Improving Treatment Outcome for Cervical Cancer Using 2-Point Assessment of Quality of Life Among Nigerian Women: A Protocol for a Multi-Center Study

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ABSTRACT

BACKGROUND: Cervical cancer is the fourth most common cancer among women globally, with quality of life (QOL) being a major concern for patients with cervical cancer, especially in low- and middle-income countries (LMICs). This is largely due to the advanced nature of the disease at presentation. Although there are a higher number of studies focusing on the QOL of high-income countries, the QOL of cervical cancer patients in LMICs is not available. The aim of this study is to evaluate QOL among women with cervical cancer in Nigeria using a 2-point assessment.

METHODS: A multi-center prospective cohort study will be conducted in 6 tertiary health facilities randomly selected from the 6 geopolitical zones of Nigeria and consisting of a 2-point assessment of the QOL of participants at the time of diagnosis of cervical cancer and after treatment. Women who were recently diagnosed with histologically confirmed cervical cancer (treatment naïve) will be included. QOL will be assessed using Quality of Life Questionnaire domains (EORTC QLQ30) as developed by the European Organization for Research and Treatment of Cancer (EORTC). In addition to the QOL assessment, relevant and clinicopathological variables will be obtained using a self-structured data extraction sheet designed for this study. All data will be anonymized and will be analyzed using SPSS version 25. Levels of QOL will be calculated using EORTC QLQ30. Ethical approval was obtained from National Health Research Ethics Committee (NHREC/01/01/2007-08/11/2021).

DISCUSSION: In view of the paucity of data on QOL in LMICs like Nigeria, where most women with cervical cancer present with advanced disease, this research was designed to help in formulating evidence-based interventions to improve the QOL and treatment outcomes provided to women with cervical cancer in Nigeria and other LMICs. The study is expected to fill these knowledge gaps.

KEYWORDS: Cervical cancer, women, Nigeria, quality of life, treatment, women

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Introduction

Cervical cancer is the fourth most common cancer among women globally, with an estimated 570 000 new cases and 311 000 deaths worldwide in 2018.[1,2] It is the second most common cause of cancer-related deaths in women in low- and middle-income countries (LMICs).[1,2] About 86% of all cervical cancer cases occur in LMICs, along with 88% of women who die of cervical cancer worldwide every year.[1-3] Most cervical cancer patients in LMICs usually present in advanced stages of the disease, which is associated with health and psychological difficulties affecting their quality of life (QOL).[4]

Quality of life is therefore a major concern for patients with cervical cancer, especially LMICs, because of the advanced nature of the disease at presentation. The World Health Organization defined QOL as involving a person's physical health, psychological state, degree of independence, social relationships, personal beliefs, and environment.[5] In cancer care, QOL can be defined as a sense of well-being. It is a multi-dimensional perspective that includes dimensions such as physical, psychological, social, and spiritual. Changes in 1 QOL dimension can influence perceptions in other dimensions too.[6] The QOL of patients with cervical cancer is an essential assessment for personalizing treatment and providing better care.[4] According to Tax et al, data on health-related QOL is paramount for shared and evidence-based decision-making.[6]

Studies assessing aspects of QOL among women living with cervical cancer are severely limited, especially in LMICs.[7,8] A recent systematic review of published studies on strategies to improve cervical cancer outcomes in Africa reported that QOL studies accounted for only 4.1% of all the publications. The author concluded that the QOL of cervical cancer patients is one of the most severely understudied areas in Africa. Although there is more research focusing on QOL in high-income countries, there are few studies on it in LMICs.[7-10]

In view of the paucity of data on QOL in LMICs like Nigeria, where most women with cervical cancer present with advanced disease, this research was designed to assess the QOL of the patients with cervical cancer in Nigeria at the point of diagnosis and after treatment.[11] This 2-point assessment of QOL will provide important information about the burden of the disease at the point of diagnosis and the impact of treatment on QOL. These data can help in formulating evidence-based interventions to improve the quality of care and treatment outcomes provided to women with cervical cancer in Nigeria and other LMICs.

