katika utafiti huu.

UJUMBE KWA WATAKAOSHIRIKI UTAFITI HUU

Kushiriki kwako katika utafiti huu ni kwa hiari yako mwenyewe. Iwapo utaamua kutoshiriki, au kujiondoa kwenye utafiti huu, uamuzi wako hautadhuru matibabu yako hata kidogo.

MASWALI

Ukiwa na maswali yoyote, ama maelezo yoyote kuhusu utafiti huu, unaweza kuwasiliana na mtafiti mkuu, daktari Susan Kahumburu kupitia nambari ya simu 0724503973. Au barua pepe kahumbs@gmail.com ama daktari Catherine Nyongesa 0723698888.

Unaweza pia kuwasiliana na mkurungenzi wa kamati ya utafiti ya hospitali ya Kenyatta kupitia nambari ya simu 726300-9 au 020-2726300 Ext 44102.

SEHEMU YA PILI

SAHIHI YAKO

Nimesoma maelezo haya na kuyaelewa vizuri, na nitashiriki utafiti huu kwa hiari yangu.

Sahihi:....

au

Alama ya kidole gumba:

APPENDIX 2: QUESTIONNAIRE

- 1. Age
- 2. Education

None	Prima	ry	Secondary	Technical college	University
3. Employment					
Employed	Unemployed		Self-employe	d Retired	
4. Living					
Alone	With partner/Husband				
5. Sexual partner					
Yes	No				
6. FIGO disease stage					
Stage I	Stage II	Stage III			
7. Treatment					
Surgery	Chemotherap	y Radio	ochemotherapy	Brachytherapy EBR	Т
8. Menopausal status before treatment					
Premenopausal			Postn	nenopausal	
9. Hormone Replacement Therapy					
Yes	No	Unknown			

Please indicate the extent to which you have experienced these symptoms or problems, please answer by circling the number that best applies to you.

During the past week

10. Have you had cramps in your abdomen?

YES [] NO [] I DON'T KNOW []

11. Have you had difficulty in controlling your bowels?

YES [] NO[] I DON'T KNOW []

12. Have you had blood in your stools?

YES [] NO[] I DON'T KNOW []

13. Did you pass urine frequently?

YES [] NO [] I DON'T KNOW []

14. Have you had pain or a burning feeling when passing urinating?

YES [] NO [] I DON'T KNOW []

15. Have you had leaking of urine?

YES [] NO [] I DON'T KNOW []

16. Have you had difficulty emptying your bladder?

YES [] NO [] I DON'T KNOW []

17. Have you had swelling in one or both legs?

YES [] NO [] I DON'T KNOW []

18. Have you had pain in your lower back?

YES [] NO [] I DON'T KNOW []

19. Have you had tingling or numbness in your hands or feet?

YES [] NO [] I DON'T KNOW []

20. Have you had irritation or soreness in your vagina or vulva?

YES [] NO [] I DON'T KNOW []

21. Have you had discharge from your vagina?

YES [] NO [] I DON'T KNOW []

22. Have you had abnormal bleeding from your vagina?

YES [] NO [] I DON'T KNOW []

23. Have you had hot flushes and/or sweats?

YES [] NO [] I DON'T KNOW []

24. Have you felt physically less attractive as a result of your disease or treatment?

YES [] NO [] I DON'T KNOW []

25. Have you felt less feminine as a result of your disease or treatment?

YES [] NO [] I DON'T KNOW []

26. Have you felt dissatisfied with your body?

YES [] NO [] I DON'T KNOW []

During the past 4 weeks

27. Have you worried that sex would be painful?

YES [] NO [] I DON'T KNOW []

28. Have you been sexually active?

YES [] NO [] I DON'T KNOW []

Answer these questions only if you have been sexually active during the past 4 weeks

29. Has your vagina felt dry during sexual activity?

YES [] NO [] I DON'T KNOW []

30. Has your vagina felt short?

YES [] NO [] I DON'T KNOW []

31. Has your vagina felt tight?

YES [] NO [] I DON'T KNOW []

32. Have you had pain during sexual intercourse or other sexual activity?

YES [] NO [] I DON'T KNOW []

33. Was sexual activity enjoyable for you?

YES [] NO [] I DON'T KNOW []

For no. 34 and 35 estimate frequency either weekly or monthly

34. How frequent were you engaging in sexual activity before the diagnosis of cancer?

35. How frequent are you engaging in sexual activity after treatment for the cancer?

DODOSO/ORODHA YA MASWALI YA UCHUNGUZI. (SWAHILI TRANSLATION)

1 Umri wangu------

- 2. Masomo yangu.A
 - i) Sijasoma
 - ii) Msingi
 - iii) Upili
 - iv) Chuo cha ufundi
 - v) Chuo Kikuu.
- 3. Kazi yangu
 - i) Nimeajiriwa.
 - ii) Sina kazi
 - iii) Kazi ya kujiajiri
 - iv) Nimestaafu.

