

**THE INCIDENCE AND EFFECTS OF LOWER LIMB LYMPHOEDEMA IN WOMEN TREATED
WITH RADIOTHERAPY FOR GYNAECOLOGICAL CANCER IN AN ACADEMIC HOSPITAL
IN JOHANNESBURG**

Joyce Vuyiswa Khutjwe

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DECLARATION

I, Joyce Vuyiswa Khutiwe declare that this research is my own work. It is being submitted for the Master of Science (in Nursing) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other university.

Signature: Joyce

8th day of JUNE 2018 in Johannesburg

PROTOCOL NUMBER: 170461

DEDICATION

In memory of my loving father

Benjamin Sebetlela

1942-2017

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I would like to give special thanks to my supervisor and mentor, Professor Lize Maree for her immense contribution towards the success of this study. She held my hand from the conceptualisation phase, right through to the end of the study. What a remarkable woman!

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Lastly but most importantly I thank God for His grace, without which dreams remain just that, dreams!

ABSTRACT

Even though cancer treatment has improved survivorship, women who receive radiotherapy as part of treatment for gynaecological cancer have a lifetime risk of developing lower limb lymphoedema. Little is known about cancer related lower limb lymphoedema in South Africa as there is a dearth of South African literature focusing on the subject. It might be argued that international literature can inform South African nurses; however, South Africa faces unique challenges in terms of cancer control such as poor health care seeking behavior among women and a poor referral system.

The purpose of the study was to describe the incidence of lower limb lymphoedema and its effects on women treated with radiotherapy for gynaecological cancer at an academic hospital in Johannesburg. The study was conducted at the chosen academic hospital's department of radiation oncology. A quantitative survey design and convenience sampling for a calculated sample size of 155 were used. Data was collected through structured interviews using the Gynaecological Cancer Lymphoedema Questionnaire (GCLQ) and limb circumference measurements from which limb volumes were calculated. Lower limb lymphoedema was defined by an inter limb volume difference of 200ml and graded according to the percentage volume difference; >20% for mild, 20% to 40% for moderate and >40% for severe lymphoedema. Data was analysed using descriptive statistics and quantitative content analysis. Statistical level of significance was set at 0.05 ($p < 0.05$).

Lower limb lymphoedema was detected in 29.7% of the respondents; 93.5% with Stage I and 6.5% with Stage II lymphoedema. External beam radiotherapy, age and body mass index were not associated with lymphoedema. On the contrary, brachytherapy and the type of gynaecological cancer had a statistically significant association with the development of lower limb lymphoedema; $p=0.030$ and $p=0.017$ respectively. Respondents reported experiencing changes such as taking long to finish tasks, increased hospital charges and feeling unattractive due to the lymphoedema.

Outpatient gynaecological clinics may consider regular assessment of patients for lower limb lymphoedema during follow up care through history taking and leg measurements, to detect lymphoedema early.

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NOMENCLATURE

CT: Computed Tomography

CANSA: Cancer Association of South Africa

GCLQ: Gynaecological Cancer Lymphoedema Questionnaire

HPCSA: Health Professions Council of South Africa

ICC: Intraclass Correlation Coefficient

MRI: Magnetic Resonance Imaging

WHO: World Health Organisation

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CHAPTER 1

OVERVIEW OF THE STUDY

1.1 INTRODUCTION

Survivorship for gynaecological cancer patients has improved in recent years thus calling for preparedness for late side effects often associated with cancer treatment. Pelvic radiotherapy, which forms part of treatment for gynaecological cancer, leads to an array of side effects, among them lower limb lymphoedema a result of damage caused to the lymphatic vessels and their subsequent decreased capacity to transport lymph (Zuther and Norton, 2013). According to studies conducted in the west, swelling of the extremities, with profound effects on daily living, characterises this condition (Devoogdt et al., 2014).

1.2 BACKGROUND

Cancer is a global health problem and according to the 2012 Globocan statistics (International Agency for Research on Cancer and World Health Organization, 2014), there were 14.1 million new people diagnosed with cancer and 8.2 million cancer related deaths worldwide. Of the new cancer diagnoses recorded in 2012, 57% (8 million) of them and 65% (5.3 million) of the associated deaths occurred in the less developed regions. Gynaecological cancer, which includes cancers of the vulva, cervix, vagina, uterus and ovary, accounts for 17% of all female cancers (Dunberger et al., 2013). Cancer of the cervix is the most common of all the gynaecological cancers and the fourth most common cancer in women worldwide (Nelson, 2013), however, in the Sub-Saharan and Southern African region, cervical cancer is the second most common cancer in women after breast cancer, but has the highest mortality rate (International Agency for Research on Cancer and World Health Organization, 2014). In South Africa, cervical cancer is the third most common cancer after breast cancer and basal cell carcinoma in women, contributing 15.6% of new cancer diagnoses made in 2013, followed by uterine cancer with 3.2%, and 1.2%, 0.9% and 0.4% for cancers of the ovary, vulva and vagina respectively (CANSA, 2014).

Gynaecological cancer is treated in various ways, including a combination of surgery, chemotherapy and radiotherapy, depending on the stage of the disease and type of cancer, individual patients' general health status and specific treatment goals (Morice et al., 2012). In developing countries where cancer is often diagnosed at advanced stages, chemo-radiation or radiotherapy only is the ultimate treatment of choice. Cancer treatment is associated with many undesired side-effects: chemotherapy can cause a wide range of side-effects including nausea

and vomiting, fatigue, hair loss, anaemia and changes in appetite and taste (Hardy, 2012), surgery could involve removal of lymph nodes, which can cause sluggish flow of the lymphatic fluid (Lin and Qui, 2015), while radiotherapy causes activation of cytokines and growth factors, which can eventually result in fibrosis of the lymph vessels and as a result, the capacity of the lymph vessels to transport lymph is reduced, leading to a build-up of lymph in the interstitial space of the subcutaneous tissue and development of secondary lymphoedema (Lind et al., 2011).

Lymphoedema is defined as the accumulation of protein rich fluid in the interstitium of subcutaneous tissues due to altered lymph flow and is commonly known to affect the upper and lower limbs, although it can affect other parts of the body such as the abdomen, groin, head, neck and lungs (Wanchai et al., 2016). Cancer, through direct tissue invasion, and its treatment, specifically surgery and/or radiotherapy, are the major causes of lymphoedema, which is referred to as secondary lymphoedema. Primary lymphoedema is due to defects in the development of lymphatic vessels and may be present at birth, but can also develop later in life with no cause (Stolldorf et al., 2016). Cancers, such as breast and gynaecological cancers, and their treatment, which involves surgical removal of lymph nodes and/or radiotherapy, have a high risk of lymphoedema development. The risk seems to increase with the number of lymph nodes removed and the dose of radiotherapy received (Chafranskaia et al., 2011). It is estimated that up to half of breast cancer survivors develop lymphoedema, with an overall incidence of upper limb lymphoedema ranging from 8% to 56% (Wanchai et al., 2016). Studies done in the developed world report the incidence of lower limb lymphoedema associated with gynaecological cancer to range from 7% to 78%, with an onset range of one month to 32 months after surgery (Füller et al., 2008, Kim et al., 2012a). Cervical cancer however, seems to have a higher incidence compared to other gynaecological cancers, even though some studies found vulvar cancer to have a higher incidence of lymphoedema (Shaitelman et al., 2015, Tada et al., 2009).

Symptoms of lymphoedema include swelling, pain or discomfort, feeling of heaviness, tightness, hypersensitivity or lack of sensitivity in the affected limb. Lymphoedema is present if the circumference measurements show a difference of 200ml, or 10%, between the affected and unaffected limb (Mori et al., 2015). Lymphoedema is divided into four stages, 0 to 3, Stage 0 being asymptomatic while Stage 3 is characterised by extreme increase in limb volume and skin changes. Lymphoedema cannot be cured but symptoms can be managed through complete decongestive therapy, a conservative therapy involving manual lymphatic drainage, skin and nail care, exercises, application of short stretch bandages and the use of compression garments

(Wanchai et al., 2016). Unmanaged, this condition has serious implications for patients and those with lower extremity lymphoedema often experience difficulties in walking and fitting into their clothes. Its cosmetic deformities are not easy to hide and complications, such as fibrosis, cellulitis, lymphangitis and lymphorrhea, occur frequently (Zuther and Norton, 2013); emotional distress, such as anxiety and depression, associated with lymphoedema has also been reported (Fu et al., 2013). This is aggravated by the tendency of clinicians to trivialise this condition in cancer survivors and general lack of expertise in its management (Zuther and Norton, 2013). Knowledge of the occurrence of lymphoedema needs to be a priority for nurses caring for gynaecological cancer survivors to allow them to apply early interventions to avert difficulties associated with its management when it has progressed, as well as its effects on quality of life (Carter et al., 2010). In addition, studies on the incidence of lower limb lymphoedema in gynaecological cancer patients have been conducted in the first world and researchers recommend that more studies be done to confirm the incidence (Kim et al., 2015). To date evidence has not been collected on this clinical problem in South Africa.

1.3 RESEARCH PROBLEM

The research problem for this study relates to the incidence of lower limb lymphoedema. Although there is documented evidence that cancer treatment has improved survivorship, women who receive radiotherapy as part of treatment for gynaecological cancer have a lifetime risk of developing lower limb lymphoedema. However, little is known about cancer related lower limb lymphoedema as there is a dearth of South African literature focusing on this subject. It might be argued that international literature can inform South African nurses; however, South Africa faces unique challenges in terms of cancer control, such as poor healthcare seeking behaviour among women and a poor referral system (Sibiya, 2012). In addition, cervical cancer, a preventable disease, which forms part of gynaecological cancer, primarily affects women living in the developing world where they present with advanced cancer (Lohlun et al., 2015). Factors such as a low capacity to analyse Pap smears at public sector laboratories and low compliance to follow up care among women with low education levels, play a role in late presentation, and this is not only applicable to cervical cancer, but cancer in general (Sibiya, 2012). Basic healthcare is also not guaranteed for women living with gynaecological cancer. Ntinga and Maree (2015), in a study describing the late complications women treated for cervical cancer experience, found these women are not necessarily attended to at primary health clinics but referred to the hospital where they were treated for cancer. It was also found that cancer related lymphoedema is considered a small price to pay for being cured from cancer, which adds to the challenges women living with the complications of gynaecological cancer and its treatment face (Ntinga and Maree, 2015). Knowledge about the incidence and effects of gynaecological cancer

related lymphoedema might create awareness among nurses practising in cancer care settings, which could lead to a high suspicion, assessment and the provision of care to manage this distressing problem.

1.4 SIGNIFICANCE OF THE STUDY

The researcher believes this study would contribute to the holistic management of women living with gynaecological cancer, as it would raise awareness about the incidence of lower limb lymphoedema, a late cancer treatment side-effect that has been neglected. The study would also reveal the effects that this condition could have on South African gynaecological cancer survivors, thus encouraging nurses to be more alert and responsive to symptoms suggestive of lower limb lymphoedema.

1.5 RESEARCH QUESTION

The study attempted to answer the following research question:

- Which lower limb lymphoedema related changes do women treated with radiotherapy for gynaecological cancer experience, and what is the incidence and effects of the lymphoedema, in an academic hospital in Johannesburg?

1.6 PURPOSE AND OBJECTIVES OF THE STUDY

The purpose of the study was to describe the incidence and effects of lower limb lymphoedema in women treated with radiotherapy for gynaecological cancer, in an academic hospital in Johannesburg.

The objectives of the study were:

- To describe the lower limb lymphoedema related changes women treated with radiotherapy for gynaecological cancer at an academic hospital in Johannesburg experience
- To describe the incidence and identify the stages of lower limb lymphoedema in these women
- To describe the psychosocial effects of lower limb lymphoedema in the group diagnosed with this condition.

1.7 DEFINITION OF TERMS

The following terms were defined for use in this study.

- **Gynaecological Cancer**

Gynaecological cancer includes cancers of the vulva, cervix, vagina, uterus and ovary, accounting for 17% of all female cancers (Dunberger et al., 2013).

- **Radiotherapy**

Radiotherapy is defined by Price (2013) as the medical use of ionisation radiation for treatment of illnesses, particularly cancer. The goal of radiotherapy is to deliver a therapeutic dose to a region while minimising the damage to surrounding healthy structures.

- **Brachytherapy**

Brachytherapy refers to treatment of tumours with placement of the radioactive source adjacent to the tumour (intracavitary), into the tumour (interstitial application) or into a lumen (intraluminal), with the goal of delivering a high dose of radiation to the small volume of the tumour while delivering a limited dose (Itano, 2016).

- **Lower Limb Lymphoedema**

Lower limb lymphoedema is characterised by accumulation of lymph in the interstitial space due to the reduced lymphatic's transport capacity, presenting as swelling of the legs (Beesley et al., 2015). In this study, lymphoedema refers to lower limb lymphoedema.

- **Incidence**

Incidence is defined by (Brink et al., 2012) as the number of individuals who develop a particular disease or condition per population at risk at a specified time period.

- **Complete Decongestive Therapy**

Zuther and Norton (2013) define complete decongestive therapy as a non-invasive, multi-component approach to treat lymphoedema and related conditions. It comprises a combination of manual lymph drainage, compression therapy, decongestive exercises and skin and nail care.

- **Adjuvant Therapy**

This is a treatment given in addition to primary treatment. In cancer treatment, surgery is often the initial or primary treatment, followed by chemotherapy and/or radiotherapy as adjuvant treatment (Itano, 2016).

1.8 RESEARCH DESIGN AND METHODS

A quantitative cross sectional survey design (Brink et al., 2012) was used for the study. The study was conducted in the Radiation Oncology Department of one academic hospital in Johannesburg. The study population consisted of all women who were treated for gynaecological cancer at the chosen academic hospital. The researcher used the Fisher's Sample size formula to calculate the sample size ($n=155$) and convenience sampling selected the sample. The inclusion criteria were women 18 years and older, having been diagnosed with gynaecological cancer and at least twelve months, but not more than 24 months, after completing radiotherapy treatment.

Data were collected using the Gynaecological Cancer Lymphoedema Questionnaire, for which permission had been obtained (Appendix 1). Respondents were also assessed for lower limb lymphoedema through limb volume measurements (Appendix 2). Data from the instruments were entered into an Excel spreadsheet and STATA version 14 was used for analysis.

Descriptive statistics analysis was used for the first and second objectives, to describe the changes women treated with radiotherapy for gynaecological cancer experience, and describe the proportions of women who developed lower limb lymphoedema and their proportions in different stages of the lymphoedema. Chi square (X^2) and Fisher Exact tests were computed to determine associations across the variables and P values less than 0.05 ($p=0.05$) were set to indicate statistical significance. Quantitative content analysis was used for the third objective on effects of lower limb lymphoedema and for analysis of data obtained through the open-ended questions.

1.9 RESEARCH REPORT OUTLINE

The study will be presented as follows:

Chapter 1: Overview of the study

Chapter 2 Literature review

Chapter 3: Research design and methods

Chapter 4: Results of the study

Chapter 5: Discussion, Justification, Limitations, Recommendations and Conclusion

1.10 SUMMARY

In this chapter, a brief introduction to the study was presented and the background, problem statement, significance and purpose of the study explained. The researcher then outlined the specific objectives and research methods. Chapter 2 will focus on literature reviewed regarding lower limb lymphoedema as a sequela of treatment of gynaecological cancer.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

Chapter 1 presented an introduction for the study. This chapter presents a discussion of literature reviewed on cancer, gynaecological cancer and its treatment and lower limb lymphoedema. Literature review was conducted using Cinahl Plus, Pub Med, Science Direct, Wiley Online Library and Google Scholar.

2.2 CANCER AS A WORLDWIDE PUBLIC HEALTH PROBLEM

The burden of cancer worldwide remains high largely because of the aging and world growth population as well as adoption of cancer predisposing lifestyles, which include tobacco and alcohol, unhealthy eating habits, obesity, physical inactivity and the escalating HIV infections in the developing world (WHO, 2017). In 2012, 14.1 million people were newly diagnosed with cancer and 8.2 million deaths were recorded worldwide. This was an increase from the 2008 statistics, where 12.7 million people were diagnosed with cancer and 7.6 million died of the disease worldwide. Most of the newly diagnosed (57% or 8 million) and cancer related deaths (65% or 5.3 million) occurred in less developed countries (International Agency for Research on Cancer and World Health Organization, 2014).