Nigeria is the highest contributor to the cervical cancer burden in African in the number new cases diagnosed and reported deaths annually.[11] The cervical cancer control strategy in Nigeria is a comprehensive approach anchored on human papillomavirus infection (HPV) immunization and health education advocacy as primary prevention. School-based HPV vaccination is about to roll out. Secondary prevention is anchored on screening and treatment of screen-positive individuals using HPV testing (where available) or visual inspection with acetic acid (VIA) using the see-and-treat approach.[2,11] Pap smear and colonoscopy services remain available in some tertiary health facilities and private hospitals. Treatment of invasive cervical cancer is done by surgery, radiotherapy, and chemotherapy, which are available in tertiary and some private health facilities. A substantial portion of the population lacks access to these services and presents with advanced cervical cancer. Palliative care services are not widely available.[2,11] Therefore, QOL care is important for women with cervical cancer. Also, the lack of a population-based screening program has resulted in 75% of women presenting in the advanced stages of cervical cancer, which are usually associated with comorbidities. In addition, the relatively weak health system in Nigeria has limited access to diagnostic and treatment facilities for these women with cervical cancer.[11] These factors may adversely affect the QOL of the women.

The aim of this research is to evaluate QOL among women with cervical cancer in Nigeria using a 2-point assessment. The specific objectives include determining the QOL in women with cervical cancer at the time of diagnosis in Nigeria; assessing the QOL after treatment for cervical cancer in Nigeria; comparing the QOL before and after treatment for cervical cancer in Nigeria; and identifying socio-demographic and clinical correlates of QOL among Nigerian women with cervical cancer.

Methods

Research design

This will be a prospective longitudinal study with 2-point assessment of the QOL of participants at the time of diagnosis of cervical cancer and after treatment.

Study site

Participants will be recruited from 1 randomly selected tertiary level health facility in each of the 6 geopolitical zones in Nigeria. The 6 geopolitical zones include North-Central zone, North-East zone, North-West zone, South-West zone, South-South zone, and South-East zone. In this proposed study, 6 tertiary health care facilities selected by simple random sampling among the tertiary health care facilities in the 6 geopolitical zones. The study centers randomly selected in addition to the central Institution, National Hospital, Abuja, Nigeria (North-Central) are:

1. University of Maiduguri Teaching Hospital, Maiduguri (North-East).
2. Aminu Kano Teaching Hospital, Kano (North-West).
3. University College Hospital, Ibadan (South-West).
4. University of Benin Teaching Hospital, Benin-City (South-South).
5. Nnamdi Azikiwe University Teaching Hospital, Nnewi (South-East).

Only health facilities that have the capacity for diagnosis and management of cervical cancer were eligible for selection.

Study duration

The study will last for 12 months.

Study population

The study population will be women who were recently diagnosed with histologically confirmed cervical cancer (treatment naïve) and who provide written informed consent to participate in the research.

Inclusion criteria

Women with histologically diagnosed cervical cancer who present for treatment at the selected study site will be included.

Exclusion criteria

Women already on treatment, completed treatment, or have recurrent cervical cancer will be excluded.

Recruitment of participants

Every consecutive eligible patient who presents at each of the study site will be recruited for the research after they provide written informed consent until the desired sample size is obtained.

Study duration

The data will be collected until the desired sample size is obtained.

Study tools

Quality of life will be assessed using Quality of Life Questionnaire domains (EORTC QLQ30) as developed by the European Organization for Research and Treatment of Cancer (EORTC) (Supplemental Appendix 1). Trained interviewers (research assistants) will administer EORTC QLQ30 on the participants. In addition to the QOL assessment, relevant socio-demographic (such as age, marital status, parity, level of education) and clinicopathological (such as histological type, stage of the cancer, nature of treatment received and laboratory test results) variables will be obtained using a self-structured data extraction sheet designed for this study.

