AN EXPLORATION INTO THE QUALITY OF LIFE OF WOMEN TREATED FOR CERVICAL CANCER AT AN ACADEMIC HOSPITAL IN GAUTENG, SOUTH AFRICA.

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A research report submitted to the
Faculty of Health Science, University of the Witwatersrand, Johannesburg,
in partial fulfilment of the requirement for the degree
of
Master of Science in Nursing

Johannesburg, 2017

DECLARATION

DECLARATION

I Caroline Jepkemei Sabulei declare that the research report is my own work. It has been submittedfor the degree of Master of Science (Nursing) in the University of Witwatersrand, Johannesburg. It has not been submitted before for a degree or examination at this or any other university.

Signature .....

Date.. 31/03/2017

Protocol Number: M 150441

DEDICATION

I dedicate this to my children, Byron, Ruby and Skider. I have set the pace for you, may God guide you to take the same.

ABSTRACT

Quality of life is a multidimensional, subjective and individualized concept influenced by culture and value systems.

Cancer as a disease remains a major health problem globally and it's estimated that 528 000 women are diagnosed with cervical cancer annually whilst 266 000 will die each year. In Africa cervical cancer statistics indicate that there are 99 038 incidences and 60,098 cervical cancer related deaths (International Agency for Research in Cancer and World Health Organization, 2012).

Women with cervical cancer experience physical, psychological and sex-related problems as the consequences of both the disease and treatment and this affects their quality of life.

Research Question: What is the quality of life of women treated for cervical cancer at an academic hospital in Gauteng?

Purpose of the study was to explore the quality of life in cervical cancer during treatment, at six months and twelve months post treatment at an academic hospital in Gauteng.

Aims of the study: The objectives of the study were (1) to explore the quality of life in cervical cancer patients treated with radiation therapy and (2) to compare with the quality of life of women at six months and twelve months after completion of treatment at an academic hospital in Gauteng.

Research Design: This is a cross sectional and explorative study. A sample of 153 women was recruited using a convenience sampling for the three groups and data were collected using the EORTC QLQ-C30 and QLQ-CX24 questionnaires. The data were captured on an excel spreadsheet and analysed using SPSS IBM 22.0.

Results: The overall quality of life of the respondents was affected by the acute side effects experienced during treatment. Cancer related symptoms improved with radiotherapy treatment. Physical functioning was reported as the most affected domain while social functioning was the least affected.

ACKNOWLEDGEMENTS

I thank God for His Grace that is sufficient every day in my life.

I would like to thank the following people and organizations for their various contributions:

- My Family and children for your support throughout this degree. My siblings Robert, Faith, Jocelyn and Ceaser, it's you prayers that saw me through this degree.
- My supervisor, Professor Johanna Maree, thank you for the unceasing support, patience and guidance.
- My parents: Mr. and Mrs. William Murgor, I can't thank you enough for your prayers, inspiration and the pillar of strength.
- The institution where the study was carried out and the relevant personnel of the institution. The staff at the Radiation therapy department thank you for your support and dedication in caring for patients living with cancer.
- Mr Christmal de la Christmals for editing of the final document
- To Margret McNamara Memorial Fund for the financial support during the second year of my study.
- To Moi Teaching and Referral Hospital, for granting me the study leave.
- To all my friends, colleagues.
- The study participants for their time and willingness to participate in the study.

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CHAPTER 1

OVERVIEW FOR THE STUDY

1.0 INTRODUCTION

This chapter orientates the reader to the study and provides a brief overview of cervical cancer, the research problem and question, the objectives of the study and the research methods to be used to achieve the objectives.

1.1 BACKGROUND

Cancer as a disease remains a major health problem globally. According to the Globocan 2012 statistics (Farley et al. 2012), approximately 14 million people were newly diagnosed with cancer and 8.2 million deaths were directly attributed to cancer in 2008. In Africa, the 2008 estimates of the incidence of cancer were 846,961 and the mortality 591,169; South Africa had an estimated incidence of 77,440 and a mortality rate of approximately 47,350. Cervical cancer has become the fourth most common cause of mortality amongst women of reproductive age in the world. It is estimated that 528,000 women are diagnosed with cervical cancer annually, whilst 266,000 will die from this disease each year. In Africa, cervical cancer statistics indicate there are 99,038 incidences and 60,098 cervical cancer-related deaths annually. This is the second highest mortality rate after breast cancer in Africa. According to the Cancer Association of South Africa (CANSA 2015), there were 5,433 histologically diagnosed cervical cancers in 2010. In addition, cervical cancer was the leading cause of cancers deaths in females with 3,498 women dying from this disease (Herbst 2014).

Cervical cancer is a preventable disease and detection at an early stage is associated with excellent survival, however, most women in developing countries present with advanced and often terminal disease (Denny 2012). Many women are diagnosed between the ages of 25 and 64 years when they are at the peak of their productive lives, careers and family life(Kumar et al. 2014) and face various challenges. According to Pasek et al. (2013), women face a time of depression, anxiety and worry over the outcomes of the disease and the possibility of loss of life. During treatment with radiotherapy the women experience various side effects such as fatigue,

radiotherapy induced skin changes, vaginal stenosis leading to dyspareunia and pelvic, bone and back pain. Ancuța et al. (2012) noted that the physical, psychological and sexual problems women with cervical cancer experience, as a consequence of both the disease and treatment, have negative influence on their quality of life.

Quality of life is a multidimensional concept (Goker et al. 2011; Du Toit 2013; Maree & Jansen Van Rensburg 2015) and there is no common definition or standard of measurement (Ferrans 1990). The multi-dimensional aspect of quality of life, according to Cella (1994), refers to the broad coverage of content which includes physical, functional, emotional and social wellbeing. The World Health Organization defines quality of life as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns."(Vaz et al. 2007pg. 584)

1.2 RESEARCH PROBLEM AND QUESTION

Little is known about the quality of life in women treated for cervical cancer in Africa. Although the quality of life of women living with cervical cancer has been explored, these studies originate primarily from countries such as Poland (Barnaś et al. 2012), Romania (Ancuța et al. 2012) and China (Zeng et al. 2010). It also seems as if this topic has not been explored on the African continent as no literature could be found. The research question for the study was therefore: What is the quality of life of women treated for cervical cancer at an academic hospital in Gauteng?

1.3 PURPOSE AND AIMS OF THE STUDY

The study aimed to explore quality of life in women diagnosed and treated for cervical cancer.

- whilst being treated with radiotherapy, at six months after completion of treatment and at twelve months after treatment at an academic hospital in Gauteng, and
- to compare the quality of life of these three groups of women

1.4 RESEARCH SETTING AND METHODS

The research setting was an academic hospital in Johannesburg which offers specialised care to cancer patients. This was an exploratory cross sectional study. The study population consisted of

all women diagnosed with cervical cancer and were either receiving treatment at the academic hospital or had completed treatment six or twelve months prior to the investigation. Convenience sampling was used to select a calculated sample of 153 (n=153) based on an estimate that approximately 662 to 721 women are treated annually for cervical cancer (Msadabwe 2009). Structured interviews were used to collect data. The EORTC QLQ-C30 (version 3) (Appendix A) and EORTC QLQ CX24 (Appendix B) were used as data collection instruments. Data were captured on an Excel spreadsheet and imported to an SPSS IBM 22.0 computer programme for analysis. Descriptive statistical analysis was used to analyse socio-demographic variables and the Kruskal-Wallis test compared the mean responses of the different study groups. Data were analysed under the supervision of a statistician.

1.5 OPERATIONAL DEFINITIONS

Radiotherapy: Radiotherapy involves the use of ionising radiation directed at the tumour with the aim of damaging and destroying the cancer cells. Radiotherapy is one of the treatment methods used in cervical cancer (World Health Organization 2006).

Screening: This is an intervention provided to asymptomatic target populations aimed at identifying the people at risk of developing the disease or any predisposing factors(World Health Organization 2014)

Side Effects: Side effects are undesirable effects that resulting from disease and/or treatment. Some side-effects some could clear shortly after completion of treatment while others may persist for longer times (World Health Organization 2006).

1.6 CHAPTERS OF THE STUDY

The study will be presented as follows:

Chapter 1. Overview for the study

Chapter 2. Literature Review

Chapter 3. Research designs and Methods

Chapter 4. Findings

Chapter 5. Discussion and conclusion

1.7 SUMMARY

In summary, this chapter introduced cervical cancer as a global health problem, presented the problem statement and question, the objectives of the study, the research method used to answer the research objectives and the operational definitions.

CHAPTER 2

LITERATURE REVIEW

2.0 INTRODUCTION

Chapter 1 presented an overview for the study. In Chapter 2, the researcher addresses cervical cancer as a worldwide health problem. Cervical cancer is further discussed in relation to risk factors, prevention and early detection, diagnosis and staging, treatment and prognosis. In addition, quality of life, the various views relating to this phenomenon, the various domains that affect quality of life, measurement of quality of life and quality of life in cancer and finally cervical cancer women, will be discussed.