Cancer seems to be more common amongst men than in women (International Agency for Research on Cancer and World Health Organization, 2014). The overall age standardised cancer incidence rate is almost 25% more in men than it is in women, with incidence rates of 205 and 165 per 100 000 respectively (CANSA, 2014). Lung cancer is the most common cancer among men followed by cancer of the prostate, nonetheless there has been a sharp increase in the breast cancer incidence rate among women, which is now the second most common cancer worldwide after lung cancer (International Agency for Research on Cancer and World Health Organization, 2014)

Even though some high-income countries continue to have the highest incidence rates for certain cancers, such as breast, lung, prostate and colorectal cancer, the mortality rates in these countries have declined due to the decline in risk factors, rigorous screening and early detection, as well as improvement in treatment. Conversely, some low and middle income countries now experience the highest rates in some of the aforesaid cancers because of a shift towards lifestyles representative of industrialised countries, which leads to an increase in risk factors such as smoking, physical inactivity, unhealthy eating habits and obesity (Torre et al., 2016,

CANSA, 2014). Infections such as the human papilloma virus and hepatitis virus contribute to increasing cancer incidence rates, accounting for up to 25% of all cancers in low and middle income countries (WHO, 2017).

South Africa, as a middle-income country, is equally affected by the soaring cancer prevalence, which is driven by urbanisation and subsequent obesity linked to food choice habits. Estimates of prevalence rates of overweight and obese South Africans are 57% and 30% respectively (Nnyepi et al., 2015). Significantly higher rates are found in women with a trend indicative of increasing body mass index with age for both genders (Shisana et al., 2013). There has been a shift towards consumption of meat, fatty and oily foods, sweet and savoury snacks, condiments and soft drinks, and a contrary drift away from vegetables over the years, which has propelled the escalation of obesity (Ronquest-Ross et al., 2014). Obesity is linked to various cancers, such as breast, prostate, oesophagus, uterine and ovarian cancers, a predisposition which extends beyond cancer to include other non-communicable diseases such as hypertension and diabetes (CANSA, 2014).

Tobacco smoking is another major setback to cancer control programmes in South Africa, as the number of people who smoke daily remains significantly high, 62% and 76% for females and males respectively, according to a recent survey report (Shisana et al., 2013). Smoking accounts for a wide range of cancer types including leukaemia, pancreas and kidney in addition to the commonly known smoking associated cancers such as lung and head and neck cancers (Stassen, 2015). Other factors known to have a significant contribution to cancer development are alcohol and infection with the human papilloma virus, which is linked to cervical, oral, throat and anal cancers among others (CANSA, 2014). Good cancer control programmes are in place in many low and middle-income countries, however their success is marred by poor coordination and implementation strategies, hence the continued escalation of cancer prevalence. Moreover, there is still an inclination towards traditional medicines in many communities in these countries, South Africa included, leading to advanced cancer at presentation (Tindall et al., 2014).

2.3 GYNAECOLOGICAL CANCER

Gynaecological cancer includes cancers of the vulva, cervix, vagina, uterus and ovary and accounts for 17% of all female cancers (Dunberger et al, 2012). Cervical cancer is the most common of all the gynaecological cancers and the fourth most common cancer in women worldwide (Nelson, 2013). However, in the Sub-Saharan and Southern African region, cervical cancer is the second most common cancer in women after breast cancer, but has the highest mortality rate (International Agency for Research on Cancer and World Health Organization, 2014). According to the Globocan Statistics, International Agency for Research on Cancer and

World Health Organization (2014), cervical cancer accounted for 7.5% of all female cancer deaths worldwide in 2012, with 87% of these occurring in less developed regions. While cervical cancer is predominant in less developed regions, uterine and ovarian cancers are more common in high income countries (Banas et al., 2016, Evans et al., 2011). These tend to be more prevalent in the older population, contrasting with cervical cancer which is seen in the younger population and attributable to the human papilloma viral infection (Kuku et al., 2013). Most cervical cancer patients are diagnosed in early adulthood to middle age, with an average age of 40 at diagnosis in developed countries, such as Japan, and possibly lower in developing countries (Ohba et al., 2011). Meanwhile vulvar cancer is relatively uncommon, with less than 4000 new diagnoses made per year in the United States of America, while it accounted for 0.94% of all new female cancer diagnoses made in 2013 in South Africa (CANSA, 2014, Hassanzade et al., 2013).

2.3.1 Treatment of gynaecological cancer

Treatment modalities for gynaecological cancer include surgery, chemotherapy and radiotherapy. Combination therapy is the mainstay of treatment, with the stage of the cancer, the individual patients' general health status and the treatment goal as the determinant factors in the choice of treatment (Morice et al., 2012). Surgery often precedes the other two modalities as the primary treatment. For early stage disease, surgery alone is sometimes enough to yield a cure, however adjuvant therapy is used on the bases of risk factors such as age, histological grade, myometrial invasion and lymph-vascular invasion (De Boer et al., 2016).

De Boer et al. (2016) assert that a significant percentage of all patients diagnosed with early stage gynaecological cancer have high-risk disease with substantial lymph-vascular invasion, thus making adjuvant therapy imperative. Patients with advanced disease can still derive benefit from primary debulking surgery; studies have confirmed an inverse relationship between survival and the bulk of residual disease following surgery, with a median survival of 106 months for patients left with no macroscopic disease, contrary to 30 to 36 months for those left with residual disease (Chi et al., 2012).

Radiotherapy, with or without chemotherapy, plays a pivotal role in the management of gynaecological cancer in low and middle-income countries. Cervical cancer, though preventable, is highly prevalent in these countries with most women presenting with advanced disease that is beyond cure (Ntinga and Maree, 2015). Ginsburg (2013) attributes this to lack of implementation of organised cancer screening services in most of these countries. The International Atomic Energy Agency recommends that such patients be treated with radiotherapy and brachytherapy, with or without concurrent chemotherapy, as surgery is often not possible for late stage cancer.

Nonetheless clinical trials have revealed increased pelvic relapse with use of adjuvant chemotherapy alone, hence use of pelvic radiotherapy with concomitant chemotherapy where possible is highly recommended (De Boer et al., 2016).

Yu and Garcia (2015) argue that current treatment for cervical cancer, which includes radiotherapy with concurrent Cisplatin, can yield a cure in 80% to 90% of women with early Stage I and II cancer, while prognosis for those with advanced disease remains poor. This essentially means that even though concomitant use of Paclitaxel and Cisplatin has proven to improve response, it does not significantly improve the overall survival.

The recent introduction of targeted therapy agents, such as Bevacizumab, in some countries has improved overall survival for patients with advanced cervical cancer, however the severe toxicities associated with this drug may impede its use in some patients (Yu and Garcia, 2015). In low and middle-income countries, Africa included, the overall benefit of Bevacizumab containing regimens may be outweighed by the cost in addition to toxicities linked to this agent (Phippen et al., 2015, Tewari et al., 2014).

Treatment for vulvar cancer is mainly surgery for early stage disease, with chemotherapy and radiotherapy used for advanced disease, either before surgery to reduce the tumour size and improve its operability or after surgery, or in combination as adjuvant therapy (Woelber et al., 2013). Similarly, surgery is the primary treatment for uterine cancer and involves a hysterectomy and removal of the ovaries and lymph nodes. Adjuvant chemoradiation is recommended for patients with high risk and advanced stage disease (Creasman, 2015).

2.4 LYMPHATIC SYSTEM FUNCTION

The lymphatic system consists of lymph vessels, lymph nodes, the thymus gland, spleen and tonsils. The lymphatic system functions to maintain fluid homeostasis by absorbing fluid and macromolecules, such as proteins, from the interstitial spaces, enables reuptake of dietary lipids and vitamins in the intestine and serves as a trafficking route for immune cells (Schulte-Merker et al., 2011). Lymphatic vessels are found in all areas of the body with blood supply and transport lymph fluid from the interstitium via the lymph nodes, which serve as filters for harmful substances like cancer cells and pathogens, into the thoracic duct and lastly the venous circulation. At the extremities, lymph fluid is transported from distal to proximal through vessels that run parallel to the arms and legs (Zuther and Norton, 2013).

2.5 LOWER LIMB LYMPHOEDEMA DUE TO GYNAECOLOGICAL CANCER TREATMENT

Treatment of gynaecological cancer often results in late side effects which include lower limb lymphoedema, a chronic potentially debilitating condition that occurs when the lymphatic system's transport capacity declines, resulting in accumulation of lymph in the subcutaneous tissues (Yost et al., 2013). The onset of secondary lower limb lymphoedema is often insidious but can be sudden, and develops due to surgery and/or radiotherapy, which are among the recommended treatment modalities for gynaecological cancer. Radiotherapy may cause direct cellular death through breakage of the DNA double strands and also induce activation of cytokines and growth factors leading to fibrosis and decreased compliance of the lymphatic vessels (Lind et al., 2011). Surgery on the other hand often involves lymph nodes' resection causing disruption in lymph transport, and potentiating lymphoedema development (Zuther and Norton, 2013). Other causes of secondary lymphoedema are direct cancer invasion, trauma and infection affecting the lymphatic system.

Primary lymphoedema is the result of developmental defects in the lymphatic system, which can be congenital or hereditary. According to Zuther and Norton (2013), even though defects may be present at birth, the lymphatic system may remain functional without any symptoms, provided it still has the capacity to manage the lymphatic loads.

Lower limb lymphoedema is present when there is a 2cm circumferential measurement difference or a 10% volume difference between the affected and unaffected limb (Mori et al., 2015, Murdaca et al., 2012). The severity or grading of lymphoedema is based on the interlimb volume discrepancy. It is considered mild when the discrepancy is less than 20%, moderate between 20% and 40%, and severe above 40% (Ki et al., 2016).

Lymphoedema is divided into four stages, the subclinical stage and stages one to three. In the subclinical stage, the lymphatic system's transport capacity is subnormal, but still adequate to manage the lymphatic load thus not causing any symptoms (Zuther and Norton, 2013). Accumulation of protein rich fluid in the interstitial space and subsequent oedema that is amenable to elevation begins in Stage I, whilst Stage II is characterised by increased interstitial fluid accumulation with some fibrotic skin changes (Davey, 2014). Stemmer sign, which is characterised by inability to lift the skin on the dorsal parts of the toes of the affected leg, may be positive from Stage II as the lymph accumulation and dermal changes become progressive. Unlike Stage I, the oedema in Stage II is not spontaneously reversible, but requires active treatment. Meanwhile Stage III is characterised by gross lymphostatic oedema and tissue fibrotic changes, with loss of skin elasticity and development of other skin alterations such as papillomas, cysts, fistulas, hyperkeratosis and infections. Stemmer sign is present also in this

stage (Zuther and Norton, 2013). If interventions are not instigated in the early stages, progression to Stage III, which is very difficult to manage, ensues.

2.5.1 Diagnosis of lower limb lymphoedema

Various methods are used to diagnose lymphoedema and range from objective external volumetric assessments to invasive lymphatic mapping, as well as subjective tools that require patients to report the symptoms they are experiencing. According to Shaitelman et al. (2015), objective measurements or diagnostic methods for lymphoedema should be reliable, efficient, inexpensive, non-invasive and easy to use. Objective methods used include extremity circumferential measurements, water displacement, optoelectronic volumetry and imaging. The subjective measurement tool that is commonly used for the diagnosis of the lower limb lymphoedema is the self-report Gynaecological Cancer Lymphoedema questionnaire.

The extremity circumferential measurement method often uses an interlimb difference threshold of >2cm to define the presence of lymphoedema. The method involves measuring around the limbs at predetermined points using a non-stretch measuring tape, for instance, 4cm and 10cm intervals for upper and lower extremity lymphoedema respectively. Each segment volume is computed using formulae for volume calculation for either a cylinder, C^2/π (for 4 cm measurement intervals), or a truncated cone, $h (C_t^2 + C_t C_b + C_b^2) / 12\pi$, for other measurement intervals (Williams and Whitaker, 2015). The volume of the limb is the sum of the volumes of all segments (Murdaca et al., 2012). Even though this method is relatively inexpensive and highly flexible, as the measuring tapes can be used for any part of the body, Murdaca et al. (2012) criticise the high degree of intrarater and interrater variability associated with this measurement tool. Nevertheless, one validation study of this method found both intrarater and interrater reliability to be excellent for circumferential measurements at all defined sites (intra class coefficient [ICC] >0.90, $p < 0.05$ for all comparisons), with standard error of measurement ranging from 0.5% to 1.3% (Haesler, 2015). The method is widely used for its practicality and was used for this study, with only the researcher taking leg measurements to optimise consistency.

The water displacement method uses volumeters filled with water and equipped with an overflow spout and a beaker for collection of displaced water, as the limb is immersed in the water. It follows the scientific principle that an object or matter displaces its own volume of water, thus the volume of water displaced represents the limb volume (Zuther and Norton, 2013). This method is also relatively inexpensive and considered more sensitive and accurate in terms of volumetric measurements, however, it is not appropriate for clinical settings because of its unwieldiness with regard to hygiene and its lack of the ability to localise the lymphoedema to a specific limb segment. The method is also contraindicated in patients with open skin lesions and may also

prove difficult for patients at end of life, who are too weak to submerge their legs in the water and maintain the same position until outflow of water ends (Shaitelman et al., 2015).

Perometry, or optoelectronic volumetry method, uses infrared light to quantify limb volume and detect abnormalities. Three-dimensional graphs are mapped on both the affected and unaffected limbs using light beams and images of the limbs generated in a computer linked to the perometer. Transections are measured every 3mm, and the limb volume is calculated using the data captured (Armer and Ridner, 2006). This method is hailed by Shaitelman and colleagues (2015) for its efficiency and the level of hygiene associated with it, as the perometer has no contact with the patient. This method may nonetheless prove expensive in low resource settings and requires consistency in positions when multiple measurements are taken (Li et al., 2015). In their study, investigating the reliability and limits of circumferential measurement, water displacement and optoelectronic volumetry in the measurement of upper limb lymphoedema, Deltombe et al. (2007) found circumferential measurement to have better reliability than the water displacement technique. It was also preferred because of its affordability and practicality in the clinical setting, as it could be used across all patients, whereas the water displacement method can only be used in patients who have no open wounds. While the optoelectronic volumetry technique was the most preferred of the three in terms of reliability, its affordability would be a setback.

Imaging of the lymphatic system is essential to outline the underlying disturbances in the lymphatic system. Even though history and assessment of signs and symptoms is often used for lymphoedema diagnosis, imaging authenticates the diagnosis as it visualises the changes in the lymphatics (Zuther and Norton, 2013). Lymphoscintigraphy, the gold standard technique for lymphoedema imaging, uses a radioactive tracer linked to a sulphur colloid and is injected into the skin, depicting any aplasia, hyperplasia, alternative lymphatic channels, areas of lymphatic obstruction and subsequent diffusion of the tracer into the tissues and reflux into the chest and abdomen (de Almeida et al., 2017).

In one randomised control study, lymphoedema was detected early through lymphoscintigraphy even before the appearance of clinical signs among patients who had been treated with surgery and radiotherapy (Paskett et al., 2012). Unfortunately, because of the slow uptake of the radiocolloid, patients often have to wait for some time before imaging can be done (O'Donnell et al., 2017).

Other imaging techniques used include magnetic resonance imaging (MRI), computed tomography (CT) and some ultrasound types, which can detect the presence of extra fluid in the

tissues. The setback of these imaging techniques is their inability to pinpoint the cause of the extra interstitial fluid, which is not only limited to lymphoedema. Moreover, being expensive these are not available in all radiological departments (Paskett et al., 2012).