Outcome variables

The primary outcome variables are as follows:

1. QOL at diagnosis of cervical cancer.
2. QOL after treatment for cervical cancer.

The secondary outcome variables are as follows:

1. The relationship between socio-demographic factors and QOL.
2. The relationship between clinical variables and QOL.

Sample size

The minimal sample size is 88, which was determined using the Woodward formula[12]: $n = (z^2 * p * q)/e^2$; where p is the prevalence of participants with cervical cancers (among other cancers) and had poor physical domain QOL in Ibadan, Nigeria, taken from the previous study by Nuhu et al,[13] ie, 6.1%, z is 1.96 at 95% confidence level, q is (1 – p), and e is the error margin (type 1 error), ie, 5% and 106 when we considered 20% attrition rate. This will require a minimum of 106 participants with minimum of 18 persons to be recruited from each site.

Data management and analysis

All data will be anonymized and accessible only to the investigators or designated research team members trained on data management in biomedical research. It will be analyzed using SPSS version 25. The levels of QOL will be calculated using EORTC QLQ30 and categorized as low (0-49) and high (50-100). Descriptive statistics will be used to analyze the socio-demographic and clinical characteristics of participants and compare them to the QOL scores. The *t*-test and chi-square will be used to determine association between socio-demographic and clinical characteristics with QOL performance for continuous and categorical variables, respectively. We will conduct univariable binomial logistic regression models to assess factors influencing the QOL of women with cervical cancer. For each variable, *P* values along with odds ratios (ORs) and 95% confidence intervals (CIs) will be reported. A *P* value of 0.05 will define the chosen level of statistical significance whereas odds ratio at 95% CI will be computed to identify factors associated with QOL categories.

Discussion

The motivation for this study is that cervical cancer remains the fourth most common cancer among women worldwide, with an estimated 569,847 new diagnoses and 311,365 deaths per year.[1,14] In view of the paucity of data on QOL in LMICs like Nigeria, where most women with cervical cancer present with advanced disease, this research was designed to assess the QOL of the patients with cervical cancer in Nigeria at the point of diagnosis and after treatment. The study is expected to fill these knowledge gaps. Nigeria joining the rest of the world to eliminate cervical cancer rests on the availability of adequate and reliable data generated from an appropriately designed and powered study using representative population samples.

Therefore, this study is being planned to involve women living in the 6 geopolitical zones of the country. This will ensure equitable distribution in the assessment of data on QOL among cervical cancer patients for in-country policy planning. Nonetheless, the present weakness in the Nigerian health care system is that the radiotherapy centers are not widely distributed in Nigeria.[11,14,15] Most women being studied will likely benefit from radiotherapy treatment to restore their quality of care. This is because most women with cancer in Nigeria have International Federation of Gynaecology and Obstetrics (FIGO) stage II+ disease.[14,15] However, the essence of the study is to demonstrate whether there will be significant changes in the QOL of the women following treatment.

A foremost strength of this study is that it is one of the few studies in Nigeria that will measure QOL among women with cervical cancer using a 2-point assessment. Furthermore, authorization for the study came from the National Health Research Ethics Committee located at the Federal Ministry of Health, Nigeria, which will make the implementation of the policy stress-free. Moreover, virtually all the investigators in this proposed study are members of the Society of Obstetrics and Gynaecology of Nigeria (SOGON), which will also make translation to Practice Guideline tranquil.

Declarations

Ethics Approval and Consent to Participate

An ethical approval was obtained from the National Health Research Ethics Committee (NHREC) with registration no. NHREC/01/01/2007-08/11/2021. In addition, permissions will be obtained from the authorities of the selected tertiary hospitals. An informed consent will be obtained from each study participant prior to the involvement in the study. The collected data will be kept confidential and accessed only by the research team member.

Consent for publication

The consent for publication will be obtained from the participants.