2.1 CANCER AS WORLD WIDE HEALTH PROBLEM

According to the 2008 statistics from Globocan (Ferlay et al. 2014), it is estimated that 14 million people globally were newly diagnosed with cancer, whilst 8.2 million died of this group of diseases. Cervical cancer was the seventh most common cancer overall and fourth amongst the cancers in women. In Africa, the estimates of the newly diagnosed with cancer was 846,961 and the deaths associated with cancer were estimated at 591,169. South Africa has an estimated 77,440 newly diagnosed people with cancer and 47,350 deaths from cancer (Farley et al. 2012).

In the world, it is estimated that 527,624 women were newly diagnosed with cervical cancer and 265,672 of them died of the disease during 2008. Africa had an estimated 99,038 women newly diagnosed and 60,098 deaths, which accounted for 22.6% of the global deaths related to cervical cancer. The Cancer Association of South Africa (2014) reported that cervical cancer was the leading cause of cancer deaths in women, estimated at 3,498 in 2000. However, the 2009 South African Cancer Registry reports that 5,270 women were histologically diagnosed with cervical cancer in the same year (Herbst 2015).

2.2 DESCRIPTION OF CERVICAL CANCER

Cervical cancer is a disease that forms in the cells of the cervix. The two main types of cells covering the cervix are *squamous* cells at the ectocervix and *glandular/columnar* cells at the endocervix. These two cell types join at the squamocolumnar junction, also called the *transformation zone*. Most cervical cancers develop in the transformation zone and usually grow gradually in a multi-stage process from a pre-cancerous lesion to a cancerous tumour (World Health Organization 2014).

2.2.1 Risk Factors

The exact cause of cervical cancer is not known, but persistent infection of the cervix with human papilloma virus (HPV)has been recognised as the leading cause (Denny 2012). The World Health Organization (WHO 2014) states that the untreated HPV infection takes 10 to 20 years to progress from pre-cancerous lesions to cancer. Many other factors predispose the development of cervical cancer such as, smoking, immunosuppression, multi-parity of more than five children, early onset of sexual intercourse, multiple sexual partners, untreated human immunodeficiency virus (HIV) infection and a family history of cervical cancer(World Health Organization 2014).

2.2.2 Prevention and early detection

Denny (2012) states that since HPV play an important role in cervical cancer development. Prevention and early detection is key in the prevention of cervical cancer. Prevention and early detection strategies are either primary or secondary. Primary prevention entails the HPV vaccination of girls between the age 9 to 13 years before they are sexually active, as well as sex education to both boys and girls to delay initiation of sexual activities and the reduction of risk factors mentioned earlier that predispose to HPV transmission (WHO 2014).

Secondary prevention targets asymptomatic women aged between 30 to 49 years and involves screening and identifying pre-cancer lesions (WHO 2014). In addition, the WHO (2014) further recommends treating women in the pre-cancerous stage before the lesions progress to invasive cancer. Various methods are used to screen women for cervical cancer. For instance, the International Atomic Energy Agency (IAEA 2012) suggests the use of visual inspection with acetic acid (VIA) and visual inspection with Lugol's Iodine (VILI) in resource limited countries. Women who are VIA or VILI positive should be treated with cryotherapy. However, those with lesions suspicious for cancer should be sent for colposcopy and biopsy.

Symptoms of invasive cervical cancer are broadly divided to two categories - early and advanced - based on the severity (World Health Organization 2014). Early symptoms include: foul smelling vaginal discharge, post-menopausal bleeding, post-coital spotting or bleeding and any irregular bleeding in women of reproductive age. Advanced symptoms include backache, weight loss, lower abdominal pain, urinary frequency and urgency, swelling of lower limbs, breathlessness and vesical vaginal fistula (World Health Organization 2014).

2.2.3 Cervical cancer diagnosis and staging

According to the WHO (2006), conclusive diagnosis of cancer is by histopathological examination of tissue taken from the suspicious lesion and should be done before commencement of any therapy. Various techniques could be used to biopsy suspicious cervical lesions for example, conventional cytology, HPV DNA testing and visual inspection methods with vinegar or Lugol's solution (World Health Organization 2006).

Cervical cancer staging is based on tumour size and the metastasis to the pelvis region and distant organs (World Health Organization 2006). Various systems are available but the recommended one for cervical cancer was developed by The International Federation of Gynaecology and Obstetrics (FIGO)(World Health Organization 2006),which is presented in Table 2.1.

Table 2.1 The FIGO Staging

Stage	Description
I	Cervical carcinoma confined to the cervix.
IA	This is the earliest form of stage 1. There is very small amount of cancer that can only be seen under a microscope.
IA1	The area of invasion is less than 3mm deep and less than 7mm wide.
IA2	The area of invasion is between3mm and 5mm deep and less than 7mm wide.
IB	Clinically visible lesions limited to the cervix uteri or preclinical cancers greater than stage IA.
IB1	Clinically visible lesion less than 4.0 cm in greatest dimension.
IB2	Clinically visible lesion greater than 4.0 cm in greatest dimension.

II	Cervical carcinoma invades beyond the uterus but not to the pelvic wall or to the lower third of the vagina.
IIA	Without parametrial invasion.
IIA1	Clinically visible lesion less than4.0 cm in greatest dimension.
IIA2	Clinically visible lesion greater than 4.0 cm in greatest dimension.
IIB	With obvious parametrial invasion.
III	The tumour extends to the pelvic wall and/or involves lower third of the vagina and/or causes hydronephrosis or non-functioning kidney.
IIIA	Tumour involves lower third of the vagina with no extension to the pelvic wall.
IIIB	Extension to the pelvic wall and/or hydronephrosis or non-functioning kidney.
IV	The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum. A bullous oedema, as such, does not permit a case to be allotted to stage IV.
IVA	Spread of the growth to adjacent organs.
IVB	Spread to distant organs beyond the pelvic area.

Source: Adapted from the FIGO committee of Gynecologic Oncology

2.2.4 Treatment

Cervical cancer can be treated by means of surgery, radiotherapy which includes both external beam radiation and brachytherapy and with or without concomitant chemotherapy (IAEA 2013). The IAEA (2013), guiding the management of women with cervical cancer in resource restricted care settings, is of the opinion that every woman without metastatic disease should be treated as aggressively as can be tolerated to improve her chances of being cured. Patients with metastatic disease should receive palliative treatment and care.

Women with early cervical cancer can be treated with surgery, external beam radiation and brachytherapy, those with stage IB2 to IIA2 cervical cancer can also be treated by means of surgery, whilst those with Stage IIB to IVA and not candidates for surgery can be treated with the

standard treatment of external beam radiation, brachytherapy with or without concomitant chemotherapy. Cisplatin is commonly used as concomitant chemotherapy drug (IAEA 2013), however treatment is mainly dependent on patient factors such as the patient's medical condition, presence of other co-morbidities, age, nutritional status and the physician's judgment alongside the availability of treatment modalities (IAEA 2013).

Women treated for cervical cancer experience various side effects which could have a negative influence on their quality of life as side effects can last for months and even years after treatment. Early effects occur during radiotherapy or immediately after radiotherapy and affect tissues that are rapidly multiplying, for example the mucosa, bone marrow, gastrointestinal tract and skin, and soon heal after completion of radiotherapy. Sub-acute effects occur in a few weeks to months after radiotherapy, while the late effects occur months to years after radiotherapy and affect tissues that are slow proliferating, for example the tissue of the kidneys (Joanne 2015).

2.3.5 The prognosis for women diagnosed with cervical cancer

The prognosis for women diagnosed with cervical cancer depends on the stage at which diagnosis is made (Sankaranarayanan et al. 2010). Sankaranarayanan et al. (2010) observed that the survival of women with cervical cancer was influenced mainly by the availability, accessibility and development of health care services to enable early detection and treatment. Countries such as Hong Kong and Singapore have well established screening, diagnosis and treatment programmes and therefore a higher five year survival rate (63% to 79%)compared to less developed countries in sub-Sahara Africa, such as Uganda which has a less than 13% five year survival rate (Sankaranarayanan et al. 2010). A five year survival with ideal treatment is estimated highest at 98% for stage IA and lowest >5% for stage IVB (World Health Organization 2006).

Other prognostic indicators are the patient's performance status, FIGO stage and lymph node status (Kosary 1994; Xiao et al. 2015). Pre-treatment anaemia and nutritional status were prognostic indicators observed by Xiao et al. (2015).

2.3 QUALITY OF LIFE

Quality of life is a multidimensional concept (Goker et al. 2011; Du Toit 2013; Maree & Jansen Van Rensburg 2015) and there is no common definition or standard of measurement (Ferrans

1990). The multi-dimensional aspect of quality of life, according to Cella (1994), refers to the broad coverage of content which includes physical, functional, emotional and social wellbeing. Ferrans (1990) views the multidimensionality of quality of life as the ability to lead a normal life, happiness and satisfaction, achievement of personal goals, social utility and natural capacity. Maree and Cella (1994) both agree on the concept of quality of life being subjective. Subjectivity refers to the fact that quality of life judgement can only be made by the individual (Maree & Jansen Van Rensburg 2015), furthermore patients in the same situation and stage of illness can rate their quality of life differently, being good or poor.