Subjective measurement tools play a key role in early detection of lymphoedema and these often precede use of objective measurement tools. The self-report Gynaecological Cancer Lymphoedema questionnaire, developed by Professor Jane Armer, (Carter et al., 2010), has been widely used providing valuable information on signs and symptoms often indicative of lymphoedema. A study conducted by Yost et al. (2013), to validate this questionnaire, revealed 80% of signs and symptoms, as shown from this set of questions, to be significantly associated with lymphoedema. Early signs and symptoms of lymphoedema include clothing or footwear feeling smaller or tighter than usual, experiences of heaviness, tightness, fullness or stiffness and unusual aches in the affected limb (Hardy, 2012); these symptoms are covered by the self-report Lower Extremity Lymphoedema Screening Questionnaire. Not only is this method of diagnosing lymphoedema easy to use and applicable to all settings, but it may be the solution to the quest for early detection of lymphoedema and hence its selection for this study.

In a study conducted by Brown et al. (2013a), 35% of cancer survivors reported at least one symptom in their legs or feet following completion of cancer treatment. The most common reported symptoms were achiness, puffiness, pain and difficulty walking. The study also uncovered an interesting finding of failure of previous clinical assessments to diagnose lower lymphoedema in 18% of the patients; this further emphasises the significance of self-report data in the diagnosis of lymphoedema.

Armer and Stewart (2005), assessed upper limb lymphoedema due to breast cancer using four methods, 200ml limb volume change using perometry, 10% limb volume change as measured by perometry, 2cm change in arm circumference as measured by tape and patients' report of heaviness and swelling of the arms. The study found lymphoedema incidences to differ significantly, 42%, 21%, 70% and 40% respectively, according to each assessment criteria used, which led to the conclusion that the most conservative criteria for defining lymphoedema was a 10% limb volume change, with a 2cm limb circumferential change being the most liberal.

2.5.2 The onset, incidence and risk factors of lower limb lymphoedema

Variations exist in the onset time for lower limb lymphoedema, with clinical symptoms presenting as early as six months to late presentation of three years or more after primary treatment (Deura et al., 2015). Lindqvist et al. (2017), attributes these variations to the complex pathophysiology of lymphoedema, which seems to be more than just a simple obstruction of lymphatic pathways, but involving a sequence of events after cancer treatment. The authors further assert that the

occurrence and magnitude of lymphoedema may vary significantly in patients with a similar extent of lymphadenectomy, making predictions for the occurrence of lymphoedema almost impossible. Kim et al. (2012a) link the variations that exist in the incidence of lower limb lymphoedema presented by different studies, to lack of homogeneity in the participants, treatment procedures and diagnostic techniques, while Mendivil et al. (2016) claim that underreporting, divergent surgical approaches, timing of assessment, measurement and co-morbidities are attributable to these discrepancies.

Vulvar cancer, though generally uncommon, seems to have the highest incidence of lower limb lymphoedema, ranging between 30% and 70% (Ki et al., 2016, Novackova et al., 2012). Vulvar cancer associated lower limb lymphoedema often includes the genitals and mons pubis and factors associated with this have been investigated with inconsistent results (Biglia et al., 2017). Lower limb lymphoedema was frequently associated with the occurrence of early complications, such as early wound break down and infection (20%-40%), while postoperative radiation, lymph node metastases and age above 65 were not significant predictors of lower limb lymphoedema (Gaarenstroom et al., 2003). However, Gould et al. (2001), in their study, did not identify early complications as a risk factor for lower limb lymphoedema development, as the incidence rate was not significantly different between single, combination or sequential treatment modalities. Novackova et al. (2012) and Berger et al. (2015), in their studies, found a greater association of higher incidence of vulvar cancer associated lower limb lymphoedema with inguinofemoral lymphadenectomy.

Cervical cancer, the most prevalent gynaecological cancer worldwide, is associated with the second highest incidence of lower limb lymphoedema. In a study by Kim et al. (2012a), on the incidence and risk factors of lower limb lymphoedema following cervical cancer treatment, 12.6% (75) of their 596 respondents had lower limb lymphoedema, 42.7% of which were diagnosed within a year and 78.3% within three years after primary treatment. A higher cervical cancer associated lower limb lymphoedema incidence (20.0%) was found in another study (Ohba et al., 2011) and several studies found a significant association between adjuvant radiotherapy and development of lymphoedema (Kim et al., 2012a, Lind et al., 2011)

Beesley et al. (2015), in their study on uterine cancer associated lower limb lymphoedema, recorded a 13% incidence, with the median diagnoses made at seven months following surgery. This was consistent with the results of a review study by Lindqvist et al. (2017), which found uterine cancer associated lower limb lymphoedema ranging between 0% and 50%, with the highest incidence associated with lymphadenectomy, particularly dissection of the circumflex

iliac nodes; pelvic radiotherapy also proved to be an independent contributor to high lymphoedema incidence (Todo et al., 2015).

The prevalence of lower limb lymphoedema among patients treated for ovarian cancer in one study was 10.3%, 65.4% of which were diagnosed within the first year after primary treatment (Ki et al., 2016). The number of pelvic lymph nodes dissected and adjuvant chemotherapy using different chemotherapeutic agents was associated with the development of lower limb lymphoedema. However, in their study, that investigated taxane-based chemotherapy on breast cancer associated lymphoedema, Swaroop et al. (2015) found no association.

It is worth noting that it is challenging to dissociate the effects of radiotherapy from those of surgery on lymphoedema development, as very few studies offer a detailed description of radiation as part of the treatment for gynaecological cancer. Even though it is thought to augment the effects of surgery on the lymphatic system, it remains very difficult to delineate radiotherapy's contribution to lymphoedema genesis (Shaitelman et al., 2015). Other factors found to be associated with lymphoedema occurrence are obesity and a higher number of lymph nodes dissected (Achouri et al., 2013, Beesley et al., 2015, Mendivil et al., 2016, Beesley et al., 2007).

2.5.3 Prevention of lower limb lymphoedema

According to Covens et al. (2015), sentinel lymph node biopsy is an option to reduce the risk of lower limb lymphoedema. The sentinel lymph node, which is the first regional node that drains directly from the tumour, is the first one to receive lymph borne metastatic cancer cells and if this lymph node is negative of metastatic cancer cells, then it should follow that the rest of the nodes in the lymphatic basin will also be negative (Ennik et al., 2011). This prevents unnecessary dissection of lymph nodes and reduces post-operative morbidity that includes lymphoedema. However, Hassanzade et al. (2013) warn that caution should be exercised for midline tumours as unilateral sentinel node detection can lead to false negative results for metastatic disease in the opposite side. Lymph node dissection in such instances becomes imperative.

In their systematic review, Sanghani et al. (2009) found that axillary lymph node dissection for breast cancer patients does not necessarily offer any survival benefit when compared to no dissection for patients with negative sentinel lymph nodes. The American College of Surgeons Oncology Group also found that no survival benefit is achieved by performing axillary lymph node dissection in patients with one or two positive sentinel lymph nodes in patients who are treated with breast conservation, whole breast irradiation and systemic therapy (Giuliano et al., 2011). The aforementioned findings evoke questions of whether lymph node dissection should

be done in the first place, and if similar trials would uncover similar findings for patients with gynaecological malignancies.

Early detection and intervention remain the main strategy for reducing lymphoedema incidence (Armer et al., 2013). Hardy (2012) emphasises the need for thorough assessment, which includes history taking and physical examination during follow up consultations of gynaecological cancer survivors. Deura et al. (2015) echo the same sentiments as some patients with Stage I lymphoedema do not notice changes in their limbs. Hardy (2012) further asserts that lymphoedema can be greatly improved and effectively controlled and managed, if reported as soon as it starts. Patients potentially at risk need to be made aware of this risk and support systems and structures should be emplaced.

2.5.4 Management of lower limb lymphoedema

The damage caused to the lymphatic vessels by cancer and its treatment is irreversible, thus making lymphoedema incurable. However symptoms can be effectively controlled and treated if it is detected before significant progression (Paskett et al., 2012). The current standard care for lymphoedema is complete decongestive therapy, which involves manual lymph drainage, compression therapy, decongestive exercises and skin care (Liao et al., 2012). Manual lymph drainage involves application of directional light pressure over the subcutaneous tissues, which results in manipulation of lymph capillaries and smooth musculature in lymph angions' walls, enhancing lymph fluid flow (Lasinski, 2013). Compression therapy uses short stretch bandages during the decongestive phase, or compression garments once decongestion is achieved to prevent lymph re-accumulation. Some of the benefits of exercise in lymphoedema include increasing the uptake of fluid by initial lymphatics and improving the pumping action of the lymph collectors. Optimal benefit is realised when compression on the affected limb is used through bandages or garments (Zuther and Norton, 2013).

The goal of complete decongestive therapy is to aid transport of lymph from the limbs and therefore reduce swelling, bringing lymphoedema to the latency stage. The therapy starts with the intensive phase of daily exercises and manual lymph drainage followed by use of multi layered bandaging to aid lymph flow. This phase continues until optimal limb volume reduction is achieved (Lasinski, 2013). Skin care also forms an important part of the therapy, while bandages are replaced with compression garments in the maintenance phase and only used at night (Zuther and Norton, 2013).

Many studies have reported up to 73.4% reduction in excess volume depending on the different stages of lymphoedema and number of complete decongestive therapy sessions attended. In a study conducted in Taiwan, 66 patients who had developed lower limb lymphoedema after

gynaecological cancer treatment, underwent complete decongestive therapy (Liao et al., 2012). The study documented a significant percentage reduction from a baseline percentage excess volume of 32.9% to 18.8% and a reduction from moderate to mild lymphoedema after decongestive therapy, indicating the efficacy of this therapy. The study also revealed that receipt of radiotherapy as part of cancer treatment does not affect the efficacy of complete decongestive therapy.

Complete decongestive therapy also proved favourable over micro lymphatic surgery in a study by Maegawa et al. (2012). The main goal of such surgery is to form conduits between the lymphatic system and the venous system to facilitate return of fluid into venous circulation. Patients with moderate to severe lower limb lymphoedema underwent preoperative complete decongestive therapy and when their legs' circumferential measurements reached a plateau, they underwent lymphatico-venous anastomoses procedure. This surgical procedure achieved a mere 2% (100ml) reduction in limb volumes as opposed to 11% (600ml) achieved through complete decongestive therapy. The study revealed short stretch bandaging to be more effective than compression stockings, even though compression stockings are favoured for their convenience (Maegawa et al., 2012).

Early instigation of complete decongestive therapy can prevent lymphoedema associated complications, such as cellulitis, lymphorrhea and infections (Lasinski, 2013). In their study, which examined the influence of a comprehensive approach to management of lymphoedema incorporating the use of complete decongestive therapy on the rate of hospitalisation for recurrent cellulitis in patients with lymphoedema, Arsenault et al. (2011) found the therapy effectively prevented recurrent cellulitis in the affected limbs, subsequently eliminating the need for hospitalisation.

Positive results were realised in another study that sought to investigate the long-term effect of complete decongestive therapy on lower limb lymphoedema, comparing the distal and proximal part of the leg. The reduction in limb volume was 28.6% after the intensive decongestive phase of the complex decongestive therapy that lasted for two weeks. The participants were followed up at three, six, 12 and 24 months during the maintenance phase and 24.9%, 23.8%, 17.2% and 19.5% lymphoedema volume reduction, respectively, was obtained. The study also revealed significant lymphoedema volume reduction ($p < 0.01$) for the distal leg and whole leg contrary to the insignificant difference in the proximal part of the leg, indicating that management of lymphoedema in the proximal part is more challenging (Kim et al., 2012b).

Skin care forms an important part of the complete decongestive therapy, the sole purpose being prevention of skin breakdown as much as possible. If the aforementioned goal is not achieved and lymphoedema wounds develop, then the wound bed moisture balance and bacterial colonisation control become paramount for effective wound healing. Randomised control trials conducted to determine the efficacy of certain dressing products consistently found that correcting the causative factors of ulcer formation, such as pressure or oedema, was more important than choosing a particular dressing product (Fife et al., 2017).

Even though evidence points to complete decongestive therapy as the standard of care, factors such as lack of expertise to offer the service, its tendency to be labour intensive and cost prohibitive often mars its utilisation (Rodrick et al., 2014). Therefore, exploring ways of abating such challenges and/or considering adjunctive treatment approaches, including modalities to augment complete decongestive therapy is important.

Advanced Stage III lymphoedema, known as lymphostatic elephantiasis, sometimes requires reductive surgical procedures. However, post-surgical complications, such as adipose tissue necrosis, wound dehiscence and infection, are often eminent. Kiefer et al. (2016) investigated the use of complete decongestive therapy peri-operatively to reduce the risks of surgical related complications in patients with Stage 3 lower limb lymphoedema, and found favourable results; patients in the intervention group experienced fewer complications than their counterparts in the control group. However, integration of the complete decongestive therapy failed to prevent blood loss, which Kiefer et al. (2016) attributed to the high amount of tissue excised in the intervention group.

Low-level laser therapy has also been used in lymphoedema management. Low laser therapy is the use of energy in the spectrum of light to create biochemical changes in injured tissues, which result in anti-inflammatory, analgesic and regenerative effects (Rodrick et al., 2014). It is postulated to help in softening scar tissue by affecting fibroblasts and reducing interstitial fluid through stimulation of the lymph flow, lymphangiogenesis and macrophages activity (Bracciano and Bracciano, 2008). In a study that evaluated the use of low level laser therapy in managing breast cancer related lymphoedema, measurable physical improvement, as well as improvement in subjective pain scores, was achieved (Dirican et al., 2011). The study also discovered that repeated cycles of low-level laser therapy led to more significant lymphoedema reduction as opposed to only one cycle. Ridner et al. (2013) found significant improvement in symptom burden with the use of concurrent low-level laser therapy and complete decongestive therapy.

No drug therapy has been shown to be effective against lymphoedema. Diuretics may offer temporary reduction in the oedema, however their long-term use may potentiate fluid and electrolytes derangement. Even though benzopyrones and other flavonoids increase macrophages activity, and theoretically reduce proteins in the interstitium, they have been found to be ineffective in treating lymphoedema and are associated with hepatotoxicity (Harris et al., 2012).

Physical activity, conversely, may help reduce the severity of lower of lower limb lymphoedema. Brown et al. (2013b) examined the association of physical activity, walking specifically, with lower limb lymphoedema and discovered favourable outcomes for the respondents who engaged in more physical activity, as they experienced relatively fewer symptoms. Among uterine cancer survivors who participated in the highest level of physical activity or walking, there were 69% and 81% reduced odds of reporting lower limb lymphoedema comparative to those who took part in the lowest level of physical activity respectively. These positive results were more inclined to participants who had a body mass index less than 30. Based on such findings it is reasonable to include a physical activity programme in the discharge plan of gynaecological cancer patients after radiotherapy.

2.5.5 Effects of lower limb lymphoedema

The chronic nature of lower limb lymphoedema affects various aspects of patients' lives, including the psychosocial aspect, which this study seeks to elicit in the South African context. Physical consequences include swelling, heaviness, tightness, pain, fatigue and recurrent infection and inflammation (Meiklejohn et al., 2013).

In their study, Dunberger et al. (2013) found lower limb lymphoedema to have an effect on overall quality of life, sleep and daily life activities among gynaecological cancer survivors. Not only did these survivors have to deal with lower limb lymphoedema, but occasional faecal and urinary incontinence as well. Survivors with lower limb lymphoedema avoided exercise, social activities, such as going to the cinema, and avoided meeting friends. Only 31% of these survivors actively sought health care for lymphoedema.

Low quality of life scores among gynaecological cancer survivors were also recorded in another study by Kim et al. (2015). Lower limb lymphoedema had profound physical impact on the survivors, ranging from difficulties in walking, pain, swelling and heaviness as observed in other studies (Dunberger et al., 2013, de Melo Ferreira et al., 2012). Survivors with lymphoedema also had more financial difficulties than did their counterparts in the control group. Even though this was not further explored, Kim et al. (2015) cite the possibility of not being able to continue with employment for this group as the reason for the struggle with finances.

Shaitelman et al. (2015) also alluded to the fact that functional wellbeing is often affected by gynaecological cancer associated lymphoedema. Of the 616 survivors that participated in the survey, 221 (36%) reported to have lymphoedema and lower overall quality of life scores, when compared to their counterparts who did not have lymphoedema. They also had trouble with sleeping and had an increased urgency to void, a finding consistent with that of Dunberger and colleagues (2013).