Author contributions

MUU, GUE, TAO, ME, HAU, and AR were involved in the overall conceptual design and implementation of the project, and overall revision of the manuscript. JSG and CMA were involved in the writing of this manuscript and overall revision. All the authors were involved in revision of the manuscript. The authors read and approved the final manuscript.

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Competing interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Availability of data and materials

No data were generated during the current status of the study. Once the study is finalized and the results are published, a specific procedure for obtaining access to the database will be made.

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Supplemental material

Supplemental material for this article is available online.

REFERENCES

1. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin* 2018;68:394-424.
2. The Global Cancer Observatory. *GLOBOCAN 2018 Nigeria Population and Cancer Fact Sheets*. Lyon, France: International Agency for Research on Cancer; 2018:1-2.
3. Arbyn M, Weiderpass E, Bruni L, et al. Estimates of incidence and mortality of cervical cancer in 2018: a worldwide analysis. *Lancet Glob Health* 2020;8:e191-e203. doi:10.1016/S2214-109X(19)30482-6.
4. Sengayi-Muchengeti M, Joko-Fru WY, Miranda-Filho A, et al. Cervical cancer survival in sub-Saharan Africa by age, stage at diagnosis and Human Development Index: a population-based registry study. *Int J Cancer* 2020;147:3037-3048.
5. WHO. Measuring of quality of life. https://www.who.int/tools/whoqol#:~:text=WHOQOL%20%2D%20Measuring%20Quality%20of%20Life&text=The%20World%20Health%20Organization&text=WHO%20defines%20Quality%20of%20Life,%2C%20expectations%2C%20standards%20and%20concerns. Accessed 5 November 2023.
6. Tax C, Steenbergen ME, Zusterzeel PL, Bekkers RL, Rovers MM. Measuring health-related quality of life in cervical cancer patients: a systematic review of the most used questionnaires and their validity. *BMC Med Res Methodol* 2017;17:15.
7. Finocchario-Kessler S, Wexler C, Maloba M, Mabachi N, Ndikum-Moffor F, Bukusi E. Cervical cancer prevention and treatment research in Africa: a systematic review from a public health perspective. *BMC Womens Health* 2016;16:29.
8. Thapa N, Maharjan M, Xiong Y, et al. Impact of cervical cancer on quality of life of women in Hubei, China. *Sci Rep* 2018;8:11993.
9. Klügel S, Lücke C, Meta A, et al. Concomitant psychiatric symptoms and impaired quality of life in women with cervical cancer: a critical review. *Int J Womens Health* 2017;9:795-805.
10. Singh U, Verma ML, Rahman Z, Qureshi S, Srivastava K. Factors affecting quality of life of cervical cancer patients: a multivariate analysis. *J Cancer Res Ther* 2019;15:1338.
11. Oguejiofor CB, Okonkwo JE, James JE, et al. Perception and practice of cervical cancer screening among female professionals attending gynaecology clinic at a university teaching hospital. *J Diagn Case Rep* 2023;4:2-6.
12. Woodward M. Formulae for sample size, power and minimum detectable relative risk in medical studies. *J R Stat Soc Ser A Stat Soc* 1992;41:185-196.
13. Nuhu FT, Adebayo KO, Adejumo O. Quality of life of people with cancers in Ibadan, Nigeria. *J Ment Health* 2013;22:325-333. doi:10.3109/09638237.2012.734644.
14. Eleje GU, Eke AC, Igberase GO, Igwegbe AO, Eleje LI. Palliative interventions for controlling vaginal bleeding in advanced cervical cancer. *Cochrane Database Syst Rev* 2019;3:CD011000. doi:10.1002/14651858.CD011000.pub3.
15. Ikechebelu JI, Onyiaorah IV, Ugboaja JO, Anyiam DCD, Eleje GU. Clinicopathological analysis of cervical cancer seen in a tertiary health facility in Nnewi, South-East, Nigeria. *J Obstet Gynaecol* 2010;30:299-301.