The World Health Organization defines quality of life as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (Vaz et al. 2007). Culture has a set of beliefs, values and practices which are unique to each group. In addition, culture is an important determinant of quality of life as it expresses the purpose and meaning of life in sickness and in health (Kagawa-Singer et al. 2010)

Kagawa-Singer et al. (2010) had an example of Japanese–Americans who had the view that side effects of treatment, as expected outcomes, were to be endured to maintain family harmony, while Anglo-Americans perceived it as a problem to be overcome. However, Zeng et al. (2010) observed that cultural differences among cancer survivors has led to different interpretations of the concept of quality of life.

Quality of life has become an important consideration in evaluating the effectiveness of healthcare and particularly significant in the field of cancer care, where treatments are often incapacitating butat the same time long-term survival is increasing (Pilkington & Mitchell 2004). Goker et al. (2011) indicates that cancer itself causes co-morbid symptoms and treatment strategies are also debilitating by decreasing cardio-respiratory capacity, pain, fatigue and suppressing immune function, thus all aspects of life are affected negatively.

Cancer can dramatically change a person's life, in particular, gynaecologic cancer and its treatment which are thought to affect women's experience of themselves as sexual beings

(Pilkington & Mitchell 2004). Women treated for cervical cancer reported physical, emotional, role domains and financial difficulties at different stages of treatment (Pasek et al. 2013). Ancuta et al. (2012) note that women with cervical cancer experience physical, psychological and sex-related problems as the consequences of both the disease and treatment and this affects their quality of life.

2.4 DOMAINS OF QUALITY OF LIFE

The domains of quality of life also seem to be a complex issue. For instance, Kuyken and group (1995), in the World Health Organization quality of life assessment (WHOQOL), identified six domains which form the quality of life namely: physical domain, psychological domain, level of dependence, social relationships, environment and spiritual beliefs. Pearman (2003) and Cella (1994), in contrast, referred to only four domains namely: physical, functional, emotional and social domains. Maree and Jansen Van Rensburg (2015) also identified four domains: health and physical functioning, psychological/spiritual, social and economic and family. In contrast, Ashing-Giwa (2005) identified two levels of paradigms: individual and systemic, with each consisting of four domains. The individual level consists of general health, medical factors, health efficacy and psychological well-being domains; the systemic level is composed of: social-economic, cultural, and demographic and health system domains.

2.4.1 The physical domain

The physical domain refers to perceived and observed physiological changes which patients experience and represents a combination of disease symptoms, treatment-related side effects and general physical wellbeing, as perceived by the patient Women living with cervical cancer experience various disease and treatment related symptoms, not only during treatment but also after completion of treatment. Examples of such symptoms include pain, nausea and fatigue (Vaz et al. 2011). Pain is subjective and can either be acute, lasting less than three months or chronic, lasting more than three months (Joanne 2015).

Fatigue, described by The National Comprehensive Cancer Network (NCCN 2015) as "a distressing persistent, subjective sense of physical, emotional and/or cognitive tiredness or exhaustion related to cervical cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning," may be caused by poor nutrition, pain, anaemia, stress,

depression and some drugs such as chemotherapy. Physical exhaustion, fatigue and a general feeling of tiredness and weakness are some of the symptoms experienced by women while undergoing treatment for cervical cancer (Pasek et al. 2012; Klee et al. 2000).

Klee et al. (2000) and Kumar et al. (2014) observed that some women who were treated for cervical cancer while undergoing radiotherapy experienced nausea, vomiting, diarrhoea and loss of appetite; however, diarrhoea may persist for up to twelve months after treatment. Maher & Denton (2008) noted that the main source of anguish for the women treated for cervical cancer was diarrhoea and faecal urgency, or incontinence, as it causes discomfort in public places and they have to remain confined to the house feeling socially isolated. In addition, constipation was reported at some point while undergoing treatment and during follow up ((Pasek et al. 2013). Radiotherapy-induced proctitis, bloating, flatulence, enteritis and proctopathy have also been reported by women treated for cervical cancer (Kuku et al. 2013), whilst some experienced rectal bleeding resulting from ulceration, easily damaged blood vessels or stenosis in the bowel (Kuku et al. 2013; Pfaendler et al. 2015).

The urinary system is also affected and the women treated for cervical cancer experienced urine incontinence, radiology-induced cystitis, haematuria, urinary frequency and dysuria (Klee et al. 2000;Maher & Denton 2008; Pfaendler et al. 2015).

Damage to the lymphatic vessels can be caused by either the disease obstructing the lymphatic system or alteration of the connective tissues by radiotherapy, leading to retention of lymphatic fluid causing lymphedema of the lower extremities. Women living with lymphedema present with swelling of the feet, leg heaviness and discomfort, skin texture changes and feel tight and tingling sensations in the legs limiting their ability to perform daily tasks or work thus affecting negatively the quality of life (Pfaendler et al. 2015).

Sexual health is an important determinant in the quality of life in women, yet up to 65% of women treated with radiotherapy experience one or more sexual problems (Maher & Denton 2008). In addition, women experience physical side effects, such as lack of lubrication and decreased sexual interest, and menopausal symptoms such as hot flushes (Maher et al. 2008; Barnaś et al. 2012; Kumar et al. 2014). Vaginal stenosis (shortening of the vagina), which develops between

three to six months after treatment, leads to dyspareunia which leads to other problems such as inelastic vaginal tissue and tendency to experience pain and bleeding during sexual intercourse (Greime et al. 2008; Ancuța et al. 2012). All these changes compound and cause the women to have reduced desire for sex, arousal and orgasm (Barnaś et al. 2012).

2.4.2 The Psychological and Socioeconomic Domains

Psychosocial domain includes the need to be cherished, to have friends, to be treated with dignity and respect and role fulfilment (Maree & Jansen Van Rensburg 2015). In addition, the economic domain consists of the ability to provide for basic commodities and food (Maree & Jansen Van Rensburg 2015).

Raoof et al. (2015) observed that emotional domain was least affected and could be related to the unity of people, which is characterised by intimate and close relationships between family members, friends and neighbours; most of them are living amongst extended families. Social support includes the presence of a strong family network and community support system which provides positive social and emotional support to women treated for cervical cancer Adequate social support has led to improved quality of life, whereas a lack of social support has led to poor quality of life and a higher death rate (Ashing-Giwa 2005).

Ashing-Giwa (2005) describes the socioeconomic status as level of education, income and employment status. Ashing-Giwa (2005) further goes on to observe that socioeconomic status is closely linked to the quality of health and an identifiable risk to poor quality of life. Financial problems are a challenge faced by most women in Africa and the cost of treatment compounds the existing poor economic status. Inability to perform exhausting activities while undergoing treatment and during convalescence, or resuming work for those who were employed, increased the financial burden affecting the quality of life negatively Upon diagnosis of cervical cancer, women may experience depression and the possible outcomes and possibly loss of life. Klee et al. (200b) observed that depression and anxiety scores were high initially, at the time of diagnosis, but decrease over time as the women living with cervical cancer went through psychological adaptation to cope with the effects on everyday life.

Pasek et al. (2012), Klee et al. (2000b) and Maher & Denton (2008) all agreed that correct information and communication enables women to have better coping abilities toward the disease. Maher & Denton (2008) write out the and further acknowledge the importance of psychosocial interventions aimed at improving the psychosocial functioning, for example relaxation techniques and counselling sessions by a member of the health care team.

2.5 MEASURING QUALITY OF LIFE

Measuring quality of life is a standardised way of describing the effect of disease and its treatment and is based on the patient's own rating of simple questions. In addition, Klee et al. (2000) provides an overview of how and to what degree a disease and its treatment affect the lives of the patients. Besides the evaluation of the treatment toxicities, quality of life reflects the patients' perspective (Klee et al. 2000). Pearman (2003) observed that until recently, treatment for gynaecologic cancers has focused almost entirely on prolongation of life and few research studies have sufficiently addressed issues related to quality of life.

Kaasa and Loge (2003) divide quality of life assessment instruments into three categories: generic instruments, disease-specific instruments and domain-specific instrument. Generic instruments are not specific to any population or disease and are therefore applicable to patients living with more than one condition. In addition, generic instruments allow for comparisons across populations and conditions (Maree & Jansen Van Rensburg 2015). The disease-specific instruments are developed for specific groups of patients, for instance, the European Organization for Research and Treatment of Cancer (EORTC-QLQ-C30) was developed for cancer in general, whilst the EORTC Quality of Life questionnaire (EORTC QLQ-CX24),cervix cancer site-specific instrument, was developed for patients with cervical cancer (Zeng et al. 2010). Domain-specific instruments assess the specific domain that comprise overall quality of life, for example pain, anxiety, fatigue and psychological distress.