Progression of untreated lower limb lymphoedema results in massive limb swelling, which does not only affect the patients psychologically, but also physically because of the high rate of catastrophic associated infections. Inflammation of the skin and soft tissues potentiates dramatic permanent cutaneous changes that result in physical disfigurement of the affected limb (Fife et al., 2017). Lymphoedema has been identified as the most prominent risk factor for cellulitis (Binas et al., 2011). In their study among patients with cellulitis, Fife et al. (2017) found lower limb lymphoedema and pre-existing ulceration as the factors that identified patients at high mortality risk. Similarly, lymphoedema-related cellulitis led to septic shock in one patient, according to a case report by Connor and Gamelli (2009), while McGilvray (2013) warns that cellulitis might prompt halting of components of the complete decongestive therapy programme, such as the manual lymph drainage, leading to more fluid reaccumulation in the interstitium and subsequent worsening of lymphoedema.

Fife and colleagues (2017) criticised the financial costs caused by lymphoedema-associated wounds because of frequent clinic visits that are tantamount to lost time at work. They cite one British case report, which estimated the long term cost related to nursing and home care alone for a patient with draining ulcers to be at £260 000, or R4 406 779.66 in 2017. This cost goes even higher when hospitalisation costs are considered.

Women with lower limb lymphoedema are also more likely to experience some form of depression and anxiety, worry about cancer recurrence and possibly interpret lower limb lymphoedema symptoms as indicative of cancer recurrence (Dunberger et al., 2013). Lymphoedema is also linked to emotional distress and limitations in performing activities of daily living and is bound to affect the survivors self-concept and lead to loss of intimacy with their partners (de Melo Ferreira et al., 2012). Of the 66% respondents that had symptoms of lower lymphoedema, 68.6% expressed a feeling of sadness, while 67.3% expressed loss of body confidence (Stolldorf et al., 2016).

2.6 SUMMARY

This chapter gave an overview of cancer in general, followed by gynaecological cancer globally, regionally and locally. Treatment of gynaecological cancer, its effects on the lymphatic system and subsequent development of lower limb lymphoedema were also presented. The researcher gave a detailed account of literature reviewed on the diagnosis, risk factors, incidence, management and effects of lower limb lymphoedema. The next chapter will describe the research design and methods.

CHAPTER 3

RESEARCH DESIGN AND METHODS

3.1 INTRODUCTION

Chapter 2 presented an account of the literature reviewed on cancer and gynaecological cancer associated lower limb lymphoedema. This chapter presents the setting, research design and methods. The methods discussed include the population and selection of the sample, data collection, data analysis and the reliability and validity of the instrument.

3.2 RESEARCH DESIGN

A research design is a plan that describes how, when and where data are to be collected and analysed (Burns and Groove, 2011). A quantitative cross sectional survey design was used for the study. Quantitative research is a systematic process used to gather and statistically analyse information as measured by an instrument, using concepts that can be measured and turned into numbers (Polit and Beck, 2012). (Brink et al., 2012) postulate that cross sectional studies are done at a specific point in time and that surveys allow data to be collected from a sample to determine the characteristics of a population. A cross sectional survey suited this study as it allowed the researcher to collect data from a relatively large sample, within the time-frame given. The researcher was also able to estimate the characteristics of the study population without collecting data from the entire target population.

3.3 SETTING

The study setting refers to the specific place or places where the data are collected (Brink et al., 2012). The study was conducted at the Department of Radiation Oncology, which forms part of an academic hospital in Johannesburg, South Africa. This hospital hosts 1088 beds and serves as a referral hospital for other hospitals in its catchment area. It also serves as clinical training platform for a renowned university in South Africa. The hospital provides an array of highly specialised tertiary healthcare services such as cardiac surgery, neurosurgery and cancer management, among others.

The Radiation Oncology Department, offers radiation and chemoradiation oncology services to patients from all over Gauteng. It houses four major clinics: head and neck, gastro-intestinal tract, breast and gynaecological clinics. The patients with other types of cancers are consulted in some of these clinics, for instance, patients with neurological cancers are managed at the gynaecological clinic, while those with prostate and skin cancers are followed up at the gastro-intestinal tract clinic. The department operates with four linear accelerators, a Cobalt 60 and an

orthovoltage machine for external beam radiotherapy. Brachytherapy is available but limited to cancers of the cervix and uterus. Cancers such as cervical, colorectal, head and neck and vulvar are treated with concomitant chemotherapy, administered within the department.

The gynaecological clinic, where the study's focus was, receives and treats approximately 900 patients diagnosed with gynaecological cancer, predominantly cancer of the cervix, annually (Lohlun et al., 2015). The patients present to the department daily from home, interim home centres, other hospitals or wards within the hospital. They are evaluated at least once a week by the Oncologist during the treatment course, to elicit any associated toxicities. Upon completion of the full radiotherapy course, patients are reviewed periodically for five years, after which they are referred to their local healthcare facilities.

3.4. RESEARCH METHODS

Research methods refer to techniques used to provide structure for the study and gather and analyse data pertinent and relevant to that study (Polit and Beck, 2012). The techniques include selection of population and sample, as well as data collection and analysis techniques.

3.4.1 Population

A population is the entire group of people that is of interest to the researcher (Burns and Groove, 2011). The population consisted of all women who received treatment for gynaecological cancer at the specific academic hospital's radiation oncology department (N = 900).

3.4.2 Sample and Sampling

(Brink et al., 2012) define a sample as a subset of the population that is selected to represent the population, and sampling as the process of selecting the sample from a population.

Convenience sampling, which involves the selection of willing and readily available people to participate in the study (Brink et al., 2012), was used. This sampling method was appropriate as the sample included women who reported for follow up care. Women who were 18 years and older, having been diagnosed with gynaecological cancer and were at least twelve months but not more than 24 months after completing radiotherapy, were eligible for the study.

A calculated sample size was used. A study by Kim et al. (2012a) investigating the incidence and risk factors of lower extremity lymphoedema after surgery with or without adjuvant radiotherapy served as a reference for the calculation of the sample size. In the aforementioned study, the percentage of respondents who experienced symptoms of lower limb lymphoedema 13 to 24 months after initial treatment was 27. The current study also included respondents who were at least twelve months but not more than twenty four months after completion of radiotherapy.

Therefore, 27% was used as the expected lower limb lymphoedema prevalence or incidence. The sample size calculated using the Fisher's Sample Size formula:

$n = Z^2 \times (P) \times (1-P) / d^2$ where:

Z is a constant; **1.96** for 95% confidence interval

P is the expected prevalence or incidence of lower limb lymphoedema

d is the margin of error set at **7%**.

$$n = 1.96^2 \times 0.27 \times 0.73 / 0.07$$

$$n = 155$$

155 was therefore accepted as the sample size.

3.4.3 Data Collection and instrument

Data collection is the gathering of information to address a research problem, while research instruments are tools designed to obtain that information (Polit and Beck, 2012). Structured interviews and limb volume measurements were used for data collection.

The Gynaecological Cancer Lymphoedema Questionnaire (GCLQ) developed by Professor Jane Armer, was used for data collection with permission (Appendix 1). A validation study found this instrument to have an internal consistency reliability score of 0.95 (Carter et al., 2010). The instrument's first section comprised 20 questions on lymphoedema signs and symptoms, and seven on the effects that lymphoedema had on the respondents' mood, lifestyle, time, finances, body image and relationship with the physician or specialist. The last seven questions were answered only if the respondents responded positively to having experienced swelling in either the leg, foot, hip or lower body after the first cancer treatment, or to having been diagnosed with lymphoedema. The second section developed by the researcher, collected data on lower limb circumference measurements, limb volumes and stemmer signs. The third section, also developed by the researcher, collected data on respondents' demographics, including data on respondents' age, cultural group, place of residence, education level and occupation, type of gynaecological cancer, stage of the disease, date and type of treatment received and any comorbidities as reported by the respondents. Body weight and height, which are routinely assessed in the department, were also recorded in this section after which body mass indices were calculated (Appendix 2).

Data collection plan and procedure

Once approval to conduct the study had been obtained from the hospital and the University of the Witwatersrand Human Research Ethics Committee (Appendix 7), the researcher approached the Radiation Oncology head of department and operational manager to discuss the study and obtain their support.

Women who were at least twelve months but not more than 24 months after completion of radiotherapy, and had reported for follow up at the academic hospital's gynaecologic clinic every Tuesday, were approached for possible inclusion in the study. After verification of the date of treatment completion, prospective respondents were individually taken to a room designated for the study, before their scheduled consultation by the medical doctors or oncologist. The purpose of the study was explained to the women recruited and patient information sheets were handed to them to enhance their understanding (Appendix 3). Consent forms were signed if they agreed to take part in the study and returned to the researcher (Appendix 4).

The researcher, who had received prior training on lymphoedema assessment, then conducted the structured interviews for each respondent. Using a non-stretch measuring tape, the researcher took circumference measurements on both lower limbs at predetermined points, starting with midfoot, ankle and then proceeding proximally at 10cm intervals, ensuring at least two measurements were taken above the knee. The measurements were carefully recorded in the instrument from which volumes of the limbs were calculated using Excel. The volume of each segment was calculated using the formula;

$$\text{Volume of segment} = L(C_t^2 + C_t C_b + C_b^2)/12\pi$$

Where L is segmental length, C_t and C_b are circumferences at the top and base of the segment, and π is 3.142.

The sum of all segments gave the volume measurement of the leg. A 200ml volume discrepancy between the limbs indicated presence of lymphoedema.

Stemmer sign, which is positive if the skin on the dorsum of the toes cannot be lifted due to lymphoedema, was also assessed for and results recorded. The data collection process for each respondent took approximately 15 minutes and each questionnaire was assigned a number (code) and placed in an envelope upon completion. Data was collected between September and November 2017, until the sample size was realised.

3. 5 DATA ANALYSIS

Data analysis entails exploration, organisation and description of raw data in more meaningful terms (Brink et al., 2012), while Polit and Beck (2012) define it as the systematic organisation and synthesis of research data.

All completed questionnaires were numbered sequentially and placed in an envelope. Data from the questionnaires were entered onto an Excel spreadsheet and STATA (version 14) statistical software package used for analysis. Descriptive statistics were used to report the results.

Descriptive statistics are used to describe and summarise data, thus rendering it more meaningful, as they condense data into various organised meaningful visual presentations (Brink et al., 2012).

Pearson's Chi-square test (X^2), defined by (Brink et al., 2012) as a non-parametric statistical test used to compare data sets that are in the form of frequencies or percentages, was used to test for statistical significance between categorical variables. Fisher's exact test was used when expected table cells values were less than 5, whilst T-tests compared continuous variables. The statistically significant level of significance was set at p-value less than 0.05.

Quantitative content analysis is a set of procedures for systematic replicable analysis of a text and it provides structure to data that are open-ended and unstructured (Canhoto et al., 2014). Quantitative content analysis was used for the third objective on psychosocial effects of lower limb lymphoedema based on the data obtained through open-ended questions. The responses were grouped into emerging themes after literature review and descriptive statistics i.e. frequency tables used to summarise the findings.

3.6 VALIDITY AND RELIABILITY

Validity is defined as the ability of the instrument to measure what it is supposed to measure (Brink et al., 2012), while Burns and Groove (2011) define reliability as the extent to which an instrument can yield the same results with its repeated use over time. To enhance content validity a validated questionnaire, the Gynaecological Cancer Lymphoedema Questionnaire, was used. The researcher was trained to take the leg measurements and conduct structured interviews beforehand, which ensured accurate data collection. Moreover, the structured interviews were conducted and leg measurements taken solely by the researcher, which optimised the level of consistency. Data was accurately recorded on the spot as the respondents gave their responses to questions.

A pretest, described by Burns and Grove (2010) as the smaller version of the proposed study was conducted with five respondents. This allowed the researcher to gain insight into the

respondents understanding of the instrument and to evaluate the process of lymphoedema assessment through leg measurements.

3.7 ETHICAL CONSIDERATIONS

The Health Professions Council of South Africa guidelines on ethics, HPCSA (2008), which are respondents right for autonomy, confidentiality and non-maleficence, were followed during the study.

Autonomy

Autonomy refers to obligations to acknowledge that people have the right to make choices and act according to their values and beliefs (Geyer, 2013). Respondents' right to self-determination, protection of their wellbeing and their right to fair selection and treatment during the study were ensured. Information about the study was availed to all respondents through information sheets that had details regarding the study. Participation was purely voluntary and respondents were asked to give written consent.

Confidentiality

The respondents' right to confidentiality and anonymity was also observed. Only codes or numbers were used on the instrument, therefore respondents' identity could not be linked to their responses. Data collected were stored in a password protected computer accessible to the researcher and her supervisor only, without disclosure of data to unauthorised persons. A room was designated for the structured interviews and limb circumference measurements to ensure privacy.

Non- maleficence

Non-maleficence simply means not doing harm to others (Geyer, 2013). If respondents expressed signs of physical discomfort during leg measurements, respondents could sit while measurements were taken. None of the respondents exhibited signs of emotional distress therefore no referrals were made to the counsellor. Meanwhile, the respondents who had symptoms suggestive of lower limb lymphoedema were referred to the academic hospital's Physiotherapy Department through the medical team.

Permission to conduct the study

The proposed study was first presented to the Nursing Department for peer review and to the Assessors Committee of the School of Therapeutic Sciences. Permission to conduct the study was obtained from the Director of the Department of Health of the Gauteng Province, the Chief Executive Officer of the academic hospital, Clinical Head and Nursing Unit Manager in the Department of Radiation Oncology of the chosen academic hospital, as well as the University of the Witwatersrand Human Research and Ethics Committee.

3.8 SUMMARY

In this chapter, the researcher presented the research design and methods. The research design, research setting and research methods, study population, sample and sampling, data collection and data analysis were discussed. The researcher also discussed the instrument and its validity and reliability, and concluded by presenting the ethical considerations of the study. The next chapter will present the results of the study.

CHAPTER 4

RESULTS OF THE STUDY

4.1 INTRODUCTION

The previous chapter presented the study's research design and methods. In this chapter, the results and analysis thereof are presented.

4.2 SOCIO-DEMOGRAPHIC DATA

The ages of the respondents ranged from 29 to 80 years, with a median of 49 and mean of 49.5 years ($SD \pm 10.84$). The sample comprised mainly of respondents from the Zulu and Sotho cultural groups (34.8%; $n=54$) and (18.7%; $n=29$), respectively, while the Tsonga and Venda cultural groups accounted for the least percentage, 1.3% ($n=2$) each. The majority of the respondents were literate, with 54.2% ($n=84$) having attained secondary education and only 2.6% ($n=4$) never having been to school. A higher proportion was unemployed (57.4%; $n=89$), while those who were employed mainly worked as domestic workers (8.4%; $n=13$). Most respondents (92.9%; $n=144$) resided in urban areas. The socio-demographic characteristics of the respondents are presented in Table 4.1.