4. Kuishi

- i) Naishi peke yangu
- ii) Naishi na mume/mpenzi
- 5. Una mpenzi/mshirika wa kimapenzi
 - i) Ndio
 - ii) Laa.
- 6. Ugonjwa wako (saratani) ulivyoenea
 - i) Hatua ya I (stage I)
 - ii) Hatua ya II (stage II)
 - iii) Hatua ya III (stage III)
- 7. Matibabu ya saratani uliyopokea
 - i) Upasuaji
 - ii) Madawa (chemotherapy)
 - iii) Mionzi (Radiotherapy)

iv) Mionzi (Brachytherapy)

8. Hedhi kabla ya matibabu (menses)

i) ilikuwa haijakoma

- ii) ilikuwa imekoma
- 9. Unatumia matibabu ya homoni kwa wakati huu?
 - i) Ndio
 - ii) Laa
 - iii) Sina hakika

Jibu maswali yafuatayo ukitumia kielekezi kifuatacho kuonyesha kiwango cha shida au maumivu uliyo nayo. Weka duara (circle)kwa nambali inayolingana na shida yako.

- 1 Hakuna hata kidogo
- 2. Kidogo tu
- 3. Kiwango cha wastani (moderate)
- 4. Kiwango kikubwa

Katika wiki moja iliyopita.....

10. Umekuwa na maumivu ya tumbo?

NDIO [] LA [] SINA HAKIKA []

11. Umekuwa na shida ya kushikilia haja kubwa/ haja kubwa kujitoa?

NDIO [] LA [] SINA HAKIKA []

12. Umeona damu kwa choo yako(haja kubwa)

NDIO [] LA [] SINA HAKIKA []

13. Unahitaji kwenda haja ndogo mara nyingi/ mara kwa mara?

NDIO [] LA [] SINA HAKIKA []

14. Umekuwa na uchungu au muwasho wakati wa kwenda haja ndogo?

NDIO [] LA [] SINA HAKIKA []

15. Una shida ya kushikilia mkojo/mkojo unajitoa wenyewe?

NDIO [] LA [] SINA HAKIKA []

16. Umekuwa na shida ya kupitisha mkojo/mkojo kukwama?

NDIO [] LA [] SINA HAKIKA []

17. Umepata shida ya kufura mguu mmoja au yote miwili?

NDIO [] LA [] SINA HAKIKA []

18. Umekuwa na maumivu ya mgongo?

NDIO [] LA [] SINA HAKIKA []

19. Umekuwa na shida ya muwasho au kufa ganzi kwa miguu au mikono?

NDIO [] LA [] SINA HAKIKA []

20. Umekuwa na uchungu au muwasho katika sehemu zako za siri?

NDIO [] LA [] SINA HAKIKA []

21. Umeona uchafu usio wa kawaida kutoka sehemu zako za siri?

NDIO [] LA [] SINA HAKIKA []

22. Umeona damu ikitoka kwenye sehemu za siri?

NDIO [] LA [] SINA HAKIKA []

23. Umekuwa na nyakati za kuhisi joto jingi mwilini, au kutokwa na Jasho?

NDIO [] LA [] SINA HAKIKA []

24. Je, umejihisi hupendezi kwa sababu ya ugonjwa huu au matibabu yake?

NDIO [] LA [] SINA HAKIKA []

25. Je, umejihisi kutokuwa mwanamke kamili kwa sababu ya ugonjwa huu au matibabu yake?

NDIO [] LA [] SINA HAKIKA []

26. Je, umejihisi kutoridhika na mwili wake kwa sababu ya ugonjwa huu na matibabu yake?

NDIO [] LA [] SINA HAKIKA []

27. Umekuwa na hofu au woga kuwa kuonana kimwili/kufanya mapenzi kutasababisha uchungu?

NDIO [] LA [] SINA HAKIKA []

28. Umefanya mapenzi?

NDIO [] LA [] SINA HAKIKA []

Jibu maswali yafuatayo ikiwa umefanya mapenzi katika wiki nne zilizopita.

29. Je, umehisi kuwa uke wako hauna unyevu wa kawaida au wa kutosha (dryness) wakati wa kufanya mapenzi?

NDIO [] LA [] SINA HAKIKA []

30. Je, umehisi kuwa uke wako umekuwa mfupi kuliko kawaida?

NDIO [] LA [] SINA HAKIKA []

31. Je, umehisi kuwa uke wako hauna upana wa kutosha?

NDIO [] LA [] SINA HAKIKA []

32. Umepata maumivu/uchungu wakati wa kufanya mapenzi?

NDIO [] LA [] SINA HAKIKA []

33. Je, kufanya mapenzi kunakupa raha inavyostahili?

NDIO [] LA [] SINA HAKIKA []

Kwa maswali yafuatayo, kisia (estimate) ni mara ngapi kwa wiki au kwa mwezi.

34. Ulikuwa unafanya mapenzi kadri ya mara ngapi kabla ya kupatikana kuwa ma ugonjwa huu?

35. Kwa sasa unafanya mapenzi kadri ya mara ngapi baada ya kutibiwa?