The most widely used cancer-specific instruments are the EORTC QLQ-C30 and FACT-G (Functional Assessment of Cancer Therapy-general). The EORTC QLQ-C30 consist of 30 items and includes five functional domain scales namely: physical, role, cognitive, emotional and social functions along with disease specific symptoms, dyspnoea, loss of appetite, insomnia, constipation and diarrhoea and perceived financial implications of the disease (Aaronson et al.

1993). The FACT-G is composed of 27 items and covers primarily four domains: physical, emotional, social and functional wellbeing (Zeng et al. 2010).

2.6 SUMMARY

In summary, cervical cancer has been presented as a major health problem affecting women worldwide. Quality of life is subjective and multidimensional. The quality of life has in the past not received much attention (Pearman 2003) and yet cervical cancer affects all domains (psychological, functional, social, sexual, physical and financial) of women's life.

The next chapter will describe the research methods.

CHAPTER 3

RESEARCH DESIGN AND METHODS

3.0 INTRODUCTION

The previous chapter presented cervical cancer as a major health problem and described quality of life. In this chapter the research design and methods will be discussed.

3.1 RESEARCH DESIGN

This was an exploratory and cross-sectional study. A cross sectional study is a design which seeks to examine the respondents at various stages of development simultaneously; exploratory design is conducted when little is known about the topic of interest in a given population (Burns & Grove 2011). This is applicable to the study as the researcher examined the respondents on treatment, at six months and twelve months after treatment with radiotherapy simultaneously

3.1.1 Study Setting

Burns and Grove (2011) described a setting as the location in which a study was conducted. It paints a picture and gives clarity of where and how the study was conducted. The study setting was an academic hospital which serves as a referral centre for many hospitals in Gauteng Province.

The academic hospital had a bed capacity of 1,088 beds, more than 4,000 professional and support staff and serves as a referral hospital to a number of hospitals in its referral chain in the Gauteng Province. The hospital has twelve clinical departments, one of which is radiation therapy. The radiation therapy department offers outpatient services to stable patients, whilst those who are very ill and require continuous monitoring are admitted to the inpatient wards. The radiation therapy department has several clinics for all cancers that are operational on assigned days of the week to provide holistic care to cancer patients.

The research study was carried out at the gynaecology clinic which offers specialised care to women with cervical cancer at different stages for the entire course of treatment with radiotherapy.

The gynaecology clinic is operational five days a week and the patients on radiotherapy treatment are seen by the oncologists on weekly basis until they complete their treatment. Upon completion of the radiotherapy, the women are booked for appointments every three months for the first two years, then every six months for another two years, then once yearly for five years. It is approximated that 662 to 721 women are treated annually (Msadabwe 2009) at the gynaecology clinic. The International Atomic Energy Agency has identified the department as a resource centre for training.

3.2 RESEARCH METHOD

Burns and Grove (2011) describe the research method as the operational approach of the study which includes the sample and sampling techniques, population, setting, methods of data gathering and analysis.

3.2.1 Population and sampling

The population is referred to as the individuals who meet the criteria the researcher is interested in studying (Brink et al. 2013).In this study, the population were all women diagnosed with cervical cancer and were either on treatment or have completed treatment six or twelve months prior to the investigation at the radiation department of the specific academic hospital.

Convenience sampling was used to select a sample of 153 respondents meeting the following inclusion criteria:

- The patient diagnosed with cervical cancer and undergoing treatment with radiotherapy with or without chemotherapy, alternatively six or twelve months post treatment.
- Older than eighteen years.
- Willing to participate.

According to Burns and Grove (2011), convenience sampling refers to the use of respondents who happen to be in a given place at a particular time and can provide a desired sample size. In addition, convenience sampling is commonly used in health related studies. The sampling technique was appropriate for the study as the respondents were all at the radiation therapy department at the time of the study. The sample size was calculated using finite population correction.

no= initial sample=157

N= Target population =7,735

$$n= \frac{no}{\left\{1+\left[\frac{no-1}{N}\right]\right\}}$$

$$n= \frac{157}{\left\{1+\left[\frac{157-1}{7735}\right]\right\}}$$

n=153

The total sample was determined as 153 (n=153) to achieve a confidence level of 95%. The total sample consisted of three samples of 51(n=51) : one sample for during treatment, another at six months and at twelve months post treatment.

The respondents, those waiting for treatment and those on follow up waiting to see the oncologist, were recruited whilst in the waiting bays. All women were invited indiscriminately and the consenting ones were given the information sheet to read then the consent form to sign once they had understood the research study. A total of 189 women were recruited, but 23 were found not to be within the study criteria, on treatment, at six months or twelve months, whilst 13 were excluded due to language barriers.

3.2.2 Data Gathering

Data gathering is defined by Burns and Grove (2011) as the precise, systematic collection of information that is relevant for the specific research objectives in the study. Structured interviews were used to collect data. This involves the use of a structured instrument and all respondents are asked the same questions in the same order (Polit and Beck 2012). The researcher built rapport and provided privacy during the structure interviews in order to enhance genuineness in respondents' responses to the interview questions. The researcher also informed the respondents that there are no write or right answers. The researcher, a female registered nurse, administered the instruments, the devices the researcher uses to gather the relevant data (Brink et al. 2013), during a structured interview in a quiet and private room, in English.

Two instruments were used to gather data: EORTC QLQ-C30 (version 3) and EORTC QLQ CX24. Permission was sought to use the instruments (Annexure C). The EORTC QLQ-C30 (version 3) assesses quality of life in all cancer patients, while EORTC QLQ CX24 is specific to cervical cancer. Both instruments have been used widely in studies pertaining to cervical cancer thus allowing for comparison of findings.

The EORTC QLQ-C30 instrument uses two Likert scales: 4 point and 7 point. The first part consists of 28 questions measuring the functional and symptom domain and has a 4 point Likert scale, where 1 indicates not at all, 2 a little, 3 quite a bit and 4 very much. Questions 29 and 30 have a 7 point Likert scale to assess the overall quality of life with 1 indicating very poor and 7 being excellent.

All the scales and single-items measure range in score from 0 to 100. A high score represents a corresponding functional, global health status or symptomatology. Thus a **high score for a functional scale** represents a *high / healthy level of functioning*; a **high score for the global health status / QoL** represents a *high QoL*, but a **high score for a symptom scale / item** represents a *high level of symptomatology / problems*

The EORTC QLQ-C30 is divided into three parts namely: functional, symptomatic and global health status. The functional domain is further divided into five parts: (1) Physical domain which is assessed in questions1 to 5, (2) Role functioning domain in questions 6 and 7 (3), Emotional functioning in questions 21 to 24 (4), Cognitive functioning are questions 20 and 25 and (5) Social functioning are questions 26 and 27.

Symptom domain scores are divided into nine parts: (1) Fatigue is assessed using questions 10, 12 and 18. (2) Nausea and vomiting are questions 14 and 15, (3) Pain are questions 9 and 19, (4) Dyspnoea question8, (5) Insomnia is question 11, (6) Appetite loss is question 13, (7) Constipation is question 16, (8) Diarrhoea is question 17 and (9) Financial difficulties is questions 28. Overall global health status is assessed using questions 29 and 30.

The EORTC QLQ-CX24 instrument has a 4 point Likert scale where 1 indicates not at all, 2 a little, 3 quite a bit and 4 very much. The EORTC QLQ-CX24 is divided into two parts namely: functional domain and symptom domain. Functional domain are further divided into four sub sections (1) Body image represented by variables -questions 45 to 47, (2) Sexual activity is question 49, (3) Sexual enjoyment is question 54 and (4) Sexual/vaginal functioning are questions 50 to 53. Symptom scores is divided to five sub sections (1) Symptom experience represented by questions 31 to 37, 39 and 41 to 43, (2) Lymphedema is question 38, (3) Peripheral neuropathy is question 40, (4) Menopausal symptoms is question 44 and (5) Sexual worry is question 48.

The respondent's demographic information on the stage of the cervical cancer was extracted from the clinical records by the researcher. The age, employment status and marital status were provided by the respondent to the researcher. The demographic information was recorded on the information sheet attached (Appendix D).

Dependent variable is described as the outcome the researcher wants to predict, while the independent variable is the activity that is varied by the researcher to create an effect on the dependent variable (Burns & Grove 2011). The dependent variables were the scores of the two instruments used (EORTC QLQ-C30 (version 3) and EORTC QLQ CX24). The variables include, physical functioning, role functioning, emotional functioning, social functioning, cognitive functioning and overall quality of life. The independent variables were, age, marital status, employment status and the stage of disease at the time of diagnosis.