Table 4.1 Socio-demographic data (n = 155)

Criteria	N	%
Age group		
20-29	1	0.6
30-39	30	19.4
40-49	52	33.5
50-59	42	27.1
60-69	24	15.5
70-79	5	3.2
80-89	1	0.6
Cultural Group		
Zulu	54	34.8
Sotho	29	18.7
Tswana	16	10.3
Pedi	9	5.8

Ndebele	3	1.9
Xhosa	17	11.0
Afrikaans	6	3.9
Tsonga	2	1.3
Venda	2	1.3
Non-citizen	17	11.0
Education Level		
Never been to school	4	2.6
Primary School Education	57	36.8
Secondary School Education	84	54.2
Tertiary Education	10	6.5
Occupation		
Unemployed	89	57.4
Pensioner	11	7.1
Self-employed	11	7.1
Domestic Worker	13	8.4
Cleaner	5	3.2
Shop Assistant	4	2.6
Clerk	3	1.9
Security Guard	1	0.6
General Worker	3	1.9
Hairdresser	5	3.2
Administration	4	2.6
Field Marketing	1	0.6
Teaching	1	0.6
Pharmacy Assistant	1	0.6
Part time Employment	3	1.9
Place of Residence		
Urban	144	92.9
Rural	11	7.1

4.3 CLINICAL HISTORY OF THE RESPONDENTS

The body mass indices for the respondents ranged from 16.1 to 49.2, with a mean of 27.6 (SD; ± 6.92) and a median of 26.8. More than one third of the respondents (35.5%; n=59) were obese (body mass index ≥ 30.0) and 29.9% (n=46) were overweight (body mass index $25 \leq 29.9$). The human immunodeficiency virus (HIV) was the most commonly reported comorbidity (48.4%; n=75), 20% (n=31) of the respondents had hypertension while an additional 7.1% (n=11) had both HIV and hypertension. One respondent (0.6%) reported having a kidney disease, while 23.2% (n=36) reported no known comorbidities. Cervical cancer accounted for the largest proportion of the reported cancer diagnoses (87.7%; n=136), while vulvar and uterine cancers followed with 6.5% (n=10) and 5.8% (n=9) respectively. The majority of the sample reported having been diagnosed with Stage II cancer (53.5%; n=83), 39% (n=61) had Stage III and only one respondent (0.6%) presented with Stage IV disease. All respondents indicated having undergone surgery for diagnostic purposes, while 3.4% (n=5) reported having had a total abdominal hysterectomy. More than half of the sample received chemotherapy (65.2%; n= 101), whilst 34.8% (n=54%) did not. All respondents (100%; n=155) received radiotherapy; 98.1% (n=152) had received external beam radiotherapy while 1.9% (n=3) received brachytherapy only. Less than 10% of the respondents (6.5%; n=10) did not receive brachytherapy. In 2016, 61.3% (n=61.3) of respondents were treated, and 38.7% (n=60) in 2015. Table 4.2 gives a summary of the clinical history of the respondents.

Table 4.2: Respondents' clinical history (n=155)

Criteria	n	%
Body Mass Index (kg/m²)		
Underweight <18.5	5	3.2
Normal weight 18.5 - 24.9	49	31.6
Overweight 25 - 29.9	46	29.7
Obese ≥ 30.0	59	35.5
Comorbidities (Reported)		
HIV	75	48.4
Hypertension	31	20
HIV & Hypertension	11	7.1
Renal disease	1	0.6
Arthritis	1	0.6
None	36	23.2

Gynaecological Cancer		
Cervix	136	87.7
Uterus	9	5.8
Vulva	10	6.5
Stage of the Disease		
Stage I	10	6.5
Stage II	83	53.5
Stage II	61	39.4
Stage IV	1	0.6
Treatment Received		
Surgery (Biopsy)		
Yes	155	100
No	0	0
Hysterectomy		
Yes	5	3.2
No	150	96.8
Chemotherapy		
Yes	101	65.2
No	54	34.8
Radiotherapy (External beam radiotherapy)		
Yes	152	98.1
No	3	1.9
Radiotherapy (Brachytherapy)		
Yes	145	93.5
No	10	6.5
External beam radiotherapy and brachytherapy		
Yes	141	91.0
No	14	9.0
Year of Treatment		
2015	60	38.7
2016	95	61.3

4.4 EXPERIENCES WITH MOVEMENT AND THE USE OF THE LEG

When the respondents were asked if they had limited movement of the hip, knee, ankle, foot or toes, the highest percentage (41.3 %; n=64) indicated they experienced limited movement of the hip now, while 18.1% had experienced this symptom during the past year. The respondents' experiences with movement, use and sleep are presented in Table 4.3. It should be noted that (n) might be over 155 as some respondents responded positively to both options under now and during the past year.

Table 4.3 Experiences with movement, use and sleep now and during the past year (n=155)

Criteria	Now		During the past year	
	N	%	n	%
Limited movement of the hip				
Yes	64	41.3	28	18.1
No	91	58.7	127	81.9
Limited movement of the knee				
Yes	38	24.5	21	13.5
No	117	75.5	134	86.5
Limited movement of the ankle				
Yes	37	23.9	21	13.5
No	118	72.1	134	86.5
Limited movement of the foot				
Yes	41	26.5	25	16.1
No	114	73.5	130	83.9
Limited movement of the toes				
Yes	23	14.8	18	11.6
No	132	65.2	137	88.4
Weakness of the leg or foot				
Yes	37	23.9	22	14.2
No	118	76.1	133	85.8

Respondents who reported having limited movement of various parts of the leg (n=97) were asked to give a further description of the experience and the majority linked this to pain, and that it had affected their functionality in various daily activities. The majority of the respondents indicated having experienced limited movement of the hip, which made it difficult for them to walk (44.3%; n=43). Cramps, swelling and distorted sensation were also cited as reasons for restricted movement of the leg. Table 4.4 gives detailed descriptions of the respondents' experiences of limited leg movement.

Table 4.4 Description of the experience of limited leg movement (n=97)

Criteria	Description	Now		During the past year		Total	
		n	%	n	%	n	%
Limited movement of the hip (n=92)	Experienced hip pain, which made it difficult to walk.	32	33.0	11	11.30	43	44.3
	Experienced hip pain, which made it difficult to bend.	18	18.6	11	11.3	29	29.9
	Experienced hip pain, which made it difficult stand for a long time.	5	5.2	3	3.1	8	8.2
	Experienced hip pain, which made turning in bed difficult.	2	2.1	2	2.1	4	4.3
	Experienced limited movement of the hip due to swelling.	3	3.1	1	1.1	4	4.3
	Experienced limited movement of the hip due to stiffness.	2	2.1	0	0	2	2.2
	Experienced limited movement of the hip due to occasional cramps.	2	2.1	0	0	2	2.2
Limited movement of the knee	Experienced pain, making it difficult to walk.	22	22.7	12	12.4	34	35.1
	Limited movement of the knee because of swelling.	3	3.1	2	2.1	5	5.2

(n=59)	Weakness of the knees after sitting for a long time.	6	6.2	1	1.0	7	7.2
	Experienced occasional cramps or sensation distortion.	7	7.2	6	6.2	13	13.4
Limited movement of the ankle (n=58)	Swelling after sitting or standing for a long time.	15	15.5	11	11.3	26	26.8
	Limited movement of the ankle due to pain.	15	15.5	8	8.2	23	23.7
	Experienced occasional cramps or sensation distortion.	5	5.2	1	1.0	6	6.2
	Limited movement of the ankle due to stiffness.	2	2.1	1	1.0	3	3.1
Limited movement of the foot (n=66)	Experienced occasional cramps or distorted sensation.	17	17.5	11	11.3	28	28.9
	Limited movement of the foot due to pain.	16	16.5	10	10.3	26	26.8
	Limited movement of the foot due to swelling.	7	7.2	4	4.1	11	11.3
	Limited movement of the foot due to stiffness.	1	1.0	0	0	1	1.0
Limited movement of the toes (n=41)	Experienced occasional cramps or distorted sensation.	8	8.2	5	5.2	13	13.4
	Limited movement of the toes due to pain.	5	5.2	6	6.2	11	11.3
	Limited movement of the toes due to swelling.	9	9.3	6	6.2	15	15.5
	Limited movement of the toes due to stiffness.	1	1.0	1	1.0	2	2.1
Weakness of the leg or foot	Weakness linked to pain.	6	6.2	4	4.1	10	10.3
	Weakness linked to swelling.	2	2.1	1	1.0	3	3.1

(n=59)	Weakness linked to fatigue.	12	12.4	6	6.2	18	18.6
	Experienced difficulties standing from sitting position.	6	10.2	3	3.1	9	9.3
	Leg needed to be supported at times.	3	3.1	2	2.1	5	5.2
	Weakness made it impossible to walk fast.	2	2.1	2	2.1	4	4.1
	Experienced occasional stiffness.	1	1.0	1	1.0	2	2.1
	Experienced numbness of the leg or foot.	4	4.1	2	2.1	6	6.2
	Could not wear flip-flops or strapless sandals due to loss of ability to grip.	1	1.0	1	1.0	2	2.1

4.5 SYMPTOMS EXPERIENCED

Respondents were asked if they had experienced symptoms such as tenderness, swelling, redness, blistering, firmness or tightness, numbness and aching on the foot, leg, hip, groin or lower body. Almost 50% responded affirmatively to having experienced aching of the legs (47.7%; n=74), while 35.5% (n=55) experienced swelling of the legs during the past month. Some respondents indicated having experienced symptoms both during the past year and now, which may increase the value of (n) above 155 in some instances. Table 4.5 provides the details.

Table 4.5 Symptoms experienced now and during the past year (n=155)

Criteria	Now		During the past year	
	n	%	n	%
Tenderness				
Yes	56	36.1	18	11.6
No	96	61.9	137	88.4
Swelling				
Yes	55	35.5	32	20.6

No	100	64.5	123	79.4
Swelling with pitting				
Yes	22	14.2	11	7.1
No	133	85.8	144	92.9
Redness				
Yes	4	2.3	4	2.6
No	151	97.4	151	97.4
Blistering				
Yes	1	0.6	2	1.3
No	154	99.4	153	98.7
Firmness/Tightness				
Yes	28	18.1	15	9.7
No	127	81.9	140	90.3
Increased leg temperature				
Yes	51	21.3	21	13.5
No	104	78.7	134	86.5
Heaviness				
Yes	35	15.5	13	8.4
No	120	84.5	142	91.2
Numbness				
Yes	40	18.7	14	9.0
No	115	81.3	141	91.0
Stiffness				
Yes	13	8.4	10	6.5
No	142	91.6	145	93.5
Aching				
Yes	74	47.7	27	17.4
No	81	66.5	128	82.6
Hip swelling				
Yes	10	6.5	3	1.9
No	145	93.5	152	98.1
Groin swelling				
Yes	17	11.0	11	7.1

No	138	89.0	144	92.9
Pockets of fluid				
Yes	0	0	0	0
No	155	100	155	100

Respondents who indicated having experienced symptoms of the leg, foot, groin or lower body (n=126) were asked to describe the actions they took to address the symptoms. Actions taken to abate the symptoms included the use of analgesics, massaging the area, elevation of the legs and relaxation techniques. Use of analgesics was the most common intervention, with more than 40% of the respondents taking analgesics for aching legs (35.7%; n=45) and 15.1% (n=19) for tenderness. Table 4.6 gives a detailed presentation of the results.

Table 4.6 Actions for the symptoms experienced (n=126)

Criteria	Actions	n	%
Tenderness (n=62)	Massage	10	7.9
	Analgesics	19	15.1
	Exercise	4	3.2
	Relaxation	4	3.2
	Supports the part with a blanket	1	0.8
	Wears compression stockings	1	0.8
	No action	23	18.3
Swelling (n=68)	Massage	10	7.9
	Analgesics	2	1.6
	Elevation	13	10.3
	Relaxation	2	1.6
	Herbal Remedies	1	0.8
	Yet to be consulted by oncologist	8	6.3
	Wears compression stockings	1	0.8
	Use of diuretics	4	3.2
	Cold water soaks	4	3.2
	Frequent position change	2	1.6
	Wears open shoes	1	0.8

	No action	20	15.9
Swelling with pitting (n=24)	Elevation of the leg	9	7.1
	Massage	5	4.0
	Use of diuretics	4	3.2
	No action	6	4.8
Redness (n=6)	Use of topical creams	1	0.8
	No action	5	4.0
Blistering (n=2)	Use of topical creams	1	0.8
	Wears open shoes	1	0.8
Firmness or tightness (n=28)	Analgesics	6	4.8
	Massage	9	7.1
	Wears compression Stockings	1	0.8
	Exercise	1	0.8
	No action	11	8.7
Increased leg temperature (n=54)	Wears open shoes	1	0.8
	Uncovers feet at night	14	11.1
	Walks barefooted	2	1.6
	Cold water soaks	13	10.3
	Use of a fan	1	0.8
	No action	23	18.3
Heaviness (n=36)	Wears open shoes	11	8.7
	Rest	12	9.5
	Massage	1	0.8
	No action	12	9.5
Numbness (n=42)	Daily short walks	3	2.4
	Massage	7	5.6
	Elevation	1	0.8
	No action	31	24.6
Stiffness (n=14)	Wears compression stockings	1	0.8
	Relaxation	1	0.8
	Exercise	1	0.8
	Massage	5	4.0
	No action	6	4.8
Aching	Analgesics	45	35.7

(n=78)	Massage	4	3.2
	Use of heel shields	1	0.8
	Relaxation	3	2.4
	Short walks	2	1.6
	Flat and heeled shoes alternated	1	0.8
	No action	22	17.5
Hip swelling (n=10)	Analgesics	2	1.6
	Massage	3	2.4
	No action	5	4.0
Groin Swelling (n=23)	Analgesics	1	0.8
	Massage	1	0.8
	Stopped using vaginal dilators	1	0.8
	No action	20	15.9

4.6 LIMB VOLUMES

Both legs were measured and the limb volumes ranged from 3206.2 to 12942.9ml with a mean of 6007.3ml (SD; ± 1605.4) and median of 5805.4ml. The majority of the limb volumes (46.8%; n=145) were between 4001ml and 6000ml. The limb volumes are presented in Figure 4.1.

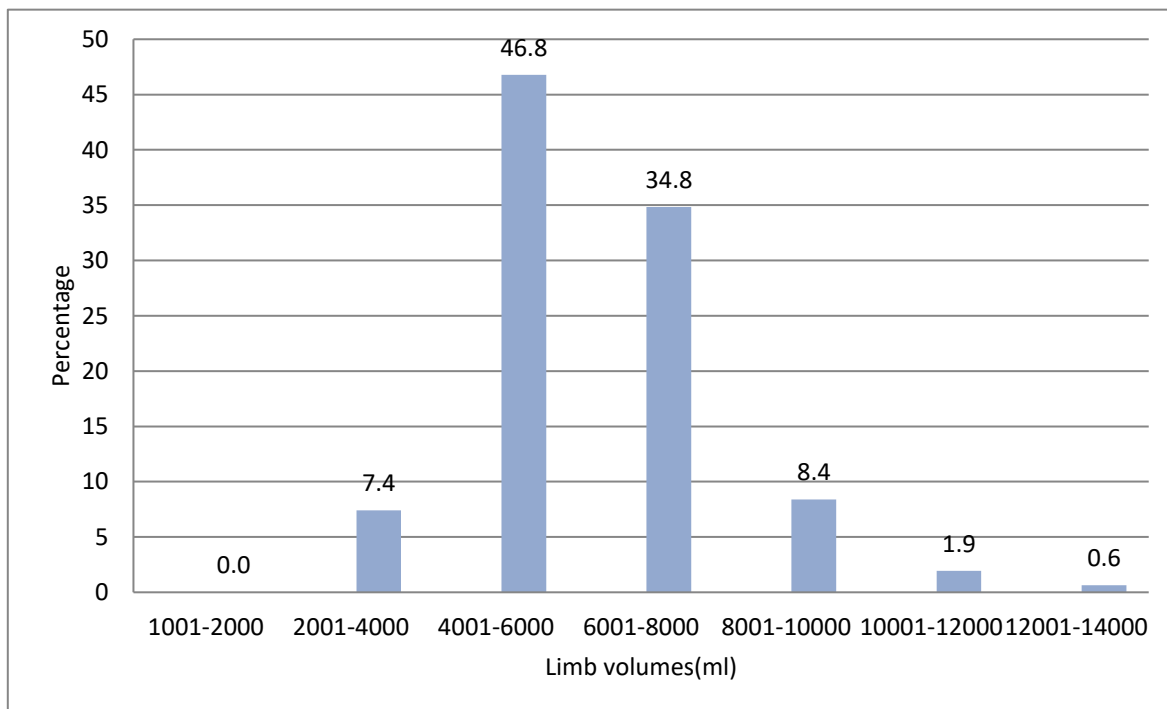


Figure 4.1 Limb volumes (ml)

When comparing the right and left lower limb volumes, inter-limb volume differences per respondent were noted and these ranged from 0.2ml to 2058.5 ml, with a mean of 213.7ml (SD; ± 292) and a median of 118.9ml. The majority of the respondents had inter-limb volume differences less than 200ml (70.3%; n=109). Figure 4.2 shows more detail of these results.