3.2.3 The planning for the data gathering

Plan for data gathering began by first getting approval of the study topic by the Faculty of Health Science. Permission from The European Organization for Research and Treatment of Cancer Quality of Life Group was sought to use the instruments for data gathering. The research protocol was peer reviewed and consequently approved by the Human Research Ethics Committee (Medical) of the Faculty of \health Sciences, University of Witwatersrand. Permission from the Chief Executive Officer of the academic hospital was sought to allow the research study to be conducted in her facility.

The women who met the inclusion criteria were invited to participate in the study by explaining to them the process involved in data gathering and that they had the right to refuse to participate or to withdraw at any point of the study without losing their entitled benefits. Consenting respondents signed the information sheet and the consent form and the researcher signed as the witness.

3.3 DATA ANALYSIS

Burns and Grove (2007) define data analysis as the technique of reducing, organising and giving meaning to data. Data that was captured on an Excel spreadsheet was imported to an SPSS IBM 22.0 computer programme for analysis. According Polit & Beck (2012), descriptive statistics are used to describe and synthesise data. Descriptive statistical analysis was used to analyse socio-demographic variables and presented using measures of central tendency: mean, mode, median and in tables and the Kruskal-Wallis test to compare the mean responses of the different study groups. Data was analysed under the supervision of a statistician.

The scoring tool for both instruments was provided by the European Organization for Research and Training on Cancer Quality of Life Group and was divided into three parts: global health status, functional scales and symptomatic scale. The raw scores are standardised to linear transformation grades which range from 0 to 100. The higher the functional scores reported indicated a better functioning status. In contrast, a higher score reported on the symptom score indicated more problems affecting quality of life. The higher the scores in the overall global health status indicated a better quality of life.

3.4 VALIDITY AND RELIABILITY

According to Polit and Beck (2012), instrument validity seeks to ascertain whether it accurately measures what it is supposed to measure. The instruments used in the study were validated in Europe between 2003 and 2005, using 346 women in nine countries by the European Organization for Research and Treatment of Cancer Quality of Life Group (Aaronson et al. 1993). The QLQ C-24 validation and translation was carried out at the Unit of Gynaecology and Oncology at Tygerberg Hospital using cervical cancer patients and is available in isiXhosa and Afrikaans (Du Toit & Nel 2012).

Reliability is the degree of consistency and dependability with which an instrument measures the variables it is designed to measured (Polit & Beck 2012). In this study the same instruments were used on all patients to ensure consistency of the instrument.

3.5 ETHICAL CONSIDERATIONS

Burns and Grove (2011) explain that ethics consist respect for people, beneficence and justice. In order to protect and respect the rights of the respondents who consented to take part in the study the following steps were taken:

- The research proposal was presented to the Department of Nursing Education for peer review.
- The research proposal was submitted to the School of Therapeutic Sciences Postgraduate Committee for permission to conduct the study.
- The proposal was submitted to the Human Research Ethics Committee (Medical), of the University of the Witwatersrand, for ethics approval (Ethics Clearance Certificate Number M150441).
- The Chief Executive Officer (CEO) of the academic hospital in which the study was conducted (Annexure E) approved the study.
- Respondents who agreed to participate in the study were given detailed information on the study were given a chance to ask questions and to seek clarifications. Respondents were assured that their participation was voluntary and they could withdraw from the study at any point with no penalty.
- Respondents were required to sign an informed consent form (Annexure G) individually prior to participating in the study.
- Confidentiality and anonymity of respondents was promoted by the use of respondent's codes during data collection

3.6 SUMMARY

In conclusion, this chapter has sought to explain the research design and method used, the population and sampling criteria and data gathering and data analysis. Issues of ethical

considerations and validity and reliability were covered in this chapter. The results of the study will be presented in Chapter 4.

CHAPTER FOUR

RESULTS OF THE STUDY

4.0 INTRODUCTION

The previous chapter presented the research design and method used in the study; this chapter will present the findings of the study.

4.1 DEMOGRAPHIC DATA

The ages of the sample (n=153) ranged from 30 to 79 years, with a mean age of 50.6 years SD ±11.9. Nearly half the sample 46.4%; (n=71) were single and unemployed (48.4%; n=74) and 26.1% (n=40) suffered from stage IIIA disease. The demographic information is presented in Table 4.1; m0 refers to during treatment, m6 to 6 months after treatment and m12 to 12 months after treatment.

Table 4.1 Demographic characteristics of the respondents (n=153)

Variables	M0 **n=51**		M6 **n=51**		M12 **n=51**		**Total**	
	N	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Age groups (years)								
30 to 39	11	21.6	12	23.5	12	23.5	35	22.9
40 to 49	17	33.3	16	31.4	16	31.4	49	32.0
50 to 59	8	15.7	8	15.7	11	21.6	27	17.6
60 to 69	12	23.5	15	29.4	8	15.7	35	22.9
70 to 79	3	5.9	0	0	4	7.8	7	4.6
Marital status								
Single	21	41.2	25	49.0	25	49.0	71	46.4
Married	16	31.2	14	27.5	18	35.3	48	31.4
Divorced	5	9.8	4	7.8	4	7.8	13	8.5
Widowed	9	17.6	8	15.7	4	7.8	21	13.7
Employment status								

Unemployed	23	45.1	25	49.0	26	51.0	74	48.4
Part-time employed	5	9.8	7	13.7	5	9.8	17	11.1
Full-time employed	14	27.5	11	21.6	11	21.6	36	23.5
Pensioners	9	17.5	8	15.7	9	17.6	26	17.0
Stage of the cancer								
IA	2	3.9	1	2.0	0	0	3	2.0
IB	3	5.9	1	2.0	1	2.0	5	3.2
IIA	12	23.5	6	11.7	11	21.6	29	19.0
IIB	14	27.5	16	31.4	9	17.6	39	25.5
IIIA	8	15.7	15	29.4	17	33.3	40	26.1
IIIB	11	21.5	12	23.5	13	25.5	36	23.5
IVA	1	2.0	0	0	0	0	1	0.7

A Kruskal-Wallis H test showed a statistical significance between age and employment status (χ^2 (2) = 46.9, p=0.000), but stage of the disease and employment status had no statistical significance. Age and marital status had a statistical significance, (χ^2 (2) = 23.3, p=0.000), but there was no statistical significance between stage of disease and marital status.

4.2 GLOBAL HEALTH STATUS, OVERALL HEALTH AND OVERALL QUALITY OF LIFE

When calculating the average global health status, overall health and overall quality of life, the latter had the highest overall mean score (maximum score 100) (*m=70.5).* The average global health status improved as the months after treatment increased. Similarly, overall health and quality of life increased with the lowest mean scores found at m0, improvement at m6 and reaching the highest level at m12. A Kruskal-Wallis H test showed a statistically significant difference in all three variables amongst the groups (Table 4.2), whilst no statistically significant differences were found between the three groups (m0, m6 and m12) and age, marital status, employment status and stage of the disease.

Table 4.2 Global health status, overall health and overall quality of life during treatment (m0) and six (m6) and 12 months after treatment (m12).

Variables	Mean Ranks			Overall Mean	SD	*p*
	m0 n=51	m6 n=51	m12 n=51			
Global health status	55.1	77.8	98.2	69.9	26.3	0.000*
Overall health	57.2	77.8	96.1	69.3	26.7	0.000*
Overall quality of life	55.6	77.8	97.6	70.5	27.5	0.000*

key =*statistically significant, *p≤0.05*

4.3 FUNCTIONING SCORES

Physical, role, emotional, social and cognitive functioning was explored. Role functioning scored the highest overall mean (*m*= 82.0) and social functioning the lowest (*m*=60.4). Physical functioning scored the lowest during treatment at m0 (*m*=65.8), with social functioning scoring the lowest overall mean in m6 (*m*=79.6) and cognitive functioning in m12 (*m*=60.4). The mean ranks of all five functioning scales improved from m0 to m6. However, there was a decline in means of all the functioning scales from m6 to m12 with the exception of emotional functioning. Despite this decrease, functioning improved from m0 to m12 in all the domains. None of the functional scores showed a statistically significant difference amongst the three groups (Table 4.4).

Table 4.3 Functional scores during treatment (m0) and 6 (m6) and 12 (m12) months after treatment (n=153).

Variables	Mean Ranks			Overall Mean	SD	*p*
Functioning scales	m0 n=51	m6 n=51	m12 n=51			
Role functioning	67.7	81.2	81.1	82.0	22.2	0.146
Physical functioning	65.8	85.2	80.0	81.8	17.7	0.068
Cognitive functioning	76.7	83.5	70.8	80.9	21.1	0.312
Emotional functioning	69.2	80.2	81.6	80.7	22.9	0.289
Social functioning	74.3	79.6	77.0	60.4	32.9	0.829

key = *statistically significant, *p≤0.05*

Kruskal-Wallis H tests showed a statistically significant difference between age and physical functioning (χ^2 (2) =3.1, *p*=0.858), marital status and physical functioning (χ^2 (2) = 1.7, *p*=0.635) and stage of disease and social functioning (χ^2 (2) = 2.3, *p*=0.516).