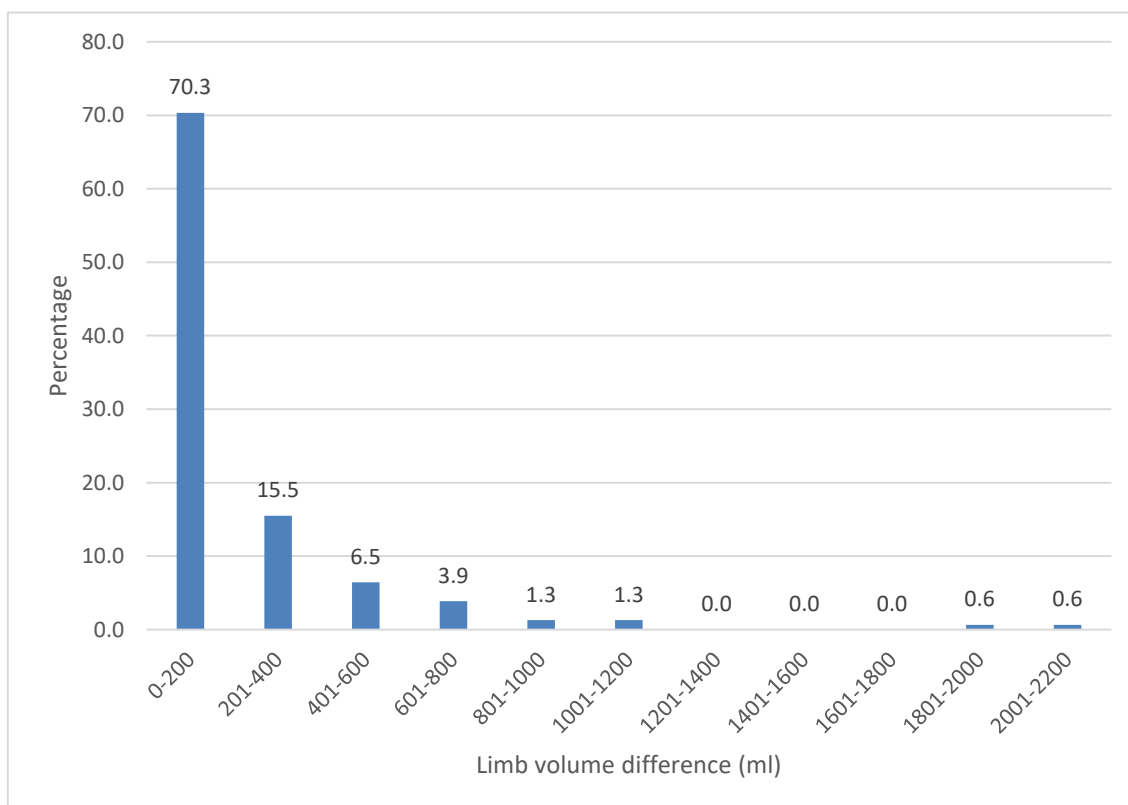


Figure 4.2 Limb volume differences (ml)

4.7 THE INCIDENCE OF LOWER LIMB LYMPHOEDEMA

Forty-six (29.7%) respondents were found to have lower limb lymphoedema through leg circumferential measurements. Most of these respondents had Stage I lymphoedema (93.5%; n=43) and the remaining 6% (n=3) had Stage II lymphoedema. Similarly, more than 90% of these respondents had mild lymphoedema (91.3%; n=42), 6.5% (n=3) had moderate lymphoedema, while 2.2% (n=1) had severe lymphoedema. Table 4.7 illustrates the details.

Table 4.7 Characteristics of lower limb lymphoedema (n=46)

Criteria	Respondents with lymphoedema	
	n	%
Lymphoedema stage		
Stage I	43	93.5
Stage II	3	6.5
Stage III	0	0
Lymphoedema grade		
Mild (<20% volume difference)	42	91.3
Moderate (20% to 40% volume difference)	3	6.5
Severe (>40% volume difference)	1	2.2
Stemmer sign		
Positive	3	6.5
Negative	43	93.5

The ages of the respondents with lymphoedema ranged from 33 years to 74 years with a mean of 47.8 years (SD; ± 9.9), and a median of 45.5 years. The average body mass index for respondents with lymphoedema was 28.04 (± 6.32), which did not significantly differ with that of those without lymphoedema. A two-sample T test indicated no statistical significance in the association between age and lymphoedema development: $t(153) = 1.3272$, $p = 0.1862$. Similarly, there was no statistical significance in the association between the body mass index and lymphoedema; $t(153) = 0.4659$, $p = 0.642$. Table 4.8 presents a summary of these results.

Table 4.8 Respondents' characteristics and lower limb lymphoedema (n=155)

Criteria	Respondents with lymphoedema				Respondents without lymphoedema				Total Sample		<i>p</i>
	n= (46)	%	Mean	SD	n= (109)	%	Mean	SD	n = 155	%	
Age			47.8	± 9.9			50.3	± 11.2			0.19
20-29 years	0	0			1	0.9			1	0.6	
30-39 years	10	21.7			20	18.3			30	19.4	
40-49 years	18	39.1			34	31.2			52	33.5	
50-59 years	13	28.3			29	26.6			42	27.1	

60-69 years	4	8.7			20	18.3			24	15.5	
70-79 years	1	2.2			4	3.7			5	3.2	
80-89 years	0	0			1	0.9			1	0.6	
Body mass index			28.0	±6.3			27.5	±7.2			0.64
Underweight	2	4.3			3	2.8			5	3.2	
Normal	10	21.7			39	35.8			49	31.6	
Overweight	16	34.8			30	27.5			46	29.7	
Obese	18	39.1			37	33.9			55	35.5	

The majority of the respondents with lymphoedema were diagnosed with cervical cancer (87.0%; n= 40), compared to 13.0% (n=6) with vulvar cancer. None of the nine respondents (n=9; 5.8%) treated for uterine cancer had lymphoedema. The Pearson's Chi square test indicated a statistically significant association between the type of gynaecological cancer and lower limb lymphoedema: ($X^2(2) = 8.2084, p= 0.017$). Table 4.9 has the details.

Table 4.9 Type of gynaecological cancer and lymphoedema (n=155)

Gynaecological cancer	Respondents with lymphoedema		Respondents without lymphoedema		Total		P
	n=46	%	n=109	%	n=155	%	
Cervix	40	87.0	96	88.1	136	87.7	0.017
Uterus	0	0	9	8.3	9	5.8	
Vulva	6	13.0	4	3.7	10	6.5	

When comparing the stage of the disease and the development of lymphoedema, it was found that a greater percentage of the respondents who developed lower limb lymphoedema had Stage II and III cancer, 45.7% (n=21) and 43.5% (n=20) respectively. A Fisher's Exact test showed no statistical significance in the association between the stage of the disease and lymphoedema: p=0.27. Table 4.10 shows the details.

Table 4.10 Stage of disease and lower limb lymphoedema (n=155)

Stage of disease	Respondents with lymphoedema		Respondents without lymphoedema		Total study sample		P
	n=46	%	n=109	%	n=155	%	
Stage I	4	8.7	6	5.5	10	6.5	0.27
Stage II	21	45.7	62	56.9	83	53.6	
Stage III	20	43.5	41	37.6	61	39.4	
Stage IV	1	2.2	0	0	1	0.7	

When comparing the treatment the respondents received with the development of lymphoedema, it was found those who developed lymphoedema (n=46; 29.7%) all received external beam radiotherapy, with or without chemotherapy. However, Pearson's Chi square test showed no statistical significance in the association between external beam radiotherapy and the development of lymphoedema: $p=0.256$. Conversely, there was statistical significance in the association between brachytherapy and the development of lymphoedema: $p=0.030$. Table 4.11 presents the details.

Table 4.11 Gynaecological cancer treatment method and lower limb lymphoedema (n=155)

Treatment	Respondents with lymphoedema		Responds without lymphoedema		Total study sample		P
	n(46)	%	n(109)	%	n(155)	%	
External beam radiotherapy and brachytherapy with/without chemotherapy							
Yes	40	87.0	101	92.7	141	91.0	0.174
No	6	13.0	8	7.3	14	9.0	
External beam radiotherapy with or without chemotherapy							
Yes	46	100	106	97.3	152	98.1	0.256

No	0	0	3	2.8	3	1.9	
Brachytherapy							
Yes	40	87.0	105	96.3	145	93.5	0.030
No	6	13.0	4	3.7	10	6.5	

4.8 EXPERIENCES WITH THE PHYSICAL FUNCTIONING OF THE LEG AMONG RESPONDENTS WITH AND WITHOUT LOWER LIMB LYMPHOEDEMA

Both the respondents who had lymphoedema (n=46) and those without lymphoedema (n=109) reported having limited movement of the hip, knee, ankle, foot or toes. Primarily, it was respondents with lymphoedema, who reported problems with the physical functioning of the leg. Twenty one (45.7%), 17 (37%), 18 (39.1%) and 11 (23.9%) of these respondents reported limited movement of the hip, ankle, foot and toes respectively while 12 (26.1%), experienced weakness of the leg or foot. Fisher's Exact bivariate analysis showed statistical significance in the association between the leg's physical function and lymphoedema: $p = 0.05$. Figure 4.3 illustrates the details.

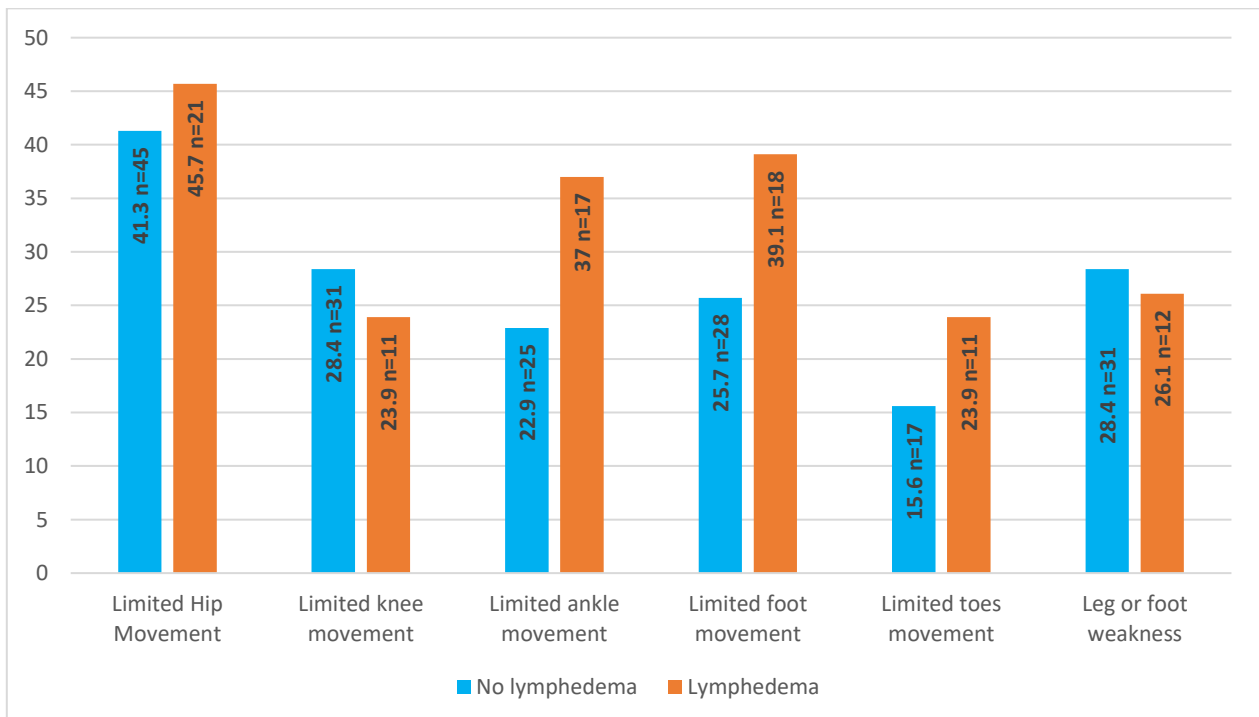


Fig 4.3 Limitations regarding movement and the use of the leg

4.9 LOWER LIMB LYMPHOEDEMA AND THE SYMPTOMS EXPERIENCED

When the respondents were asked about leg-related symptoms experienced, both those with lymphoedema (n=46) and without lymphoedema (n=109) reported mainly aching, swelling, tenderness and increased leg temperature. More respondents without lymphoedema reported these symptoms; aching (51.4%; n=56), swelling (44%; n=44), tenderness (42.2%; n=46), increased leg temperature (34.9%; n=38), contrary to 47.8% (n=22), 43.5% (n=20) and 34.8% (n=16) reported for aching, swelling and tenderness respectively by those with lymphoedema. Figure 4.4 shows the details.

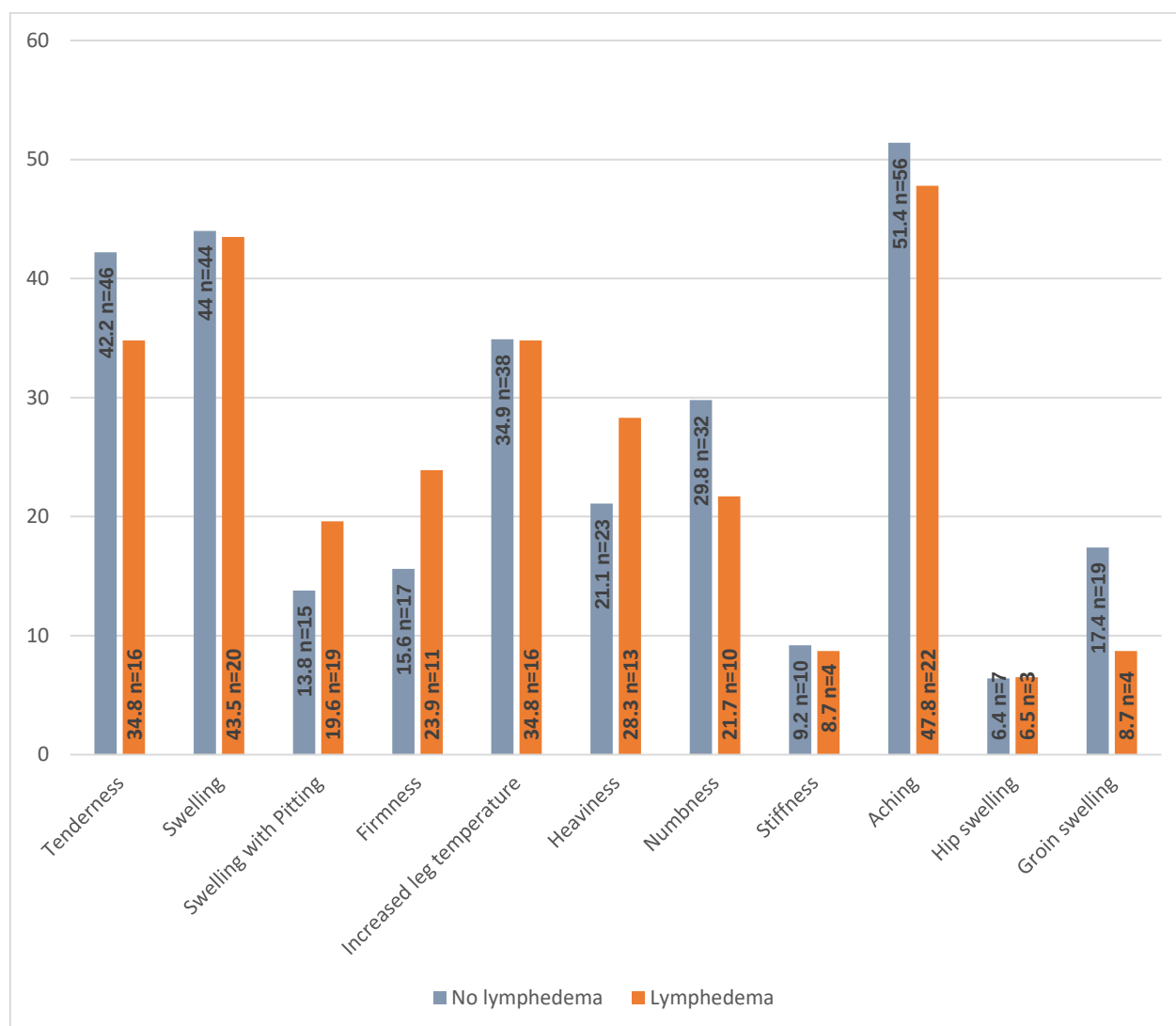


Figure 4.4 Symptoms experienced and lymphoedema

4.10. THE EFFECTS OF LYMPHOEDEMA

When the respondents who reported having experienced swelling (n=76) were asked if the symptom had changed their life in terms of mood, lifestyle, time, finances, body image, relationship to the physician and specialists, the majority indicated there had been no changes. Some respondents indicated having experienced changes primarily in their lifestyle and mood, both currently and during the past year, consequently, the number of responses obtained for both options may exceed 76. Table 4.12 presents the details.

Table 4.12 Changes in the lives of the respondents due to swelling (n=76)

Criteria	Now		During the past year	
	n	%	n	%
Mood				
Yes	30	39.5	14	18.4
No	46	60.5	62	81.6
Lifestyle				
Yes	36	47.4	15	19.7
No	40	52.6	61	80.3
Time				
Yes	19	25	7	9.2
No	57	75	69	90.8
Finances				
Yes	23	30.3	14	18.4
No	53	69.7	62	81.6
Body Image				
Yes	11	14.5	6	7.9
No	65	85.5	70	92.1
Relationship to physician				
Yes	6	7.9	3	3.9
No	70	92.1	73	96.1
Relationship to specialists				
Yes	6	7.9	3	3.9
No	70	92.1	73	96.1

The respondents who indicated having been affected by swelling (n=49) were asked to give a further description of how it had changed their lives in terms of mood, lifestyle, time, finances, body image and relationship to physician and specialists. Transport and hospital charges (43.2%; n=16), taking a long time to complete tasks (65.4%; n=17) and feeling unattractive (88.2%; n=15) were the most common concerns. Some respondents indicated having experienced these changes now and during the past year, hence n may exceed 49. Table 4.13 presents the details.

Table 4.13 Description of changes in the lives of respondents caused by swelling or lymphoedema (n=49)

Criteria	Description of the changes	Now		During the past year		Total	
		n=42	%	n=22	%	n=64	%
Mood (n=44)	Irritable	10	22.7	3	6.8	13	29.5
	Sad	10	22.7	5	11.4	15	34.1
	Despair	2	4.5	2	4.5	4	9.1
	Frustration	2	4.5	1	2.3	3	6.8
	Aggressive	1	2.3	1	2.3	2	4.5
	Concerned/ worried	5	11.4	2	11.4	7	15.9
Lifestyle (n=51)	Loss of sexual desire	12	23.5	2	3.9	14	27.5
	Preference of being alone	9	17.6	4	7.8	13	25.5
	Inability to go to church often	2	3.9	1	2.0	3	5.9
	Avoidance of long trips	2	3.9	1	2.0	3	5.9
	Wears a bigger shoe size	2	3.9	1	2.0	3	5.9
	Inability to do strenuous tasks	7	13.7	5	9.8	12	23.5
	Shifting of tasks	1	2.0	0	0	1	2.0
	Wears long dresses	1	2.0	1	2.0	2	3.9
Time (n=26)	Longer time to complete tasks	12	46.2	5	19.2	17	65.4
	Inability to keep appointments	1	3.8	1	3.8	2	7.7
	Lot of idling	2	7.7	0	0	2	7.7
	Activities performed seated	1	3.8	0	0	1	3.8
	Less time spent on business	2	7.7	0	0	2	7.7
	Some plans put on hold	1	3.8	1	7.7	2	7.7
Finances	Medications costs	7	18.9	2	5.4	9	24.3

(n=37)	Transport and hospital charges	9	24.3	7	18.9	16	43.2
	Loss of job	6	16.2	4	10.8	10	27.0
	Reliance on a grant	1	2.7	1	2.7	2	5.4
Body Image (n=17)	Feeling unattractive	10	58.8	5	29.4	15	88.2
	Feeling of being noticed	1	5.9	1	5.9	2	11.8
Relationship to physician (n=9)	Anger	1	11.1	0	0	1	11.1
	Sense of mistrust	1	11.1	1	11.1	2	22.2
	Dreads reporting for follow up	1	11.1	0	0	1	11.1
	Feels misunderstood	2	22.2	1	11.1	3	33.3
	Symptoms dismissed	1	11.1	1	11.1	2	22.2
Relationship to specialists (n=9)	Anger	1	11.1	0	0	1	11.1
	Sense of mistrust	1	11.1	1	11.1	2	22.2
	Dreads reporting for follow up	1	11.1	0	0	1	11.1
	Feels misunderstood	2	22.2	1	11.1	3	33.3
	Symptoms dismissed	1	11.1	1	11.1	2	22.2

4.11 SUMMARY

This chapter presented the results of the study using descriptive statistics. Pearson's Chi square and/or Fisher's Exact tests were used to compare associations between specified categorical variables, while T tests compared continuous variables. Data obtained from open-ended questions was analysed using quantitative content analysis. The next chapter presents the discussion of the results, justification and limitations of the study, recommendations and the conclusion.

CHAPTER 5

DISCUSSION, JUSTIFICATION, LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

5.1 INTRODUCTION

The previous chapter presented and described the results of the study; this chapter will present the discussion of results, justification and limitations of the study, recommendations and the conclusion.

5.2 DISCUSSION OF THE RESULTS

The study provides evidence that approximately one in three women treated for gynaecological cancer will develop lower limb lymphoedema, possibly within the first 24 months after the completion of radiotherapy. Lower limb lymphoedema was detected by circumferential measurements and corresponding limb volumes in 29.7 % (n=46) of the respondents. A higher incidence rate (45.2%) was reported by Deura et al. (2015) in their investigation into the incidence and risk factors for lower limb lymphoedema after gynaecological cancer surgery followed by complete decongestive therapy. Conversely, the study conducted by Hareyama et al. (2015) found a lower incidence of 21.2%.

Most of the respondents had Stage I lymphoedema, with less than 20% inter-leg volume difference. Three respondents had Stage II lymphoedema, two of which had moderate leg volume increase, while the third respondent had severe leg volume increase. This is consistent with the results of the study by Deura et al. (2015), which also showed more respondents having Stage I (35.7%) than Stage II (9.5%) lymphoedema.

Contrary to the results of the study conducted by Hareyama et al. (2015) on the prevalence, classification and risk factors for lymphoedema, where the type of gynaecological cancer was found not to be associated with lower limb lymphoedema, the current study provides evidence of the association of gynaecological cancer type and lower limb lymphoedema, $p=0.017$. The respondents diagnosed with cervical cancer accounted for 136 of the total study sample (n=155) and had the highest (87%) overall incidence of lymphoedema. A greater association of vulvar cancer with lymphoedema was observed, as six of the 10 women with vulvar cancer developed lymphoedema.

It was interesting to find that even though the respondents who developed lymphoedema had received external beam radiotherapy, there was no statistical significance in the association of

the two variables, however, the association between brachytherapy and lymphoedema development was found to be statistically significant. Various studies have cited radiotherapy as a significant risk factor for lymphoedema (Deura et al., 2015, Todo et al., 2010). The current study examined the independent association of the two forms of radiotherapy, external beam radiotherapy and brachytherapy, with lower limb lymphoedema, which might explain the current results.

Similarly, the study could not establish any significant associations between obesity, age and comorbidities with the development of lower limb lymphoedema, despite the fact that almost three quarters of the respondents with lymphoedema were either overweight or obese. Contrary to these results, Togawa et al. (2014) found a significant association between body mass index and hypertension, and lower limb lymphoedema. The aforementioned study also established an inverse association between age and lymphoedema.

It was interesting to note that more respondents without lymphoedema reported symptoms such as aching, swelling, tenderness, increased leg temperature, numbness and groin swelling than those with lymphoedema. However, the symptoms related to the physical functioning of the leg reported by the former group were primarily weakness of the leg, while the respondents who were identified as having lower limb lymphoedema complained about limited movement of the hips, knees, ankles, feet and toes. The study found a significant bivariate association between reported symptoms related to the physical functioning of the leg and lower limb lymphoedema. Conversely, even though symptoms such as firmness, swelling and heaviness were associated with lower limb lymphoedema, this was not statistically significant. Dunberger et al. (2013), in their study that examined the effect of lymphoedema on daily living among gynaecological cancer survivors, also found firmness, swelling, heaviness and clothes' marks on the skin as the most reported symptoms.

It was also interesting that some of the respondents diagnosed with lymphoedema reported no symptoms. A similar trend was found in a study that investigated the incidence and risk factors of lymphoedema after gynaecologic surgery by Deura et al. (2015), in which the majority of the respondents with Stage I lymphoedema were not aware of their symptoms.

The most commonly used strategies to alleviate the symptoms were elevation and massage of the legs, while analgesics were used by the patients who experienced tenderness and aching of the legs. Consistent with the results of this study, the respondents in the study of Dunberger et al. (2013) found limb elevation, use of compression garments, diuretics and physiotherapy to improve the symptoms. A significant number of the respondents in the current study did not act

on the symptoms experienced. Eight (11.8%) respondents who had experienced swelling only decided to inform the oncologist about it after the interview with the researcher. This observation supports the assertion by Sibiya (2012) that South African women generally have poor health seeking behaviours.

It was interesting to note that the majority of the respondents identified as having lower limb lymphoedema indicated the condition had not affected them in any way, with the highest percentage, (>90%) indicating their relationship with the physician and the specialists was not affected. The majority of the respondents had Stage I lymphoedema with no overt swelling, or had swelling that receded with elevation of the limbs. It can be speculated that this justified the negligible impact of lymphoedema on the lives of these women, but qualitative research may explore this further.

A considerable number of respondents reported they were more irritable and aggressive. Approximately 30% of the women said they were sad and concerned that they now had to deal with swelling and aching legs just when they thought their problems were over. One respondent was concerned about cancer recurrence, while another one linked the swelling to witchcraft. The fear of cancer recurrence and spread was also raised by the respondents in the study by Dunberger et al. (2013).

The study provided evidence about the effects of lymphoedema on sexuality as a considerable number of respondents voiced concerns about loss of sexual desire and feeling unattractive. Respondents also avoided social gatherings and preferred to be alone, which was consistent with the findings of the qualitative study on the experiences of people living with breast cancer related lymphoedema conducted in South Africa by Maree and Beckmann (2016). It was not clear if the loss of sexual desire was related to lymphoedema or the physical effects of radiotherapy on the reproductive organs. In their review, Jensen and Froeding (2015) echoed the profound effects of radiotherapy on women's sexuality, which ranged from vaginal dryness and shortening, lack of sexual desire and orgasmic problems. It is possible these concerns were more related to effects of radiotherapy on the reproductive organs than swelling of the legs. These concerns could be explored further through in-depth interviews.

Respondents complained about not being able to perform strenuous activities and taking long to finish tasks. One respondent, who worked as domestic worker, said she had to iron clothes seated because the task had become overly tiresome. Stollendorf et al. (2016), in their study comparing the quality of life of patients with primary and secondary lymphoedema, had similar findings of functional impairments that affected daily activities. Consistent with the results of the

study by (Stolldorf et al. (2016)), the current study found a general concern about financial costs incurred on frequent hospital charges, transport fares and medications, especially painkillers to augment what the hospital supplied. Not being able to do hobbies, such as going to church and travelling, was also worrisome to some respondents.

It was interesting to note that although the respondents generally expressed having no problems related to the medical doctors, a few conveyed a sense of mistrust for the health system and a feeling of being misunderstood and uncared for. One respondent expressed anger at the lack of sensitivity by some physicians, while one said her symptoms were always dismissed. It is worth noting that some respondents reported experiencing symptoms both during the past year and now; an affirmation of the assertion by (Maree and Beckmann (2016)) that lymphoedema is progressive and if not adequately managed, brutally impairs quality of life.

5.3 JUSTIFICATION

The purpose of the study was to describe the incidence and effects of lower limb lymphoedema in women treated with radiotherapy for gynaecological cancer, in an academic hospital in Johannesburg. The objectives were to describe the lower limb lymphoedema related changes women treated with radiotherapy for gynaecological cancer experience, to describe the incidence and identify the stages of the lymphoedema in these women and to describe the psychosocial effects lymphoedema has on them. The researcher identified 46 (29.7%) respondents who had lower limb lymphoedema, which was detected through leg volume measurements. Most of the respondents had Stage I lymphoedema, with three having progressed to Stage II. The respondents identified to have lymphoedema reported experiencing symptoms such as firmness and swelling of the legs, and subsequent limited movement of various parts of the legs, mainly the knees, feet and toes. The psychosocial effects of lymphoedema expressed by the respondents included inability to perform strenuous chores or taking longer to complete them, effects on sexuality, mood, self-perception and finances. The study is therefore justified, as its purpose and objectives were realised.

5.4 LIMITATIONS

The cross sectional design used in this study may have not been ideal, as it did not provide a concise account on the limb volume changes, because baseline pre-treatment measurements were not taken. The possibility of erroneous information obtained through self-reports can also not be ruled out. The researcher believes however that the study provided baseline data on gynaecological cancer-associated lower limb lymphoedema; most importantly the twenty four months' timeline after cancer treatment for emergence of lymphoedema which may guide future research on the subject and clinical practice.

5.5 RECOMMENDATIONS

Regular assessment of patients for lower limb lymphoedema during follow up care, through history taking and leg measurements, could prove instrumental in the early detection of this condition. There is a dire need for pre- and post-treatment patient education on the lifetime risk of lower limb lymphoedema following gynaecological cancer treatment, and the associated early symptoms. Formulation of internal guidelines and/or a policy for lymphoedema management to facilitate access to pertinent care services by patients should also be considered.

5.6 CONCLUSION

The study provided evidence that 29.7% of women treated for gynaecological cancer with radiotherapy developed lower limb lymphoedema, the majority of whom had Stage I lymphoedema. In addition, the study found statistical significance in the association between brachytherapy and lymphoedema, but not with external beam radiotherapy. The respondents indicated having experienced changes, such as taking long to finish tasks and spending more money on frequent hospital charges, since the swelling of the limbs started. In addition, they were sad, felt unattractive and preferred to be alone.

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APPENDIX A: GYNAECOLOGICAL CANCER LYMPHOEDEMA QUESTIONNAIRE

Appendix 1: **Gynecologic Cancer Lymphedema Questionnaire** ID Code # _____

Answer all questions you understand. Do not answer questions that have any words you do not understand. Circle any words you do not know. **Lymphedema** means swelling of the foot, leg, hip, groin or lower body on the side where your cancer was first treated. **Now** refers to today or in the past month.

Questions about changes that have happened to your leg or body in the last month.

The following questions pertain to your experiences with movement, use, and sleep **now*** and **during the past year:** * Now refers to today or in the past month.

Do you have limited movement of your...	Now If yes, please describe	During Past Year If yes, please describe.
1. Hip?	No ☐ Yes ☐	No ☐ Yes ☐
2. Knee?	No ☐ Yes ☐	No ☐ Yes ☐
3. Ankle?	No ☐ Yes ☐	No ☐ Yes ☐
4. Foot?	No ☐ Yes ☐	No ☐ Yes ☐
5. Toes?	No ☐ Yes ☐	No ☐ Yes ☐
6. Does your leg or foot feel weak?	No ☐ Yes ☐	No ☐ Yes ☐

The following questions pertain to the foot, leg, hip, groin or lower body symptoms **now*** and **during the past year:** * Now refers to today or in the past month.

Have you experienced:	Now	During Past Year	What action you did for this symptom: Please describe.
7. Tenderness?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:
8. Swelling?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:

	ID Code #	T	Interview Date	Staff ID
9. Swelling with pitting? (Pitting is when you press firmly on your skin and the dent stays long enough to feel it when you slide the pad of your finger across it.)	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
10. Redness?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
11. Blistering?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
12. Firmness/tightness?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
13. Increased temperature in your leg?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
14. Heaviness?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
15. Numbness?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
16. Stiffness?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
17. Aching?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
18. Hip swelling?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	
19. Groin swelling? (genital, labia/vulvar)	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action:	

	ID Code #	T	Interview Date	Staff ID
20. Pockets of fluid develop?	No ☐ Yes ☐	No ☐ Yes ☐	No action ☐ Action (for example, how many times drained):	

ID Code #_____ T__ Interview Date _____ Staff ID _____
****Have you experienced swelling in either leg, foot, hip, or lower body after your cancer was first treated, or have you been diagnosed with lymphedema?**

If YES, please answer questions 21-27.

If NO, thank you for completing the survey.

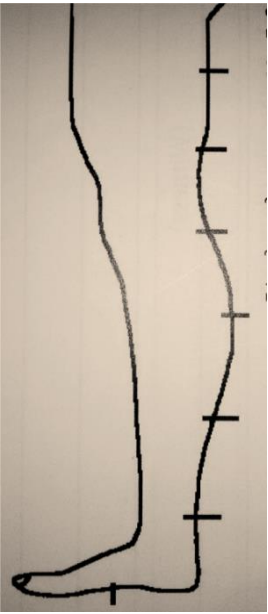
The following questions pertain to changes in your life now and during the past year:

How has lymphedema changed your...	Now If yes, please describe.	During Past Year If yes, please describe.
**21. mood?		
**22. lifestyle?		
**23. time?		
**24. finances?		
**25. body image?		
**26. relationship to physician?		
**27. relationship to specialists?		

APPENDIX B: GENERAL RESPONDENT'S INFORMATION AND LIMB VOLUME MEASUREMENT CHART

Respondent's Code No. _____ Affected leg _____

Measurements

	Predetermined Measurements	Left	Right
	100cm		
	90cm		
	80cm		
	70cm		
	60cm		
	50cm		
	40cm		
	30cm		
	20cm		
	Least ankle		
	Mid foot		
	Limb Volume (ml)		
Volume of Segment = $L/12\pi(C_t^2 + C_t C_b + C_b^2)$	Volume excess (ml)		
	% Excess Volume		

STEMMER SIGN	Positive		Negative	
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DEMOGRAPHICS

AGE		
CULTURAL GROUP		
EDUCATION LEVEL		
OCCUPATION		
BODY WEIGHT		
HEIGHT		
BMI		
PLACE OF RESIDENCE (URBAN/RURAL)		
TYPE OF GYNAE CANCER (REPORTED)		
STAGE OF THE DISEASE (REPORTED)		
TREATMENT RECEIVED & DATE	SURGERY	
	CHEMOTHERAPY	
	RADIOTHERAPY	
CO MORBIDITIES (REPORTED)		

APPENDIX C: INFORMATION SHEET

THE INCIDENCE AND EFFECTS OF LOWER LIMB LYMPHOEDEMA IN WOMEN TREATED WITH RADIOTHERAPY FOR GYNAECOLOGICAL CANCER IN AN ACADEMIC HOSPITAL IN JOHANNESBURG

Greetings.

My name is Joyce Vuyiswa Khutjwe, a student at the University of the Witwatersrand enrolled for a Master of Science in Nursing (Oncology and Palliative Care). I am conducting a study as part of the requirements for my studies, on ***The Incidence and Effects of Lower Limb Lymphoedema in Women Treated with Radiotherapy for Gynaecological Cancer in an Academic Hospital in Gauteng*** and would like to invite you to consider participating in it. Before you decide, it is important to understand why this study is being conducted and what it involves. Please take time to read the information that follows as it explains briefly what the study seeks to achieve.

Treatment of gynaecological cancer that includes radiotherapy can have a late side effect called lymphoedema which affects mainly the legs. Lymphoedema presents as swelling of the legs and occurs due to malfunction of the structures (lymphatic vessels) that are responsible for transporting excess fluids from the tissues in the legs, back into blood circulation in the upper body. Conducting this study is of great importance as it will describe the proportion of women that develops this condition and also raise awareness among nurses practicing in gynaecological cancer settings, potentially leading to improvement in assessment and management plans for cancer survivors at risk of lower limb lymphoedema.

The study focuses on women who received radiotherapy for gynaecological cancer and are at least twelve months but not more than twenty four months after completion of this treatment, hence my reason for approaching you. Should you decide to take part in this research you will be required to complete the attached Gynaecological Cancer Lymphoedema Questionnaire which comprises twenty questions and an additional seven questions if you have experienced swelling of the leg or lower body after your cancer was first treated, or you have been told by your doctor that you have lymphoedema. You will also be examined for legs' swelling or lymphoedema; with measurements taken at different points of your legs. The exercise will take utmost 10 minutes. This is a painless exercise performed with you standing, but should you feel any discomfort, inform the researcher to take the measurements with you seated. Arrangements

have been made with Ms Agnes Huiskamp to counsel respondents who experience emotional distress (Telephone; 011 488 4268).

Participation in the study is purely voluntary and no penalties will be imposed on you should you decide not to participate. If you wish to participate, please sign the consent form and complete the questionnaire. Your name should appear only on the consent form but not the questionnaire for confidentiality. Assessment of your legs will then follow.

This study has been approved by the Wits Human Research Ethics Committee and the Research Committee of Charlotte Maxeke Academic Hospital. The Wits Human Research Ethics Committee (Medical) can be contacted as follows:

Chairperson: peter.cleaton-jones1@ wits.ac.za

Administrators - Ms Zanele Ndlovu/ Mr Rhulani Mkansi/ Mr Lebo Moeng Tel 011 717 2700/2656/1234/1252

Email: HREC-Medical.ResearchOffice@wits.ac.za

Please feel free to contact me for further information on my cell phone number; 0786752143 or email; 1477945@students.wits.ac.za.

Yours faithfully

Joyce Vuyiswa Khutjwe

APPENDIX D: CONSENT FORM

The Incidence and Effects of Lower Limb Lymphoedema on Women Treated with Radiotherapy for Gynaecological Cancer in an Academic Hospital in Johannesburg

I _____ (full name) give consent to take part in the above study.

I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. I understand that my participation in this study is voluntary and that I can withdraw from the study at any time without any penalties enforced on me.

SIGNATURE: _____

DATE: _____

APPENDIX E: PERMISSION TO USE THE INSTRUMENT

Joyce Khutjwe <1477945@students.wits.ac.za>	31/08/2016
to armer	

Greetings Professor Armer

My name is Joyce Khutjwe, a Masters in Nursing Science (Oncology and Palliative Care) student at the University of Witwatersrand, South Africa, under Professor Lize Maree's instruction and supervision.

I would like to conduct a survey on "The Incidence of Lower Limb Lymphoedema in Women Treated with Radiotherapy for Gynaecological Cancer" and would like to request for the data collection questionnaire [for self-reported symptoms] and also for permission to use it for my study, as advised by Professor Maree.

I would be very grateful for your assistance.

Regards

Armer, Jane <Armer@missouri.edu>	31/08/2016
to Kandis me	

Dear Joyce,

It is very nice to make your acquaintance. You have a very expert mentor, as you know, in Prof Maree.

We are happy to share our tool for assessing symptoms in the lower extremity after gynaecological cancer.

We have a simple form we request be completed by those using our upper extremity tool, the LBCQ.

I will ask Kandis to forward that form, modified for the gynaecological tool.

The tool is in use by nurse research collaborators and in one of our national oncology cooperative group trials.

Perhaps when you finish your masters work, you and Prof Maree would be interested in comparing findings across our US studies.

I wish you great success in your academic progression.

My best,

Jane

Jane M. Armer, RN, PhD, FAAN

Sinclair School of Nursing

University of Missouri

American Lymphoedema Framework Project

armer@missouri.edu

www.alfp.org

Smith, Kandis M. <SmithKa@missouri.edu>

31/08/2016

to

me

Jane

Hello Joyce,

I have attached the form for you. If you will fill it out and return it to me, I will send you an electronic copy of the questionnaire. Have a great day.

Kandis

Kandis M. Smith, PhD
Adjunct Courtesy Faculty
Sinclair School of Nursing
University of Missouri
smithka@missouri.edu

From: Armer, Jane
Sent: Wednesday, August 31, 2016 6:11 AM
To: Joyce Khutjwe; Armer, Jane
Cc: Smith, Kandis M.
Subject: RE: REQUEST FOR DATA COLLECTION QUESTIONARE

Dear Joyce,

It is very nice to make your acquaintance. You have a very expert mentor, as you know, in Prof Maree.

We are happy to share our tool for assessing symptoms in the lower extremity after gynaecological cancer.

We have a simple form we request be completed by those using our upper extremity tool, the LBCQ.

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The tool is in use by nurse research collaborators and in one of our national oncology cooperative group trials.

Perhaps when you finish your masters work, you and Prof Maree would be interested in comparing findings across our US studies.

I wish you great success in your academic progression.

My best,

Jane

Jane M. Armer, RN, PhD, FAAN

Sinclair School of Nursing
University of Missouri
American Lymphoedema Framework Project

----- Original message -----

From: Joyce Khutjwe <1477945@students.wits.ac.za>
Date: 8/31/16 5:51 AM (GMT-06:00)
To: "Armer, Jane" <Armer@missouri.edu>
Subject: REQUEST FOR DATA COLLECTION QUESTIONARE

Greetings Professor Armer

My name is Joyce Khutjwe, a Masters in Nursing Science (Oncology and Palliative Care) student at the University of Witwatersrand, South Africa, under Professor Lize Maree's instruction and supervision.

I would like to conduct a survey on "The Incidence of Lower Limb Lymphoedema in Women Treated with Radiotherapy for Gynaecological Cancer" and would like to request for the data collection questionnaire [for self-reported symptoms] and for permission to use it for my study, as advised by Professor Maree.

I would be very grateful for your assistance.

Regards

Attachments area
Preview attachment Agreement.docx

W

Agreement.docx

16 KB

Smith, Kandis M. <SmithKa@missouri.edu>

31/08/2016

to

me

Thank you for being so prompt. I have attached the questionnaire. Please let me know if you have any questions. Have a joyous day.

Kandis

Kandis M. Smith, PhD
Adjunct Courtesy Faculty
Sinclair School of Nursing
University of Missouri
smithka@missouri.edu

APPENDIX F: ETHICS CLEARANCE CERTIFICATE



R14/49 Ms Joyce Vuyiswa Khutjiwe et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M170461

NAME: Ms Joyce Vuyiswa Khutjiwe et al
(Principal Investigator)
DEPARTMENT: Nursing Education
Charlotte Maxeke Johannesburg Academic Hospital
Radiation Oncology Department

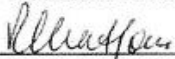
PROJECT TITLE: The Incidence and Effects of Lower Limb Lymphedema
in Women Treated with Radiotherapy for Gynaecological
Cancer in an Academic Hospital

DATE CONSIDERED: 05/05/2017

DECISION: Approved

CONDITIONS: Following GDoH Circular 10 of 2015 to GDoH Staff. It is the
responsibility of the applicant to obtain written permission to
to do the study from the study site CEO and Provincial Authorities.

SUPERVISOR: Prof Lize Maree and Dr Nokuthula Mafutha

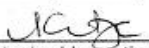
APPROVED BY: 
Prof P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 10/07/2017

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

DECLARATION OF INVESTIGATORS

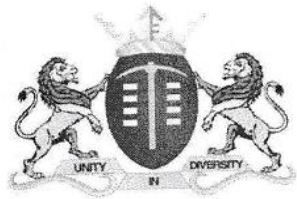
To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we 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.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in April and will therefore be due in the month of April each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).


Principal Investigator Signature

29/07/2017
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX G: RESEARCH SITE APPROVAL LETTER



GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. G. Ngwenya
Office of the Nursing Director
Tell: (011): 488-4558
Fax: (011): 488-3786
24 JULY 2017

Mrs. Joyce Vuyiswa Khutjwe
University of the Witwatersrand
Department of Nursing Education
Faculty of the Health Sciences
NHRD REF : GP_2017RP16_543

Dear Mrs Joyce Vuyiswa Khutjwe

RE: "The incidence and effects of lower limb lymphedema in women treated with radiotherapy for gynaecological cancer in an academic hospital in Johannesburg"

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.
- 5.

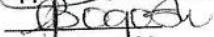
Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported / not-supported


Ms. M.M Pule
Nursing Director
Date: 2017/07/24

Approved / not approved


Ms. G. Bogoshi
Chief Executive Officer
26/07/2017

APPENDIX H: APPROVAL OF TITLE



Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

12 June 2017
Person No: 1477945
PAG

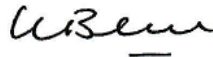
Mrs JV Khutjwe
P.o. Box 25294, Gaborone, Botswana
00267
Botswana

Dear Mrs Khutjwe

Master of Science in Nursing: Approval of Title

We have pleasure in advising that your proposal entitled *The incidence and effects of lower limb lymphedema in women treated with radiotherapy for gynaecological cancer in an academic hospital* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

A handwritten signature in black ink, appearing to read 'S. Benn'.

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

APPENDIX I: HEAD OF DEPARTMENT APPROVAL

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

The Head of Department
Radiation Oncology Department
Charlotte Maxeke Johannesburg Academic Hospital
5 Jubilee Road
Parktown 2193

Dear Professor Sharma

Re: REQUEST TO CONDUCT RESEARCH AT CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL (CMJAH)

I am a second year master's student at University of the Witwatersrand in the Department of Nursing Education, specialising in Oncology and Palliative Care. I would like to request for permission to conduct research in your department; CMJAH's radiation oncology department.

The title of my research is: "The incidence and effects of lower limb lymphedema in women treated with radiotherapy for gynaecological cancer in an academic hospital in Johannesburg".

The purpose of this study is to describe the incidence and effects of lower limb lymphedema in women treated with radiotherapy for gynaecological cancer. The study might raise awareness among nurses who practise in gynaecological cancer care centres leading to early diagnoses and provision of appropriate care to patients who develop the condition after cancer treatment.

Participation in the study will be voluntary. An informed consent will be obtained from all the research respondents. The names of the respondents and that of the institution will not be included in the report.

Ethical clearance has been obtained from the Human Research Ethics Committee of the University of the Witwatersrand and permission by the hospital's Chief Executive Officer has also been granted. Find attached copies of the Ethics Committee and CMJAH's CEO's approval letters.

Yours faithfully



Joyce Vuyiswa Khutjwe (MSc Nursing Student)

Email: 1477945@students.wits.ac.za Tel: 078675214

To see Dr Kolgan please for feasibility of the study

17/8/17 feasible 

Vuyiswa
17/8/17

APPENDIX J: OPERATIONAL MANAGER APPROVAL



**CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL
RADIATION ONCOLOGY DEPARTMENT AREA 348**

MR MAVANGA NGWANZA

OPERATIONAL MANAGER

TEL 011 488 3212

Email: mavangangwanza@gauteng.gov.za

29 August 2017

Dear Mrs Joyce Vuyiswa Khutjwe

**Re: REQUEST TO CONDUCT RESEARCH AT CHARLOTTE MAXEKE JOHANNESBURG
ACADEMIC HSOPITAL/RADIATION ONCOLOGY**

I have the pleasure to inform you that your request has been considered and permission is granted for you to conduct research in the department.

Wish you success

Mr M. Ngwanza

APPENDIX K: LANGUAGE EDITING CERTIFICATE

Gill Smithies

Proofreading & Language Editing Services

59, Lewis Drive, Amanzimtoti, 4126, Kwazulu Natal

Cell: 071 352 5410 E-mail: moramist@vodamail.co.za

Work Certificate

To	Prof L. Maree, RN DCUR (Pret)
Address	Wits Dept of Nursing Education
Date	20/02/2018
Subject	THE INCIDENCE AND EFFECTS OF LOWER LIMB LYMPHOEDEMA IN WOMEN TREATED WITH RADIOTHERAPY FOR GYNAECOLOGICAL CANCER IN AN ACADEMIC HOSPITAL IN JOHANNESBURG, by Joyce Vuyiswa Khutjwe
Ref	LM/GS/057

I, Gill Smithies, certify that I have edited the following for language and style,

Research Study: The incidence and effects of lower limb lymphoedema in women treated with radiotherapy for gynaecological cancer, in an academic hospital in Johannesburg,

to the standard as required by Wits Dept. of Nursing Education.

Gill Smithies

APPENDIX L: PLAGIARISM DECLARATION FORM



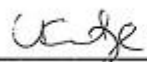
PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I JOYCE VUYISWA KHUTJWE (Student number: 1477945) am a student registered for the degree of MSc Nursing in the academic year 2018.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: 

Date: 28/02/2018