4.4 GENERAL SYMPTOMS

When exploring the general symptoms of the respondents, financial difficulties scored the highest overall mean (*m*=99.2) and dyspnoea the lowest overall (*m*=10.5). Fatigue had the highest mean score at m0 (*m*=99.2), pain the highest at m6 (*m*=78.3) and swelling of the feet at m12 (*m*=78.3). The mean ranks of fatigue, pain, insomnia, dyspnoea and financial difficulties decreased from m0 to m12, but swelling of the feet and tingling of the hands increased from m0 to m12. Statistical significance was found between the three groups (m0, m6 and m12) and various symptoms (Table 4.4).

Table 4.4 General symptoms reported by the respondents on treatment (m0) and at six months (m6) and twelve months (m12) after treatment (n=153).

Variables	**Mean Ranks**			**Overall Mean**	**SD**	***P***
	m0 n=51	**m6 n=51**	**m12 n=51**			
Fatigue	99.2	72.9	58.9	30.0	26.6	0.000*
Pain	84.4	78.3	63.3	31.5	30.7	0.168
Insomnia	92.7	73.3	65.1	33.6	39.8	0.002
Dyspnoea	88.5	76.0	66.5	10.5	21.8	0.003*
Swelling of feet	61.4	67.6	101.9	16.6	26.2	0.000*
Tingling of hands or feet	72.4	77.3	81.3	28.3	25.9	0.545
Financial difficulties	95.2	63.9	71.9	65.1	39.4	0.000*

key = * statistically significant, *p≤0.05*

When comparing age and stage of the disease with each of the symptoms, the Kruskal-Wallis H test revealed no statistically significant differences with the general symptoms.

4. 5 PHYSICAL SYMPTOMS

Physical symptoms consisted of gastro-intestinal symptoms, urologic and gynaecologic symptoms. The variables assessing gastrointestinal symptoms were: appetite loss, diarrhoea, constipation, nausea and vomiting. Diarrhoea had the highest overall mean (*n*=22.6) and nausea and vomiting the lowest (*n*=10.2). During treatment (m0) appetite loss scored the highest mean (*n*=106.2), diarrhoea at m6 (*n*=79.4) and constipation at m12 (*n*=79.2). As indicated in Table 4.3 there was a statistically significant difference between the groups (m0, m6 and m12) and diarrhoea, appetite loss and nausea and vomiting.

Table 4.5 Physical symptoms reported by the respondents on treatment (m0) and at six months (m6) and twelve months (m12) after treatment (n=153).

Variables	**Mean Ranks**			**Overall Mean**	**SD**	***P***
	m0 n=51	**m6 n=51**	**m12 n=51**			
Diarrhoea	94.4	79.4	57.3	22.6	31.7	0.000*
Appetite loss	106.2	60.7	64.0	20.0	29.5	0.000*
Constipation	83.3	68.6	79.2	14.4	28.3	0.077
Nausea and vomiting	102.8	65.8	62.4	10.2	24.8	0.000*

key = * statistically significant, *p≤0.05*

When comparing age and stage of the disease with each of the physical symptoms, the Kruskal-Wallis H test revealed no statistically significant differences between physical symptoms, age and stage of the disease.

Variables assessing urological symptoms were urine frequency, burning sensation when urinating, urine leakage and difficulty emptying the bladder. Urological symptoms persisted across

the study groups but presented the highest on treatment (*m*=90.3), reduced at six months (*m*=63.5), then increased at twelve months *(m*=77.2).

Table 4.6 Urological symptoms reported by the respondents on treatment (m0) and at six months (m6) and twelve months (m12) after treatment (n=153).

Variables	**Mean Ranks**			**Overall Mean**	**SD**	***P***
	m0 n=51	**m6 n=51**	**m12 n=51**			
Urological symptoms	90.3	63.5	77.2	23.3	18.8	0.008
Urine frequency	86.2	60.1	83.8	44.9	34.3	0.004
Burning sensation when urinating	98.3	69.1	67.7	30.5	33.8	0.000*
Urine leakage	76.2	74.4	80.4	10.5	22.4	0.625
Difficulty emptying the bladder	80.2	74.1	76.1	7.2	19.1	0.552

key = * statistically significant, *p≤0.05*

Kruskal-Wallis H tests showed no statistical significant between age, stage of the disease and all the urological symptoms.

Vaginal soreness was reported to have the highest means during treatment but reduced across the study groups; the m0 mean was (*m*=98.5), the m6 (*m*=75.0) and the m12 *(m*=57.5). These means were statistically significant (*p* = 0.000).

4.6 GYNAECOLOGIC SYMPTOMS

Variables for assessing gynaecological symptoms were hot flushes, vaginal discharge and vaginal bleeding. The respondents on treatment reported the highest gynaecological symptoms with a mean (*m*=106.1) and marked improvement at m6 (*m*=68.5) and m12 (*m*=55.9) as illustrated in Table 4.7.

Vaginal discharge was most severe during treatment (*m*=94.3) followed by a marked reduction in mean scores at six months (*m*=69.1) and at twelve months (*m*=67.7). Vaginal bleeding had the highest reported scores in respondents on treatment (*m*=91.3), followed by a marked decrease at six months (*m*=68.7) then a slight increase at twelve months (*m*=71.0). Menopausal symptoms, having hot flushes and/or night sweats, did not have any statistical significance across the study groups.

Table 4.7 Gynaecological symptoms of respondents on treatment (m0), at six months (m6) and twelve months (m12) after radiotherapy (n=153)

Variables	**Mean Ranks**			**Overall Mean**	**SD**	***P***
	m0 n=51	**m6 n=51**	**m12 n=51**			
Menopausal symptoms (hot flushes and/or night sweats)	86.1	72.7	72.2	24.2	27.6	0.151
Vaginal Discharge	94.3	69.1	67.7		26.2	0.194
Virginal Bleeding	91.3	68.7	71.0		30.7	0.256

4.7 SEXUAL SYMPTOMS

Slightly more than one third of the respondents (37.3%: n=57) indicated they were sexually active. Only 1.3% (n=2) of the respondents indicated they were sexually active during treatment, whilst 16.3%; (n=25) were sexually active at six months and 19.6%; (n=30) at twelve months post radiotherapy. Respondents on treatment had the lowest mean scores in sexual enjoyment as reported by the mean (*m*=56.1) but mean increased to (*m*=85.3) at six months and (*m*=91.9) at twelve months post radiotherapy. Respondents reported the lowest "sexual worry" mean scores at the time of treatment (*m*=66.5) and had marked increase at six months (*m*=83.8) and a slight drop at twelve months (*m*= 80.8). However, the results were not statistically significant. Sexual activity and enjoyment had significant influence on the quality of life with $p = 0.000$ as shown in Table 4.8

Table 4.8 Sexual symptoms of respondents on treatment (m0), at six months (m6) and twelve months (m12) after radiotherapy (n=57).

Variables	Mean Ranks			Overall Mean	SD	sig*
	m0 n=2**	m6 n=25**	m12 n=30**			
Sexual activity	53.7	85.3	91.9	23.1	35.5	0.000*
Sexual enjoyment	56.1	86.6	88.3	22.0	35.9	0.000*
Vaginal functioning	52.9	87.6	90.4	14.1	22.8	0.000*

key = * statistically significant =** n=2, n=25, n=30 sample size varied because only those who were sexually active gave responses for sexually related question.

4.8 SEXUAL FUNCTIONING

When investigating the factors which influenced sexual activity (Table 4.9), it was found that vaginal dryness during sexual activity, the vagina feeling short, tight and painful during sexual intercourse was statistically significant. Worry that sex would be painful influenced sexual activity at six months and twelve months, but did not influence those on treatment. Vaginal soreness did not influence sexual activity across the study groups.

Table 4.9 Factors influencing sexual functioning on treatment (m0), six months (m6) and twelve months (m12) post radiotherapy (n=57).

Variables	**m0**		**m6**		**m12**	
	p value	**Df**	**p value**	**Df**	**p value**	**Df**
Vaginal soreness	0.335	6	0.857	9	0.731	9
Sexual worry	0.260	6	0.002	9	0.002	9
Dry vagina	-	-	0.000*	9	0.000*	9
Short vagina	0.000*	2	0.000*	6	0.000*	6
Tight vagina	0.000*	2	0.000*	9	0.000*	9
Dyspareunia	0.000*	4	0.000*	9	0.000*	9
Sexual enjoyment	0.000*	2	0.000*	9	0.000*	9

key = * statistically significant

The stage of the disease was significant in terms of the social functioning on the group at twelve months (p=0.003) and marital status was statistically significant (p=0.001) in terms of the physical functioning in the at six and twelve months post radiotherapy.

4.9 SUMMARY

This chapter provides the findings of the study. The next chapter will discuss the findings and recommendations and present the conclusion.

CHAPTER 5

DISCUSSION AND CONCLUSION

5.0 INTRODUCTION

This chapter discusses the findings of the study, justifies the study, considers the limitations and recommendations and presents the conclusion.

5.1 DISCUSSION

The study provided evidence that most of the respondents were between the ages of 40 and 49, with a median age of 50.57. The ages of the respondents were relatively similar to the ages of patients reported in other studies. Bjelic-Radisic et al. (2012), in a study conducted in 14 countries including Australia, Denmark and Germany, found the median age of their sample was 49.7, whilst Klee et al. (2000), in a study conducted in Singapore, reported a mean age of 49.3 and Barnas et al. (2012), in a Polish study, a mean age of 52.89.

Nearly half the women in the current study (49.9%) presented with advanced disease a finding supported by Denny (2012). In addition, considering the ages, stage of disease and the one year survival rates of women in the current study, it comes as no surprise that the WHO (2006 states most women who die from cervical cancer are in the prime of their lives, raising children, caring for their families and contributing to the economy of their communities.

It was positive to find that the global health status, overall health and overall quality of life improved significantly during the 12 months after treatment. Pasek et al. (2013), in a study conducted in Poland focusing on hospitalised women living with cervical cancer and treated with radiotherapy, reported quality of life of the women to be good regardless of the existence of radiotherapy side effects. However, physical functioning was the lowest during treatment – which might not be strange as patients suffered from acute side effects and cancer related pain. Vaz et al. (2011) agreed that pain had a major negative influence on physical functioning. After completion of treatment with radiotherapy, acute side effects resolve leading to improvement of cancer related symptoms and support care offered to the respondents lead to an increase in physical symptoms

and Vaz et al. (2011) alludes to this. Role functioning improved at month 6 and was almost the same as at month 12. This could be linked to a decrease in physical symptoms, such as pain and reduction of cancer related symptoms in response to treatment, allowing women to resume activities of daily living although not to normality. Vaz et al. (2011) supports this finding and attributes an improvement in performance status to this phenomenon.

The results of this study showed that respondents on treatment were less emotionally distressed compared to those at six months, which contrasted with the findings of Klee et al. (2000), whilst Pasek et al. (2012) had similar findings of depreciated emotional functioning at six months post radiation treatment. The decrease in emotional functioning could be linked to the respondents' inability to resume normal functioning as per their pre-disease state and this affected their quality of life negatively.

Social functioning findings in this study illustrated that respondents on treatment experienced the highest negative impact due to cervical cancer. The physical symptoms, such as urine incontinence, nausea and vomiting and fatigue, prevented the respondents from participating in social activities such as attending social functions, findings that both Pasek et al. (2013) and Klee et al. (2000) agree with. At six months and twelve months post radiotherapy, the distressing physical symptoms reduced the social functioning improved with a better quality of life.

As seen in the current study, the respondents on treatment experienced financial difficulties as they had to attend the hospital for a period of six weeks, five days a week. The study groups at six months and twelve months reported a decrease in the financial burden as they had follow-up visits once a month for the first six months followed by a three month's appointment for the next six months. Results of this study on financial difficulties were in agreement with those of Krikeli et al.(2011a), in a study conducted in Greece comparing radiotherapy and radio-chemotherapy outcomes in one-year women survivors' with cervical cancer.

This study's findings revealed that appetite loss was the most reported symptom affecting the gastrointestinal system during the treatment period but which decreased significantly with time. Satwant et al. (2014) alludes to these findings, but Klee et al. (2000a) disagreed and indicated

that the loss of appetite symptoms were the same throughout their study groups. Diarrhoea presented as being highest whilst on treatment and a slight reduction at six months, but lowest at twelve months. Klee et al. (2000a) differs, as in their findings only a minority of the respondents on treatment reported diarrhoea as being very disturbing. Similar to the study of Klee et al. (2000a), the current study found that constipation, nausea and vomiting was highest among the respondents undergoing treatment.

The study provided evidence that the most frequently reported symptom, by women treated with radiotherapy, was frequent voiding accompanied by soreness and pain, concurring with the findings of Klee et al. (2000a). Urine leakage affected quality of life in a minority of respondents (3.3%). Pfaendler et al. (2015) reported similar results with 14.6 % cases of urine incontinence. It is quite possible that urine leakage led to the women spending most of their time indoors for fear of soiling their clothes thus causing embarrassment. In addition, nearly half (48.4%) of the respondents were unemployed and may have been unable to buy adult protection to contain the leakage.

The study provided evidence that sexual life was the most affected domain, as indicated by 37.3% of the total respondents who had been sexually active in the past month (from the time of data collection). This may be quite normal as radiotherapy damages the vaginal epithelium, connective tissues and small blood vessels causing cell death (Clinical et al. 2012). Complications caused by radiotherapy, for example vaginal stenosis, begins three to six months after treatment and leads to dyspareunia, lack of lubrication and decreased sexual interest (Maher & Denton 2008). Vaginal stenosis leads to additional problems such as inelastic vaginal tissue and the tendency to experience pain and bleeding during sexual intercourse (Greimel et al. 2009; Ancuța et al., 2012). What is going on here? All these changes compound and cause the women to have reduced desire for sex, arousal and orgasm. Experiencing a dry vagina during sexual activity was reported amongst the respondents at six months and twelve months post radiotherapy leading to pain during sexual activity. This was attributed to a tight vagina, which had stenosed as a result of the radiation damage to the vaginal epithelium. The results of this study support similar findings by Kumar et al. (2014).

Cancer induced fatigue was found to be most worrying amongst respondents in the study, with the respondents in need of rest. Goker et al. (2011), in a study conducted in Turkey, also found high scores in fatigue. Respondents undergoing radiotherapy reported the highest level of fatigue which affected their quality of life as they had to remain in bed or rest on a chair during the day. Most respondents reported being able to perform the basic daily activities of daily living, such as eating, getting dressed, washing themselves and using the toilet, but were limited in performing further strenuous tasks such as carrying heavy shopping baskets and walking long distances.

Swelling of limbs is a late complication and mainly affected the study group at twelve months post radiotherapy, findings which were also noted by Bjelic-Radisic et al. (2012). This presents with swelling of the lower limbs as a result of the blockage of the lymphatic system of the legs. Respondents living with lymphoedema present with swelling of the feet, leg heaviness and discomfort, skin texture changes, tight feeling and tingling sensations in the legs limiting the women's ability to perform daily tasks or work thus negatively affecting their quality of life (Pfaendler et al. 2015). In contrast, the respondents on treatment reported the lowest mean scores and a slight increase in those at six months as the signs of lymphoedema began to present. Similar findings were observed by Bjelic-Radisic et al. (2012).

5.2 JUSTIFICATION OF THE STUDY

The purpose of the study was to explore the quality of life of women treated for cervical cancer. The study aimed to explore the quality of life of women diagnosed with cervical cancer and currently being treated with radiotherapy, at six months after completion of treatment and at twelve months after treatment at an academic hospital in Gauteng and to compare with the quality of life of these three groups of women

In Chapter 3, the research design and methods were described in detail, Chapter 4 presented the results which included comparisons between the three groups and Chapter 5 discussed the results also referring to the time since treatment. It can therefore be stated that this study is justified as the purpose and aims were met.

5.3 LIMITATIONS OF STUDY

The researcher selected a cross sectional design which did not allow for the exploring of changes in the same respondents over time. A longitudinal design may have resulted in more accurate findings; however the researcher believes the study provided base line data regarding the quality of life of women treated for cervical cancer.

5.4 RECOMMENDATIONS

According to the findings of the study, interventions ought to be put in place by nurses practicing in cancer care settings to address the physical, role, social and emotional functioning with the aim of improving the quality of life for women treated for cervical cancer. For example; the public can be educated on the importance of screening to be able to diagnose cervical cancer in the early stages when cure rate is high and negative effects of the cancer on the quality of life is minimal. Providing effective symptom support care for cervical cancer patients receiving treatment and those on follow up could also be of benefit. Further studies should be conducted and a longitudinal design used to enable the exploration of changes in the same respondents.

5.5 CONCLUSION

In conclusion, the overall quality of life was affected by cancer related symptoms and acute side effects of radiotherapy treatment leading to low mean scores while on treatment but this improved at six and twelve months in response to radiotherapy and resolving of the acute side effects.

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APPENDIX A: EORTC QLQ-C30 (version 3)

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: _ _ _ _

Your birthdate (Day, Month, Year): _ _ _ _ _ _ _ _ _ _

Today's date (Day, Month, Year): _ _ _ _ _ _ _ _ _ _

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

ENGLISH

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

APPENDIX B: EORTC QLQ – CX24

ENGLISH

EORTC QLQ – CX24

Patients sometimes report that they have the following symptoms or problems. 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:	**Not at all**	**A little**	**Quite a bit**	**Very much**
31. Have you had cramps in your abdomen?	1	2	3	4
32. Have you had difficulty in controlling your bowels?	1	2	3	4
33. Have you had blood in your stools (motions)?	1	2	3	4
34. Did you pass water/urine frequently?	1	2	3	4
35. Have you had pain or a burning feeling when passing water/urinating?	1	2	3	4
36. Have you had leaking of urine?	1	2	3	4
37. Have you had difficulty emptying your bladder?	1	2	3	4
38. Have you had swelling in one or both legs?	1	2	3	4
39. Have you had pain in your lower back?	1	2	3	4
40. Have you had tingling or numbness in your hands or feet?	1	2	3	4
41. Have you had irritation or soreness in your vagina or vulva?	1	2	3	4
42. Have you had discharge from your vagina?	1	2	3	4
43. Have you had abnormal bleeding from your vagina?	1	2	3	4
44. Have you had hot flushes and/or sweats?	1	2	3	4
45. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
46. Have you felt less feminine as a result of your disease or treatment?	1	2	3	4
47. Have you felt dissatisfied with your body?	1	2	3	4

Please go on to the next page

ENGLISH

During the past 4 weeks:	**Not at all**	**A little**	**Quite a bit**	**Very much**
48. Have you worried that sex would be painful?	1	2	3	4
49. Have you been sexually active?	1	2	3	4

Answer these questions only if you have been sexually active during the past 4 weeks:	**Not at all**	**A little**	**Quite a bit**	**Very much**
50. Has your vagina felt dry during sexual activity?	1	2	3	4
51. Has your vagina felt short?	1	2	3	4
52. Has your vagina felt tight?	1	2	3	4
53. Have you had pain during sexual intercourse or other sexual activity?	1	2	3	4
54. Was sexual activity enjoyable for you?	1	2	3	4

APPENDIX C:QLQ-C30 download request from Caroline Sabulei

glqc30@eortc.be

May 13, 2014

Tome

Dear Sir/Madam,

Please find below the links where you can download the documents you requested.
Best regards,

Your data:
Title: Mrs
First name: caroline
Last name: sabulei
Hospital/Institution: University of Witwatersrand
Address: Private Bag 3
County/State: Gauteng
Postal Code: 2050
Country: South Africa
Phone: +27748024038
Fax: N/A
Email: csabulei@ymail.com
Protocol: Quality of life of women living with cervical cancer
Documents requested:
QLQ-C30 Core Questionnaire in English
Cervix Module (CX24) in English
QLQ-C30 Scoring Manual
Full reference values
Latest issue of the EORTC Quality of Life Group Newsletter
Scoring Instructions: Cervix CX24
URLs:
http://www.eortc.be/qol/files/C30/QLQ-C30%20English.pdf
http://www.eortc.be/qol/files/CX24/CX24%20English.pdf
http://www.eortc.be/qol/files/SCManualQLQ-C30.pdf
http://www.eortc.be/qol/files/RV/RV_complete.pdf
http://www.eortc.be/qol/files/QOL_newsletter.pdf
http://www.eortc.be/qol/files/ScoringInstructions/CX24_summary.pdf

If the links don't work, you can copy and paste the entire URL (so with .pdf included) into your browser and that should work. If you are having other technical difficulties please contact us by email: glqc30@eortc.be

APPENDIX D: DATA COLLECTION TOOL

AN EXPLORATION INTO THE QUALITY OF LIFE OF WOMEN TREATED FOR CERVICAL CANCER AT AN ACADEMIC HOSPITAL IN GAUTENG, SOUTH AFRICA.

DATA COLLECTION TOOL

SECTION 1: DEMOGRAPHIC DATA

1.1 Age (Years)

1.2 Stage of Cervical cancer

1.3 Marital Status

Single	
Married	
Divorced	
Widowed	

1.4 Employment Status

Unemployed	
Part time employed	
Full time employed	
Pensioner	

APPENDIX E: PERMISSION TO CONDUCT RESEARCH

University of the Witwatersrand
Faculty of Health Sciences
Department of Nursing Education
7 York Road,
Parktown 2193

Gauteng Department of Health/CEO of the Charlotte Maxeke Johannesburg Academic Hospital

Dear Madam /Sir,

RE: PERMISSION TO CONDUCT RESEARCH

My name is Caroline Sabulei, a student at the University of the Witwatersrand, Johannesburg. I am currently registered for Master of Science in Oncology and Palliative Care Nursing in the Department of Nursing Education. I am hereby asking for permission to undertake a study at Charlotte Maxeke Johannesburg Academic Hospital. I am investigating **"The quality of life in cervical cancer patients treated with radiotherapy".**

The purpose of this study is to gain an understanding of the experiences of women undergoing radiotherapy treatment for cervical cancer. This study will contribute to the provision of holistic care to women and after the treatment. Participation to this study is completely voluntary and confidential. The participants name will not appear anywhere and only initials of names will be used. The questionnaires will be filled by consenting patients in the radiology department and will take about fifteen minutes of the patients' time.

The information will be used for the intended purpose only. The participants may discontinue participation at any time of the study without any penalty or loss of benefits to which they are otherwise entitled. An informed written consent will be obtained from all participants to be included in the study. Participants who sign the consent will indicate acceptance to participate in the study.

I hope to conduct this study in the radiation oncology out-patients department where women come for clinics and in the oncology ward for those who are undergoing treatment. The name of the participating Hospital and patients involved will not be divulged in the research report. Ethical clearance has been obtained from the Human Research Ethics Committee of the University of the Witwatersrand. Find attached copy of my research proposal as well as the ethical clearance.

Thanking you in advance for allowing me to conduct the study. Your permission is valuable and highly appreciated.

Yours faithfully

Caroline Sabulei (MSc Nursing Student) Date…….

APPENDIX F: INFORMATION DOCUMENT

Study title: QUALITY OF LIFE IN CERVICAL CANCER PATIENTS TREATED WITH RADIOTHERAPY AT AN ACADEMIC HOSPITAL IN GAUTENG, SOUTH AFRICA.

Good day Madam**,**

My name is Caroline Sabulei. I am currently registered as a student in the Department of Nursing Education at the University of the Witwatersrand and would like to conduct a study entitled **"The quality of life in cervical cancer patients treated with radiotherapy"**.I would like to invite you to consider participating in this research study where I would use the words that people tell me. If you should you agree to take part in the study, I will provide you with a questionnaire for you to fill and will take about 15 minutes. The study will take place at the oncology ward for those who are in-patients and at the oncology clinic for the out-patients in a quiet and private place.

There are no direct benefits to you as the participant. However, the findings will assist nurses to identify and manage patient problems based on their needs. Should you decide not to participate in the study, you will not lose any benefit to which you are entitled. Even if you decide to take part in the study, you may at any time choose to withdraw and you will not lose any benefits to which you are entitled. However, upon filling the questionnaire, I will not be able to identify your questionnaire as only the initials of your name are used. This means you would not be able to withdraw from the study any more. Also, please note that you will not receive any money or goods should you choose to take part in the study. I will keep information confidential. Personal information may be made known if the law says so, research records may be inspected to look at the quality and the Research Ethics Committee can inspect how I analyzed what you told me. After analyzing the information, all data sheets will be sealed in an envelope and placed in a safe in the Department of Nursing Education for a period of three years after the report has been published where after it will be destroyed. When I write a report on what all the women filled in no names or initials will be referred to. People who will read the report would however not know that this is what you said. If you have any question, or further information about the study, do not hesitate to contact me, my cell phone number is 0612298264.Should you have any question about your rights as a study participant, or questions concerns about any aspect of this study, please call the Ethics Department of the University of the Witwatersrand on +27 11 717 1234 or my Head of Department, Prof J E Maree at 011 488 4272.

Thank you for your consideration.

……

Caroline Sabulei.

APPENDIX G: CONSENT FORM

I have been given the information sheet on the research Title: **"The quality of life in cervical cancer patients treated with radiotherapy".** I have read and understood the information sheet. If I agree to participate in the study, I will be asked to fill two (2) questionnaires which takes about fifteen (15) minutes about the quality of my life during or after the cervical cancer treatment with radiotherapy.

I understand that it is up to me whether or not to participate in study and that there will be no penalty or loss of benefits am entitled if I decide not to participate. I also understand that I may discontinue participation at any time the study with no penalty or loss of benefits to which am otherwise entitled.

I understand that the researcher involved in this study will make every effort to ensure confidentiality and my name will not be used in the study reports. No identifying information will be included when the questionnaires are analyzed. I have been given the contact details that I may call if I have any questions or concerns about the research.

This study has been explained to me. I have read and understand this consent form, I agree voluntarily to participate in the interview for this study.

…… …….....

Signature of participant Date

…… ……..

Witness Date

APPENDIX H: ETHICS CLEARANCE CERTIFICATE

R14/49 Mrs Caroline Sabulei

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150441

NAME: (Principal Investigator)	Mrs Caroline Sabulei
DEPARTMENT:	Nursing Education Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	An Exploration into the Quality of Life of Women Treated for Cervical Cancer at an Academic Hospital in Gauteng, South Africa
DATE CONSIDERED:	24/04/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Lize Maree
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	25/05/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature

Date 28/5/2015

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES