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FACULTY OF SURGERY (RECONSTRUCTIVE AND PLASTIC SURGERY)

ELASTIC VERSUS INELASTIC COMPRESSION BANDAGING IN LYMPHOEDEMA MANAGEMENT; A COMPARATIVE ANALYTIC STUDY IN KORLE BU TEACHING HOSPITAL

A dissertation submitted to the Faculty of Surgery, in partial fulfilment of the requirements for the conferment of a Fellow of the Ghana College of Surgeons

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ABSTRACT

Background

Lymphoedema is a long-term chronic condition requiring a comprehensive multidisciplinary approach as there is no cure for it. Management is therefore aimed at reducing its symptoms and improving on the aesthetics and function of the body part involved.
Currently the first line of lymphoedema management is the Complete Decongestive Therapy (CDT), which comprise of manual lymphatic drainage (MLD), compression bandaging, exercise and skin care.
CDT is cumbersome, uncomfortable, inconvenient and time-consuming making compliance a big problem. Hence most institutions place emphasis on compression therapy.
The prescription of the appropriate compression is a real challenge, since one must choose between inelastic and elastic bandages. It must be adapted to the patient and its pathology as well as provide comfort and ensure good compliance. The diversity of modalities of compression therapy is reflected by the different schools of compression within countries. In France, elastic compression is commonly prescribed whiles in Germany, Netherlands and Austria the standard treatment is inelastic compression. In UK the 4-layer system with an elastic bandage is the choice and in the USA a plaster type inelastic bandage (Unna's boot) is favoured.
The large discrepancies among treatment modalities underline the need of a research into what type of compression therapy is best suited for lymphoedema patients in our centre and to an extent in the Ghanaian population.

Aim

The study aims to compare the clinical outcomes of treating lymphoedema of the limbs with elastic compression bandaging and inelastic compression bandaging in Ghanaian patients.

Methodology

The study was a prospective randomized study involving 23 Ghanaian patients with lymphoedema of the upper or lower limbs. Using defined inclusion and exclusion criteria,

patients with extremity lymphoedema seen at the Physiotherapy Unit of the National Reconstructive Plastic Surgery and Burns Centre, Korle Bu Teaching Hospital, were selected by simple random sampling into two groups. (Group A – Inelastic bandage, Group B – Elastic bandage). Informed consent was obtained from each patient after clinical assessment. Measurements for both the affected and unaffected limbs were taken using a tape at specific parts of the limb. Manual lymphatic Drainage was done by the physiotherapist and then the appropriate bandage applied based on patient's group. Limb measurements (affected limb) and Physiotherapy sessions were repeated every two weeks for eight weeks to complete the intensive phase of Compression Bandaging.

Quality of life assessment score was taken before and after the 8 weeks of compression bandaging. Data was collected and analyzed using ANOVA to compare the percentage change in the total circumference and volume of the limb with lymphoedema in each of the groups. The quality of life score was compared before and after treatment for each group.

Results

The mean age of the participants was 48.61 years. There was a statistical significant difference in the occupational status and level of education of the patients. 70% of patients had upper limb lymphoedema and the mean age at diagnosis was 46.26 years. 82.6% 0f patients had secondary lymphoedema with malignancy being the commonest cause. Both inelastic and elastic compression bandages were effective in reducing the circumference and volume of the affected limb. Compression bandaging in all resulted in a statistically significant difference in the quality of life before and after treatment ($p < 0.0001$).

Conclusion

Compression bandaging using either elastic or inelastic compression bandages are effective in the treatment of limb lymphoedema with a better quality of life outcome. There is no statistical significant difference in the efficacy of both inelastic and elastic bandages. However inelastic compression bandage gives a better reduction in limb volume.

1 BACKGROUND

1.1 Introduction

Lymphoedema is a chronic condition that causes swelling in the body's tissue. It can affect any part of the body but usually develops in the arms and legs(1). The swelling is as a result of the accumulation of the protein rich fluid (lymph)(2). The condition can either be hereditary (primary lymphoedema) or can occur after a surgical procedure, infection, radiation or other physical trauma (secondary lymphoedema)(3).

Lymphoedema is a pandemic with about 250 million people suffering from this condition(4). Filarial infection is the most common cause worldwide, affecting over 120 million people(5). The estimate prevalence for primary lymphoedema is about 1 in 100,000 individuals and that for secondary lymphoedema is about 1 in 1,000 individuals(6). Malignancy and its treatment also account for a large number of these cases. About one out of every five patients with breast cancer will develop lymphoedema(7).

Currently there is no outright cure for lymphoedema, however there are certain effective treatments available to alleviate the symptoms(3). These treatments are either conservative (non-surgical) or surgical in nature. The conservative treatment options fall into four main categories:

1. Exercise and Physical Therapy: a combination of flexibility, stretching and aerobic exercises help in the movement of lymph throughout the body
2. Manual Lymphatic Drainage: using specific hand massage movements on the skin of the affected limb to improve lymph flow towards unaffected areas.
3. Compression Bandaging: the use of compression accessories or garments to help control and reduce lymphoedema.
4. Skin Care: using daily simple measures to protect the skin from injury and infection that can worsen the lymphoedema.

Conservative treatment modalities therefore involve any one of these or a combination of two or more of the categories(8)

Surgical options available for the management of lymphoedema in developing countries like Ghana are mainly the debulking or ablative procedures. These involve removal of excess subcutaneous tissue to improve patient comfort and facilitate conservative therapies(9).

Currently in Ghana and most developing countries the first line or “gold standard” in lymphoedema management is the Complete Decongestive Therapy (CDT)(10).

1.2 Statement of the problem

Complete Decongestive Therapy is cumbersome, uncomfortable, inconvenient and time-consuming as well as expensive, with treatment lasting throughout the lifetime of the individual. These challenges have led to poor patient compliance and in effect the poor outcome of CDT in lymphoedema management(3).

To circumvent these problems there have been the usage of the individual components of CDT alone, in combinations or with other new modalities like pneumatic compression, for better patient compliance and to ensure patients are receiving the same level of success for their lymphoedema treatment(1).

Compression bandaging aside being the single most important component of CDT, is a cheaper, more accessible and less labour-intensive method of treating lymphoedema compared to the full scale CDT. To choose an appropriate compression product for a patient, one must have a thorough understanding of these products. However, this choice can be difficult because of lack of standardized compression classifications, confusion over terminology and lack of evidence as to which type of compression system is most effective(11)(12).

Different countries have adopted different compression bandage types and techniques for lymphoedema treatment. Currently in Ghana and our Centre to be precise, the choice is a two-layer technique with elastic bandages. There is no evidence to back the choice of this system over the other systems and therefore the need to investigate to either confirm its superiority or otherwise.

1.3 Justification for the study

Lymphoedema can be a grossly disfiguring condition, usually affecting a limb, which causes discomfort and may cause pain and can be complicated by recurrent infections often requiring hospital admission. It also has considerable psychological impact on patients(2) as well as a high

morbidity and mortality from complications of long-standing untreated lymphoedema. Complications which include a malignant change i.e. lymphangiosarcoma(13)

The emphasis of treatment is on helping the patient to achieve as much self-sufficiency and independence as possible, given the chronic nature of their condition and to reduce the incidence of co-morbidity and the need intensive therapy and hospitalization.

Compressive Decongestive Therapy which has been referred to as the "gold standard" in lymphoedema management(14), is froth with many challenges especially in a developing country like Ghana. These challenges (time consuming, inconvenient, uncomfortable and expensive) have led to the poor compliance of patients to CDT and hence a poor outcome of treatment.

Compression therapy is the cornerstone and most effective therapeutic procedure in lymphoedema treatment strategy(15). It is also associated with good patient compliance but there is currently no standardized compression bandage type or technique in Ghana and the plastic surgery department in Korle Bu Teaching Hospital for that matter. A study to determine the most efficient compression bandage type and technique in the Ghanaian population will impact much on lymphoedema treatment.

1.4 Purpose of the study

The purpose of this study is to compare the clinical outcomes of treating lymphoedema of the limbs with elastic compression bandage and inelastic compression bandage in Ghanaian patients. The study will also determine the bandaging technique with the best patient compliance as well as the extent to which the various bandaging systems will improve on the quality of life of patients with lymphoedema.

2 LITERATURE REVIEW

2.1 Lymphoedema

Lymphoedema is a chronic swelling arising from the accumulation of fluid and other tissue elements that would otherwise drain via the lymphatic system(1)(16). According to the most recent International Society of Lymphology (ISL) consensus document, lymphoedema is simply "a symptom or sign resulting from underlying lymphatic disease".

Lymphoedema is characterized by chronic progressive swelling of the body part involved with protein rich fluid (lymph) and usually affects the limb(s) but may also involve the trunk, breast, head and neck and genital area(17).

These body regions are generally associated with lymphatic territories called lymphosomes(18)(19).

Lymphoedema is simply a defect of the lymphatic circulatory system, when the demand for lymphatic drainage exceeds the capacity of the lymphatic system(20).

2.2 Lymphatic system

The Lymphatic system is a subsystem of the circulatory system that consists of a complex network of vessels (lymphatics), tissues (lymph nodes) and organs throughout the body which transport fluid (lymph) from the body tissues back to the blood stream(18).

Lymph transport within tissues begin by passing into small lymphatic capillaries that is found in almost every tissue of the body. Only a few regions of the body are free of lymphatic capillaries i.e. the epidermis, mucus membranes, bone marrow and central nervous system. Whiles regions such as the lungs, gut, genitourinary system and dermis are densely packed with these vessels(21).

The lymph drains from these lymphatic capillaries into larger vessels called lymphatics. The lymphatics converge to form two large vessels known as lymphatic trunks, which then connect to veins at the base of the neck.

One of these trunks, the right lymphatic duct, drains the upper right areas of the body and returns the lymph to the blood stream via the right subclavian vein. The other trunk, the thoracic duct, drains the rest of the body into the left subclavian vein.

Lymph is transported through this system by muscle contractions and valves to prevent backward flow. Along the lymphatics are small masses of lymph tissue, called lymph nodes, which are encapsulated bean-shaped structures. Thousands of lymph nodes are found throughout the body, but they are more prevalent in areas around the armpits (axillary nodes), groin (inguinal nodes), neck (cervical nodes), and knees (popliteal nodes)(22).

The main function of lymph nodes is to identify and filter out foreign agents that cause infections with the help of B and T lymphocytes. Lymph nodes are also able to isolate and contain cancer cells at the early stages of the disease.

Functions of the lymphatic system are(23)

- Maintain the volume and protein concentration of extracellular fluid in the body
- To assist the immune system in detecting and destroying pathogens and removing waste products from the tissues
- Absorption of fat from the digestive tract system

2.3 Signs and Symptoms of Lymphoedema

They vary from person to person and develop at different rates. People with lymphoedema may describe any of the following(24)(25):

- Transient swelling of a limb or other regions of the body. Swelling may be worsened by sustained positions, prolonged activity, overuse or inappropriate external compression.
- Aching, heaviness, skin stretching and stiffness in the affected area
- Clothes, shoes or jewelry becoming tight
- Swelling that does not go away after sleeping in bed overnight
- Skin becomes very dry
- Decrease range of movement of joints in the affected area
- Spontaneous skin blisters leaking clear fluid

- Recurrent skin infections
- Fatigue related to the size and weight of the extremity
- Restrictions in activities of daily living
- Fissuring and ulcerations of the skin

2.4 Types of Lymphoedema

There are two main types of lymphoedema:

Primary Lymphoedema – caused by faulty genes that affect the development of the lymphatic system; it can develop at any age, but usually starts during infancy, adolescence or early adulthood(26).

It is usually from abnormal development of the lymph vessels and can be either(27):

- Hypoplasia (reduced number of lymphatic vessels)
- Hyperplasia (vessel that are too large to be functional)

Primary Lymphoedema in terms of presentation can also be grouped as:

- Congenital = present at birth
- Praecox = develop at the onset of puberty
- Tarda = occur many years into adulthood

Primary lymphoedema may be associated with other congenital abnormalities or syndromes and include the following(28);

- Neurofibromatosis type 1
- Hemangiomas
- Turner syndrome
- Klinefelter syndrome
- Xanthomatosis

Secondary Lymphoedema – caused by damage to the lymphatic system or problems with the movement and drainage of fluid in the lymphatic system; it can be the result of a cancer

treatment, an infection, injury (including surgery or other iatrogenic causes), inflammation of the limb, or a lack of limb movement(26).

Lymphoedema from cancer treatment is either lymph node removal or radiotherapy. It can also be from progression of the cancer to involve regional lymph nodes.

However the most common cause of secondary lymphoedema worldwide is filariasis, a parasitic infection caused by a mosquito-borne nematode infection with the parasite *Wucheria bancrofti*. This infection is common in developing countries and results in permanent lymphoedema of the limb(29).

In lymphatic filariasis, repeated episodes of inflammation and lymphoedema lead to lymphatic damage, chronic swelling and elephantiasis of the legs, breasts and genital organs(30).

Morbid obesity can also cause impairment of lymphatic drainage and result in lymphoedema commonly called obesity related lymphoedema or massive localized lymphoedema

Lymphoedema can also be associated with the following(31);

- Trauma
- Burns
- Congestive heart failure
- Peripheral vascular surgery
- Varicose vein surgery
- Portal hypertension etc.

For secondary lymphoedema, onset of symptoms may be within months of the damage or rather appear many years later(32). Secondary lymphoedema is more common (prevalence of 1:1000) compared to primary lymphoedema (prevalence of 1:100,000)(6).

2.5 Diagnosis of Lymphoedema

Diagnosis of lymphoedema is made clinically by thorough evaluation and physical examination(33). Imaging studies can be used to confirm it, to assess the extent of involvement and to determine therapeutic interventions(34).

Diagnosis is based on clinical history of lymphoedema development, including symptoms enumerated earlier on, past medical history and examination and involves assessment of limb size, and changes in the skin and subcutaneous tissues.

Severity is assessed by considering the amount of swelling, the rate of increase in size, tissue texture changes, skin changes and the incidence of cellulitis episodes.

When Lymphoedema occurs on only one side of the body (unilateral), the unaffected side is used for comparison. A difference of 2cm in girth measurements between limbs or 3-5% difference in limb volume suggests lymphoedema.

It is also important to exclude other causes of limb swelling such as(35);

- Deep Vein Thrombosis
- Venous insufficiency
- Cardiac disease
- Renal disease
- Metabolic disorders
- Infection
- Myxoedema (hypothyroidism)

Routine laboratory tests are not required to diagnose lymphoedema, however these tests help to define the underlying causes of limb swellings when the cause is unclear. The only exception to this is the diagnosis of lymphoedema secondary to lymphatic filariasis and this becomes relevant when there is an ongoing active infection at the time of presentation.

The gold standard for diagnosing active filarial infection is the identification of microfilariae in a blood smear by microscopic examination. The microfilariae that cause lymphatic filariasis circulate in the blood at night. Hence blood sample should be taken at night to coincide with the appearance of the parasite(35).

Serological techniques such as elevated levels of antifilarial IgG4 in the blood is an alternative to microscopic detection of the microfilariae for the diagnosis of lymphatic filariasis. This can be done using routine assays(36).

However it is worth nothing that lymphoedema from lymphatic filariasis may develop many years after the infection and therefore these lab tests are most likely to be negative for such patients.

Imaging studies are also not necessary for the diagnosis of lymphoedema, but they can be used to confirm the diagnosis, assess the extent of involvement or severity and to help determine and monitor therapeutic interventions. The relevant imaging studies and how they are applied include;

Ultrasonography

This can be used to evaluate both the lymphatic and venous systems. Volumetric and structural changes can be identified within the lymphatic system using this modality. Other causes of extremity swelling such as deep vein thrombosis and arteriovenous fistula, can be ruled out with ultrasound scan findings(37).

CT Scan and MRI

These imaging studies though expensive can sometimes be of help in the evaluation of lymphoedema, especially in delineating the nodal architecture of the area involved. They are also important when suspicion of malignancy as an underlying cause is high. MRI also has the advantage of showing the lymph trunk anatomy and causes of obstructive secondary lymphoedema.

Lymphangiography

Lymphangiography is an invasive technique that is used to evaluate the lymphatic system and its patency. It was previously considered the first-line imaging modality for lymphoedema, but is now rarely used due to its potential adverse effects of causing an inflammatory reaction in the

remaining functional lymphatic channels, leading to scaring, atrophy and obstruction and worsening of the lymphoedema.

Lymphoscintigraphy

Lymphoscintigraphy is the gold standard for imaging in the diagnosis of peripheral lymphoedema. It is a non-invasive procedure for the differentiation of lymphoedema from other causes of limb or truncal oedema, such as heart failure, deep vein thrombosis etc.

This is a special type of nuclear medicine imaging that provides pictures (scintigrams) of the lymphatic system. It involves the subcutaneous injection of small amounts of radioactive particles (Technitium-99m Sulphur colloid or technitiumTc 99m tilmanocept) in the involved extremity, and images taken with a special radioactive camera 3 hours later.

The test is also used to define the anatomy and patency of the lymphatics, evaluate the dynamics of flow and determine the severity of obstruction of the lymphatic system.

An early diagnosis of lymphoedema is important to support its treatment and to prevent progression of the condition.

2.6 Staging of Lymphoedema

There are four primary stages of lymphoedema and each impact the body in different ways, and can be categorized according to severity(38). Lymphoedema, if untreated, tends to progress over time and can advance in stages. Some patients may progress quicker and more than others, whiles some may go for years without progressing(39).

- Stage 0: Abnormal flow in the lymphatic system. No signs or symptoms (subclinical stage)

- Stage 1: Accumulation of fluid with swelling. Swelling resolves with elevation. Pressing on the area may leave a dent i.e. pitting oedema (reversible stage)

- Stage 2: Permanent swelling that does not resolve with elevation. Pressing on the area no longer leaves a dent. Changes in the skin with scarring and thickening (spontaneously irreversible stage)

- Stage 3: Elephantiasis (large deformed limb), skin thickening with "wart-like" growth and extensive scarring.

It should be noted that a limb may exhibit more than one stage, which may reflect alterations in different lymphatic territories. These lymphatic zones, as seen in the lymphosome concept are drained by different vessels.

And in terms of severity it is classified as follows

- Mild: < 20% increase in extremity volume
- Moderate: 20% - 40% increase in extremity volume
- Severe: > 40% increase in extremity volume.

2.7 Screening for Lymphoedema

Screening is now being advocated for to detect both subclinical and clinical lymphoedema in its early stages (stages 0 and 1) for better treatment and prognosis(40).

The approach for screening includes limb measurements (especially limb volume) by techniques as previously described above as well as advanced tissue analysis devices like the SOZO Body Scan (Bioimpedence Spectroscopy). This scan uses non-invasive methods to detect fluid changes as small as 2.4 tablespoons and takes just 30 seconds to complete(41).

A screening program developed by the Oxford Lymphoedema Practice (first of such in the UK), involves specialist surgeons fully assessing high risk patients (especially those after cancer treatment) and their lymphatic system through history, examination and Indocyanine Green Lymphography scan. The screening starts 3 months after cancer treatment has completed and done every 6 months for 3 years. As most people who get lymphoedema after cancer treatment do so within 3 years.

2.8 Complications of Lymphoedema

Aside the long standing swelling and other associated symptoms, lymphoedema may lead to serious complications that will require additional management(13).

These complications include;

- Wound dehiscence and delayed wound healing
- Infections (fungal infections, cellulitis, lymphangitis)
- Malignant transformation (lymphangiosarcoma)
- Psychological and psychosocial issues

Early treatment is therefore necessary to prevent these complications from happening as well as worsening the patient's quality of life.

2.9 Treatment for Lymphoedema

Lymphoedema is incurable hence the goal of treatment is to restore function, reduce physical and psychologic suffering, and prevent the development of infection. Treatment modality depends on the severity and extent of the condition(42)(43).

However, prevention and controlling lymphoedema plays an important role in its management. An early and accurate diagnosis and treatment is very important to alter the normal progression of the disease(44).

Most of the treatment modalities aim at improving the flow of lymph fluid through the affected area. This will help reduce swelling and improve the health of the swollen limb. Reducing the

swelling will lower the risk of infection, make movement easier and more comfortable and improve the patient's well-being(10)(45).

In secondary lymphoedema, the underlying cause should be properly treated, in order to relieve the lymphatic obstruction.

The treatment modalities can be broadly classified into two; conservative treatment and surgical treatment(46)(47).

2.9.1 Conservative Treatment

This involves the use of nonsurgical or pharmacological means to treat lymphoedema. The modalities under this group include but not limited to; Complete Decongestive Therapy (CDT), Compression Therapy, lymphatic Drainage/Massage Therapy, Laser Treatment and Lymph Taping(48)(45)(49).

Complete Decongestive Therapy (CDT)

The first line and the most important modality in the conservative treatment of lymphoedema is CDT(50). According to the International guidelines of the International Society of Lymphology, the best global treatment of lymphoedema is complete decongestive therapy.

Many studies have demonstrated the effectiveness of CDT for improving lymphoedema symptoms such swelling and pain.

Complete Decongestive Therapy is a multimodal therapy, which consists of 4 components: compression therapy, manual lymphatic drainage (MLD), exercise, and skin care. The CDT technique originated in Europe and Australia but is now becoming more prevalent in the United States.

This therapy;

- Can effectively reduce the volume of lymphoedema
- Reduce other associated signs and symptoms
- Improve patient's mobility
- increase quality of life (QOL)

The 4 key components of CDT are;

1 *Compression Therapy* = layered bandaging with foam or specially fitted garments that support the area to control swelling.
2 *Manual Lymphatic Drainage (MLD)* = a light skin stretching technique that stimulates the lymphatic system.
3 *Exercise* = together with compression helps to pump lymph out of the swollen area.
4 *Skin Care* = keeping the skin clean and moisturized to help prevent infections that often occurs with lymphoedema.

CDT involves two phases(51);

Phase 1 (Reductive phase): typically involves seeing a lymphoedema specialist five times a week for up to 8 weeks. Patient undergoes MLD, compression therapy and physiotherapy to achieve limb volume reduction.

This phase is for the mobilization of fluid (lymph) and the initiation of a decrease in the proliferated connective tissue. The frequency of hospital visits depends on the amount of swelling and tissue firmness. One-hour sessions for 4 to 5 days per week is the recommended schedule. Patients are also to wear the bandages for about 23 hours and often only removed to bathe.

Phase 2 (Maintenance phase): this is largely patient directed. It involves meticulous skin and nail care, wearing compression garments or sleeves, self-lymph drainage massage and exercise to preserve gains in limb volume reduction.

The aim of this phase is to maintain the swelling reduction and also for optimization of connective tissue reduction. It usually lasts for months or years. The patients wear elastic compression garments that fit like a second skin during the day. Patients are to also ensure that;

- They wear the bandages with foam at night to decrease daily daytime swelling
- Exercise while wearing the compression
- Carry out self-manual lymphatic drainage for about 20 minutes per day

Complete Decongestive Therapy is cumbersome, uncomfortable, inconvenient and time consuming, with treatment lasting throughout the lifetime of the individual. It also has huge financial implications considering the number of times (at least 5 times a week), the patient has to see a therapist in the first phase. These challenges have resulted in poor patient compliance to CDT and in the long run poor treatment outcome(52)(53).

Manual Lymphatic Drainage (MLD)/ Massage Therapy

This involves the use of low pressure graded sequential pressure application by trained therapist or nurse practitioners for superficial skin stretching. These sessions are done for 60minutes and repeated thrice a week for at least 4 weeks in addition to wearing of compression garments.

Pneumatic compression devices can also be used in extremities to propel lymph from distal to proximal direction. Daily sessions lasting 1 hour can be operated by the patient or relative at home and followed by compression garments.

2.9.2 Surgical Treatment

Surgical treatment of lymphoedema is suggested when conservative management fails, particularly early following the onset of the swelling. Surgical techniques have evolved over several decades, including ablative procedures such as Homans or Charles procedures, which involves excision of the subcutaneous tissue beneath the affected skin and covering the defect with skin grafts or flaps.

In the past few years, surgical treatments for lymphoedema have advanced, alongside development in microsurgery, allowing the advent of more physiologic and effective methods such as lymphovenous anastomosis and vascularized lymph node transfer.

Surgery has historically had disappointing results compared with non-surgical therapies for lymphoedema. Some people advocate for surgical treatment once lymphoedema progresses to stages 2 or 3. Surgical options include both physiological and excisional procedures(54)(55).

Excisional Procedures: This help remove the deposited fibrofatty tissue and fluid but do not address the lymphatic drainage itself. They include Charles procedure, Thompson procedure as

well as extremity liposuction. With the exception of liposuction, most of these procedures are associated with operative blood loss and poor cosmesis because of the poor healing scars and skin grafts(56)(57).

Charles procedure, involves the radical circumferential excision of subcutaneous tissue followed by full thickness skin grafting. This was further modernized by Van der Walt et al (2009) to include negative pressure wound therapy and delayed skin grafting (to improve graft take and wound recovery). This is known as Modified Charles procedure.

Excisional procedures are generally preserved only for advanced stages of lymphoedema due to the poor aesthetic, risk of recurrence, infection wound break down, and in severe cases amputation.

Liposuction is neither an excisional nor physiological procedure and yet a minimally-invasive and effective method for the treatment of lymphoedema. It involves the removal of subcutaneous adipose tissue from the affected limb using a suction-assisted lipectomy cannula. Its application is best suited for patients with chronic lymphoedema whose pitting oedema has been replaced by fatty deposits. Liposuction can also be performed as an adjunctive procedure to physiologic treatments to improve outcomes. The main limitation of liposuction therapy in lymphoedema treatment is the need for the patient to wear compressive garments indefinitely to maintain the reduced limb volume.

Physiological Procedures: These are microsurgical procedures that promote the physiological drainage of lymphatic fluid through anastomosis of lymphatic vessels with the venous system, or the recruitment (transfer) of a functional lymph node to the affected region for drainage.

These procedures attempt to reconstruct the lymphatic drainage system to provide a path for drainage into the venous system. E.g. vascularized lymph node transfer and lymphovenous bypass(58).

Advancement in microsurgical reconstruction have enabled new avenues to treat chronic lymphoedema that are less morbid than the traditional excisional surgeries. The most relevant of

these physiological procedures are Lymphaticovenular Anastomosis (LVA) and Vascularized Lymph Node Transfer (VLNT).

Lymphaticovenular Anastomosis (LVA)

This is a microsurgical technique that involves the diversion of lymphatic fluid into the venous system distal to a compromised lymphatic bed, thereby creating a bypass of the affected lymphatic region.

The anastomosis is done between subdermal lymphatic vessels (<0.8mm) and subdermal venules using 12-0 sutures under magnification. The anastomosis is either end-to-end or less common lymphatic side to end of vein allowing bidirectional flow of lymph. Some plastic surgeons also advocate for multiple small lymphatic channels being anastomosed to a single vein to overcome the intravenous back pressure. This is known as the "octopus technique"

Research has shown that LVA is especially effective in the treatment of those with early-stage lymphoedema of the upper extremity. It also decreases the rate of infection/cellulitis, which is a common complication of lymphoedema.

Vascularized Lymph Node Transfer (VLNT)

This involves the en bloc transfer of vascularized lymph nodes and its surrounding soft tissue to the site of lymphoedema, with microsurgical anastomosis of the arteriovenous blood supply. It can be done in lymphoedema with sclerotic changes and in combination with LVA or other flap surgeries for breast reconstruction.

The axillary, groin, submental, supraclavicular or omental anatomy are the most commonly used donor soft tissue. It is believed that the transferred lymph nodes reduce lymphoedema by venous shunting of lymphatic fluid and also stimulating lymphangiogenesis. This results in the creation of collateral pathways that connect with adjacent lymph nodes.

The transferred nodes can be placed orthtopically (proximally) or heterotopically (distally) in the lymphoedematous limb. While the former helps to hide the surgical scar, the later provides a gravitational advantage for lymphatic flow.

Seroma, lymphocoele formation, delayed wound closure and donor site lymphoedema are some of the donor site morbidity associated with VLNT. Reverse lymph node mapping can be used to preserve vital lymphatic vessels at the donor site to help reduce these complications.

Current trends now look at combined surgical therapy, by performing physiological and ablative procedures together, with benefits beyond volume reduction. Typical example is performing VLNT or VLA in addition to liposuction, has shown a reduced need for continuous compression therapy following liposuction.

2.10 Compression Therapy

Compression therapy is an effective treatment in every kind of oedema and it is considered the cornerstone treatment in venous oedema and lymphoedema. Compression therapy involves applying graduated pressure to the affected area to reduce swelling, contain swelling and soften any thickened tissue(11)(14)(59).

Compression Therapy reduces oedema by increasing the interstitial pressure, hence reducing the capillary filtration, increasing the lymphatic reabsorption of interstitial fluid (macromolecules first). Increasing the lymphatic flow, shifting fluid to non-compressed areas, increasing the lympho-venous-muscular pump function, protecting the skin and breaking down the fibrosclerotic tissue(60).

In tissues with lymphoedema, elastic fibers are damaged and thus unable to provide sufficient resistance to the build-up of fluid in the interstitial tissue spaces. Application of external compression provides the necessary support for these tissues that have lost elasticity and compensates for the elastic insufficiency by increasing the tissue pressure(60).

The effects of compression therapy/ bandaging on lymphoedema can be categorized into 4 main points;

- Reduction in filtration rate
- Improvement in the efficiency of the muscle and joint pumps
- Prevention of the reaccumulation of evacuated lymph fluid

- Breaking up the deposits of accumulated scar and connective tissue

Although compression therapy can be considered the most important treatment modality in chronic oedema treatment, specific evidences regarding materials, compression pressure and regime are lacking or sparsely provided(59)(61).

Compression of peripheral oedema may not always be appropriate. Contraindications for compression are important to consider and include: severe arterial insufficiency, uncontrolled heart failure, or severe peripheral neuropathy. Prior to commencing lower limb compression, vascular assessment is recommended to rule out any underlying arterial insufficiency. Ankle-brachial Pressure Index (ABPI) is considered more reliable than palpation of pulses(62)(63).

In lymphoedema, the proper application of compression therapy does not interfere with normal blood circulation. However. It is strongly recommended that a physician approves of it before compression therapy is started for any patient. To rule out any complications, it is necessary to have a complete history of the patient(64).

Compression therapy should never cause pains, pins and needles, numbness or discolouration of fingers and toes. If it does the bandage must be removed immediately.

Compression therapy involves applying graduated pressure to the affected area to reduce swelling, contain swelling and soften any thickened tissue(65).

There are different ways to apply compression(66)

- Bandages and wraps
- Compression garments
- Intermittent pneumatic compression

Bandages and Wraps

These are applied to limbs and other body parts to achieve graduated compression. They are used for the management of venous ulcers, lymphoedema and venous hypertension to reduce oedema and help the return of venous blood to the heart.

Compression bandages are the most simple and foundational forms of passive lymphoedema control. Modern technology has now made it possible for bandages and wraps to capitalize on the availability of a broad range of modern, high-tech materials and closures to ensure a snug fit, cleanliness, convenience, effectiveness, and enhances lymphatic drainage.

They range from ultra-simple, short stretch compression bandage in 100% cotton to more complex ones like the SuperWrap, which has a multi-directional elasticity and adjustable compression that is “non-migratory” (stays put with minimal fuss). The fabrics used are cool, comfortable and breathable. Some are even washable. Due to the minimal risk of allergies, many bandages are also latex-free.

Compression Garments

Most lymphoedema patients wear compression garments. They are designed to limit the formation of lymph and provide resistance against which the muscles can pump and move lymph more effectively

These garment are to be worn first thing in the morning and removed last thing at night. Once worn they are to feel firm, supportive and comfortable. They should be removed immediately if patient notices a change in the colour of his/her fingers or toes, pains in the limb or any new numbness or tingling in the affected limb.

They should be washed every two to three days with mild washing powder of liquid and allowed to dry naturally. Compression garment are to be replaced every 4 to 6 months as they lose their compression over time

Intermittent Pneumatic Compression (IPC)

This is a therapeutic technique used in medical devices that include an air pump and inflatable sleeves in a system designed to improve venous circulation in the limbs of patients with oedema or at risk of deep vein thrombosis.

The pump fills the air chambers in the inflatable sleeve which encloses the affected limb requiring treatment. Pressure is generated in the tissues of the limb, forcing fluids, in this case lymph out of the affected area to areas where it can be drained (have normal lymphatics).

Multiple chamber devices provide sequential compression in an ascending pattern up the limb, creating a “milking” effect to move fluid from the distal areas to the proximal areas. The pumps vary in timing cycles and amount of pressure produced, ranging from low-pressures, slow inflation to high-pressure, rapid inflation devices.

IPC is contraindicated in patients undergoing active, curative treatment such as chemotherapy or radiotherapy. It is also not used when there is acute inflammation of the skin e.g. cellulitis, ischaemic vascular disease, peripheral neuropathy or pains or numbness in the limb

2.11 Types of Bandages

Compression bandages are the most simple and foundational form of passive lymphoedema control. Bandaging is the mainstay of treatment for stage 2 and 3 lymphoedema (moderate to severe lymphoedema) and can be used during the both the reductive phase and the maintenance phase(43)(67).

Bandaging involves creating a soft cast on the limb by wrapping with multiple layers of specially made versatile materials.

Modern compression bandages capitalize on the availability of a broad range of modern, high-tech materials and closures to ensure a snug fit, cleanliness, convenience, effectiveness, and enhances lymphatic drainage(68)(69).

To choose an appropriate compression product for a patient, a physician must have a thorough understanding of the various bandage types and techniques. However, this choice can be difficult because of lack of standardized compression classifications, confusion over terminology, and lack of evidence as to which type of bandage and / or system is most effective(52)(70).

Two main types of bandage are used in the management of lymphoedema or chronic oedema(70)(71):

a. Elastic or long stretch
b. Inelastic or short stretch

The difference between them is the degree to which they can be stretched when pulled i.e. extensibility. Elastic bandages have a maximal extensibility greater than 100%, whiles inelastic bandages have a maximal extensibility of less than 100%.

In terms of the pressures generated by bandages, elastic bandages have high resting pressure and low working pressure but inelastic bandages rather have a low resting pressure and high working pressure(72)(73).

The traditional bandaging for lymphoedema is Multi-Layer Lymphoedema Bandaging, or MLLB(11). There are usually 4-5 components of MLLB.

- Finger/toe gauze bandages
- Tubular stockinette
- Soft padding bandage
- Foam pads/pieces
- Short-stretch bandage layer

The MLLB system is tiring, time consuming, heavy and bulky, resulting in a feeling of clumsiness as well as restricting movement of the limb(74). It is also expensive and hence poor patient compliance.

Another system is the 2-layer bandaging. This is often used when a wound is present or to increase patient compliance. Currently this system is what is being used in the management of lymphoedema at the National Reconstructive Plastic Surgery and Burns Centre (NRPS & BC). This system of compression bandaging consists of;

- Layer one (Padding bandage): it exerts a slight compression force and helps distribute the pressure evenly. This layer also protects bony areas.
- Layer two (cohesive bandage): this is applied over the padding bandage. Currently the elastic cohesive bandage is the type of bandaged used at the NRPS & BC.

The 2-layer system gives a better patient compliance, in that it is quick and easy to apply. Patients are able to move able freely and engage in normal activities, thereby providing a sense of control and well-being(74).

The diversity of modalities for compression therapy is reflected by the different schools of compression within countries. For instance;

In the United Kingdom, a 4-layer bandaging system with an elastic bandage is widely used. Whilst in Europe and Australia the inelastic two-layer bandaging system is the standard treatment(75). But in France, elastic compression is commonly prescribed and it's mainly elastic stockings and bandages.
In Germany and Austria, the standard treatment is also performed with stockings and bandages. However, inelastic compression is usually prescribed(76).

Currently a search through literature has not shown any collective or research-based decision (Standard Treatment) on the type of bandaging system for compression therapy in the management of Ghanaian patients with lymphoedema. Therefore the need for such a research among Ghanaians with lymphoedema to help standardize a bandaging system for compression therapy.

2.12 Assessment of Treatment Outcome

There are a range of significant issues that affect a person with lymphoedema which concern not only the patient, but also the clinician and other medical personnel involved in the management of the lymphoedema patient.

Lymphoedema may have severe consequences in terms of patients' functional and psycho-social aspects of life, resulting in impaired quality of life (QoL)(2)(52)((77). Loss of function can be due to the heaviness, pain, and decreased range of motion (ROM) of the affected limbs or due to infection and ulcerations with impaired wound healing(78).

Therefore, the outcome measures for lymphoedema treatment must not only focus on the severity of the lymphoedema, or how it is progressing, or what has been the effect of any treatment or management regimen on it, but a more holistic view with issues, such as the impact on quality of life (QoL), activities of daily living, productivity and social and psychological stigma(79)(80).

The outcome of lymphoedema treatment can be assessed through but not limited to the following(81)(82);

- Limb circumference
- Limb volume
- Skin thickness

- Quality of life instrument score.

Limb circumference: this involves using a measuring tape to measure the circumference of both the affected limb and the normal limb at specific determined points on the limbs. Treatment outcome is monitored by comparing the limb circumference at specific times during the treatment. It can also aid in the diagnosis of lymphoedema(83)(84).
Most practitioners measure limb circumference, and this is an important tool not only as a static evaluation but also as a dynamic, ongoing measurement to assess the patient's progress. Standardization is required if it is to be of any use, hence the need to take the measurements at the same points.

Limb volume: This is of greater use than limb circumference measurements. Limb volume can however be calculated from limb circumference measurements using specific formulas as well as other scientific based methods.

Volume measurement is essential to evaluate the size of the lymphoedema, diagnosis, and treatment monitoring. It is very important that both the normal and affected limbs are measured in exactly the same way at all times to eliminate natural volume variations(85). There are several methods to measure the volume of lymphoedema, depending on the involvement sides, technological ability, and the size of oedema(86). Commonly used methods include

Circumferential measurements: the tape method (circumference measurements) is the most common way to measure limb volume for lymphoedema. The tape is place around the affected limb at prescribed increments, measurements recorded and a formula is used to calculate the limb volume.

For this research circumferences of the limb are measured at specific intervals along the limb and the volume calculated according to the truncated formula in upper/lower extremity lymphoedema(86)(87).

Measurements of both the affected and non-affected limbs are taken and compared. The limb is divided into segments and the volume of each segment is calculated. The limb volume is

obtained by adding up the volume of all the segments. This has an advantage of being in-expensive, doesn't require special equipment, and has good test-re-test reliability.

The formula for the volume of a frustum of a cone is commonly used to calculate the limb volume. $\mathbf{V = h \times (C^2 + c^2 + Cc) / (12 \times \pi)}$, where

V = the volume of a segment of the limb

C and c are the circumferences (in cm) at determined segments of the limb
h = the distance between circumferences (C, c) in each segment

For different segments (A, B, C, D) of the limb being assessed, the limb volume is calculated as $\mathbf{V\ limb = V_A + V_B + V_C + V_D}$

There is also an Excel® formula to provide volume measurements(88).

Water displacement method: this is the gold standard for measuring limb volume and is the only reliable method available to assess oedema of the hands and feet. It is done by using specially designed arm and leg volume meters. The volume meter is fully filled with water, the limbs are drained and held in a specific position, and wait a few seconds to allow the water to flow-out. The drained water is collected in a plastic tray and the entire volume of the limb is directly measured(86). However, this method is not practical due to the difficulty in huge sized limbs, hygienic concerns, and consumed amount of water(89).

Perometry: this is an optoelectronic measuring method using a square frame with multiple perpendicular ultraviolet light beams(86). The frame is moved along the limb, and the cross-sectional area is calculated continuously and, thereby, by volume. The equipment is expensive and difficult to use in measuring hand and foot volume, but the method is accurate and fast.

Bioelectric impedance: this is a causally related direct measure of lymph accumulation. It measures the opposition (impedance) of the body's tissues to the flow of an electric current. It is a rapid, non-invasive, and relatively inexpensive method that can measure both unilateral and bilateral lymphoedema of the arms and legs(90).

Bioimpedance measurements are made by passing a harmless electric signal of low strength from one point to another. The amount of resistance the current encounters is measured and used to calculate a ratio. This ratio is used to determine if there is excessive extra-cellular fluid (volume). The test takes only minutes to perform and it is painless and results are immediate.

Skin thickness: ultrasound imaging is a non-invasive, safe, and economically feasible tool to view lymphoedematousc tissue changes in the skin including dermal thickness(91). In scanning, the dermo-hypodermal junction is clearly identified and the full skin thickness (epidermis and dermis) is measured from the anterior echogenic border of the epidermis to the posterior echogenic border of the dermis(92). The mobile ultrasound transducer can be used too on a limb, as well as on more awkward surfaces such as the hand, trunk, breast, or face – all areas susceptible to lymphoedema.

Quality of life: the impact of lymphoedema on a patient's quality of life (QoL) has generally been underestimated. However, it is now clear that it can cause physical symptoms, impaired physical and social function and emotional effects(93)(94).

In addition to limb swelling, other very common complaints among patients with lymphoedema are pains, reduced amplitude of movement, infections, and problems with body image. These clinical manifestations determine the impact on patients' lives and are frequently associated with comorbidities and psychiatric disorders(95).

Several QoL forms or questionnaire have been described in the literature for measuring lymphoedema-specific health related quality of life. These include Upper Limb Lymphoedema-27 (ULL-27), Lymphoedema Quality of Life Inventory (LyLI), Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF) and Lymphoedema Life Impact Scale (LLIS)(96)(97).

Keeyle et al developed a short and simple questionnaire named Quality of Life measure for Limb Lymphoedema (LYMQOL). It consists of two questionnaires: for upper and lower limb lymphoedema LYMQOL-Arm and LYMQOL-leg. LYMQOL is a validated tool that can be used in both types of research or in clinical routine to detect the quality of life of patients with limb lymphoedema(93)(98). It has been reported as having a good feasibility, reliability and validity in researches and hence its choice as the tool to assess QoL of the participants of this research.

2.13 NULL HYPOTHESIS

There is no difference in the treatment outcome in managing limb lymphoedema using elastic compression bandage or inelastic compression bandage.

2.14 ALTERNATE HYPOTHESIS

There is a difference in the treatment outcome in managing limb lymphoedema using elastic compression bandage or inelastic compression bandage

3 AIMS AND OBJECTIVES

3.1 AIM

The aim of the study is to compare the clinical outcomes of treating lymphoedema of the limbs with elastic compression bandaging and inelastic compression bandaging in Ghanaian patients.

3.2 SPECIFIC OBJECTIVES

- To determine differences in the limb circumference between elastic and elastic compression bandage treatment regimes.
- To determine differences in limb volume between elastic and inelastic compression bandage treatment regime
- To determine the relationship between the type of compression bandage treatment regime and the quality of life of patients before and after treatment.

4 METHODOLOGY

4.1 STUDY DESIGN

The study was a Randomized Control Trial or (randomized comparative study)

4.2 STUDY SITE

The study was conducted at the Physiotherapy Unit of the National Reconstructive Plastic Surgery and Burns Centre (NRPS & BC) at the Korle Bu Teaching Hospital (KBTH).

The NRPS & BC was chosen because currently most patients with lymphoedema are referred there for management. The definitive non-surgical treatment for most of these patients are done by the physiotherapists of the Centre with regular clinical review by the doctors (plastic surgeons) of the same Centre.

For the three year period 2019, 2020 and 2021, the physiotherapy unit of NRPS & BC have managed 15, 56 and 43 new cases of Lymphoedema respectively. Giving an average of 38 new patients with lymphoedema per year.

The physiotherapists in the Centre offer CDT as the main stay of management for the lymphoedema patients but with much emphasis on compressive bandaging and manual lymphatic drainage as well as a much flexible schedule to encourage good patient compliance.

This made the Physiotherapy Unit of the National Reconstructive Plastic Surgery and Burns Centre, the best place to get a vast majority of patients with limb lymphoedema who were recruited into the study.

4.3 STUDY POPULATION

Participants for the study were Patients with limb lymphoedema referred to the NRPS & BC for management

4.4 INCLUSION CRITERIA

The following criteria were used to select patients for the study

- Patients with Limb Lymphoedema referred for Compression Therapy
- Patients between the ages of 16 to 59 completed years at the time of recruitment
- Patients with stage 1 or 2 lymphoedema
- Newly diagnosed patients with limb lymphoedema irrespective of the underlying cause
- Old lymphoedema patients who have not received any form of treatment in the past 6 months

4.5 EXCLUSION CRITERIA

Patients with the following were excluded from the study:

- Patients with lymphoedema involving any body part other than the limbs
- Patients with ulceration(s) on the limb involved
- Presence of infection (cellulitis, erysipelas, lymphangitis) in the affected limb
- Patients with uncontrolled congestive cardiac failure or uncontrolled hypertension
- Patients with clinical features or a previous diagnosis of peripheral vascular disease
- Patients who develop complications in the course of the study.

4.6 SAMPLE SIZE DETERMINATION

The sample size was determined using a standard formula using the primary outcome measure which is the percentage change in limb volume.

The average percentage limb volume reduction in a study by Badger et al, 2000 comparing multilayer bandaging followed by hosiery versus hosiery alone as part of a Cochrane review on physical therapies for reducing and controlling lymphoedema of the limb (review in 2008) was used.

The bandage + hosiery group achieved a mean reduction of 33.5% (SD 16.9) as against 9.6% (SD 20.4) in the hosiery alone group.

The formula used to determine the sample size was as follow

$$N = \frac{(Z_{1-\alpha/2} + Z_{\beta})^2 \times (O_1^2 + O_2^2)}{d^2}$$

Where:

N = Sample size per each study group

α = Probability of type I error (usually 0.05)

β = Probability of type II error (usually 0.2)

Power = 0.8

Z = Typical Z value for a given α and β

O_1 and O_2 = Standard deviation of variable in both study groups. Which are 16.9 and 20.4 in the Badger 2000 Bandage study.

d = absolute difference between the mean volume reduction of each study group

$$N = \frac{(1.96 + 0.84)^2 \text{ X } (16.9^2 + 20.4^2)}{(33.5 - 9.6)^2}$$

$$N = \frac{(2.8)^2 \text{ x } 701.77}{571.21} \qquad \mathbf{N = 9.63}$$

Sample size for each group was at least 10 patients with total sample size being at least 20

23 patients were in the end recruited into the study.

4.7 SAMPLING METHOD

Participants for the study were selected by consecutive recruitment into the two study arms at the Physiotherapy Unit of the Reconstructive Plastic Surgery & Burn Centre. This was continued until the required sample size was reached for each study group.

There was however a simple balloting to determine which of the two groups the first qualified participant was recruited into.

4.8 STUDY PROCEDURE

The two layer bandaging technique which is currently the routine bandaging being used at the Physiotherapy Unit of NRP&BC as part of lymphoedema management was adopted for the study.

The two layer bandaging technique comprise of a first padding layer of Soff Ban and the second layer either of the two types of compression bandage for this study (i.e. Elastic or Inelastic Bandage) based on which arm of the study the participant belonged to.

The following brand of bandages were adopted for the study

1. Elastic Bandage = Somga High elastic bandage
2. Inelastic Bandage = Atico

Phase I (Reductive Phase) of compression bandaging for limb lymphoedema was the main focus of the study. Each participant underwent compression bandaging for eight weeks. Each person did once a week physiotherapy session. The session involved cleaning of the affected limb, Manual Lymphatic Drainage and then application of the compression bandage.

Participants were then to wear the bandage for about 8 to 12 hours before they remove it. Participants were then apply the bandage themselves every day for the remaining 6 days. Patients at the beginning of the compression therapy were asked to bring a close relative or friend, who was thought how to help the patient to apply the bandage at home.

After approval by the Ghana College of Physicians and Surgeons ethics committee, a minimum of 20 participants were selected by conservative recruitment into the 2 study groups at the Plastic Surgery Unit, KBTH.

All patients who met the inclusion criteria were counselled about lymphoedema, its causes, treatment plan and complications. After which the purpose of the study was explained to each patient and then a written consent obtained before they were rolled into the study.

The study groups were as follow;
Group A = inelastic bandage group
Group B = elastic bandage group

Patient's demographic details and lymphoedema history were taken by direct interview of the participants using a preformed questionnaire.

Before treatment was started each patient had the necessary measurements taken of the non-affected (contralateral) limb and the affected (lymphoedema) limb. The circumference of the limbs were taken at predetermined distances from a known landmark on the limb. These was done using a normal tape measure and a standardized lymphoedema measurement chart (of which one was already being used in the physiotherapy Unit of the NRPS & BC. Measurements taken were recorded in the lymphoedema measurement chart.

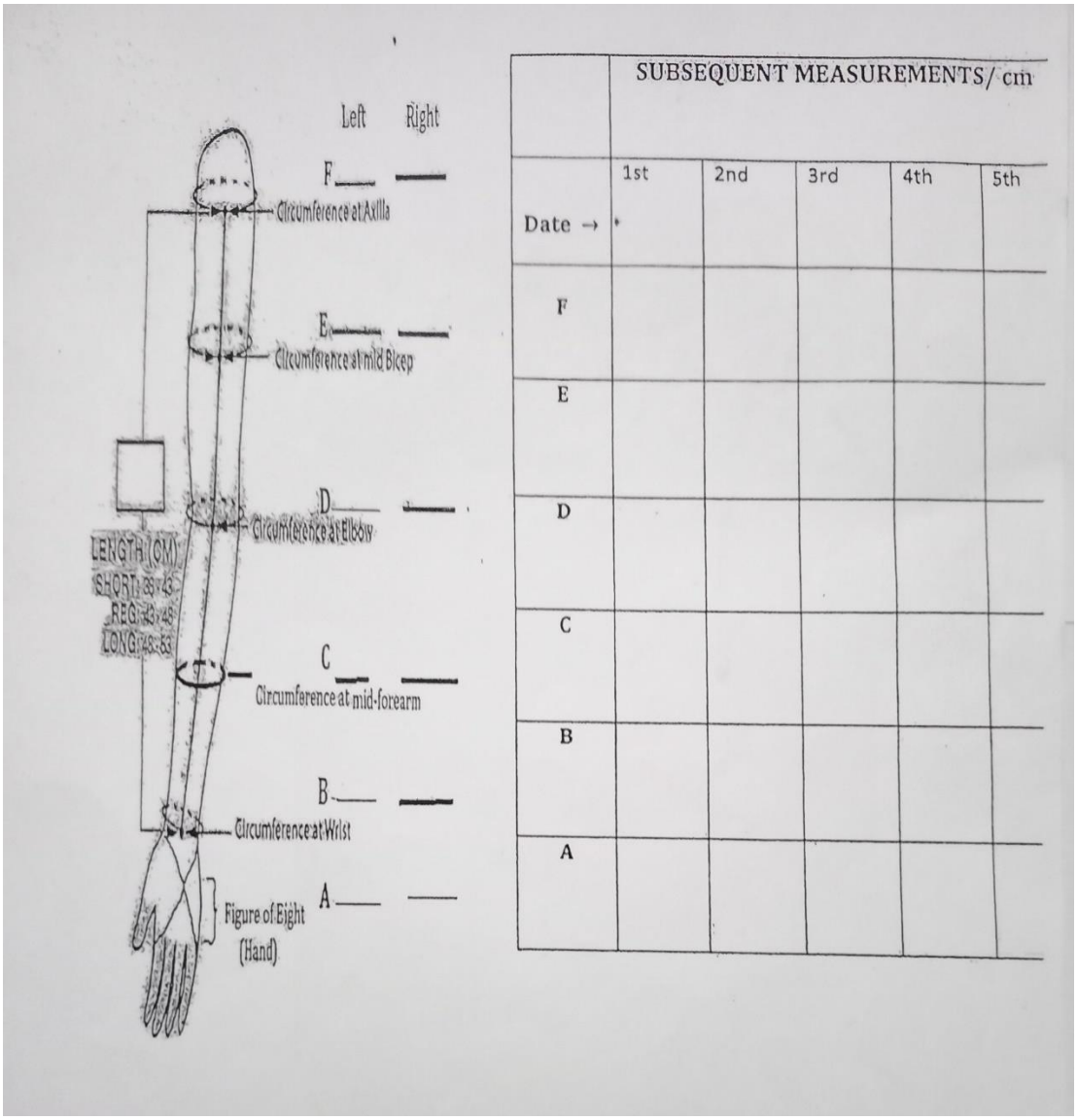
Limb volume was then calculated with the circumference measurements using the truncated formula as described in the literature review. The limb volume of both the contralateral limb and the lymphoedema limb were calculated and the difference between these volumes documented as the **EXCESS LIMB VOLUME.** The excess limb volume is the true measure of the lymphoedema in the affected limb. Hence a measure of the change in the excess limb volume would be an appropriate way of determining the effect of the two different bandage types for the treatment of lymphoedema.

These measurements .i.e. limb circumference, limb volume, excess limb volume and change in excess limb volume were measured and calculated accordingly for all participants every 2 weeks up to the end of the bandaging on the 8^{th} week.

In order to reduce bias, the application of the bandage and the measurements of the limb was not be done by the same person. The physiotherapists helping with the research did the bandaging and the measurements were done by the principal researcher or the physiotherapist assigned to the research. Neither did the principal researcher know which bandage type the participant was using nor the physiotherapist, the measurements obtained. These became known to either team after the mandatory 8 weeks.

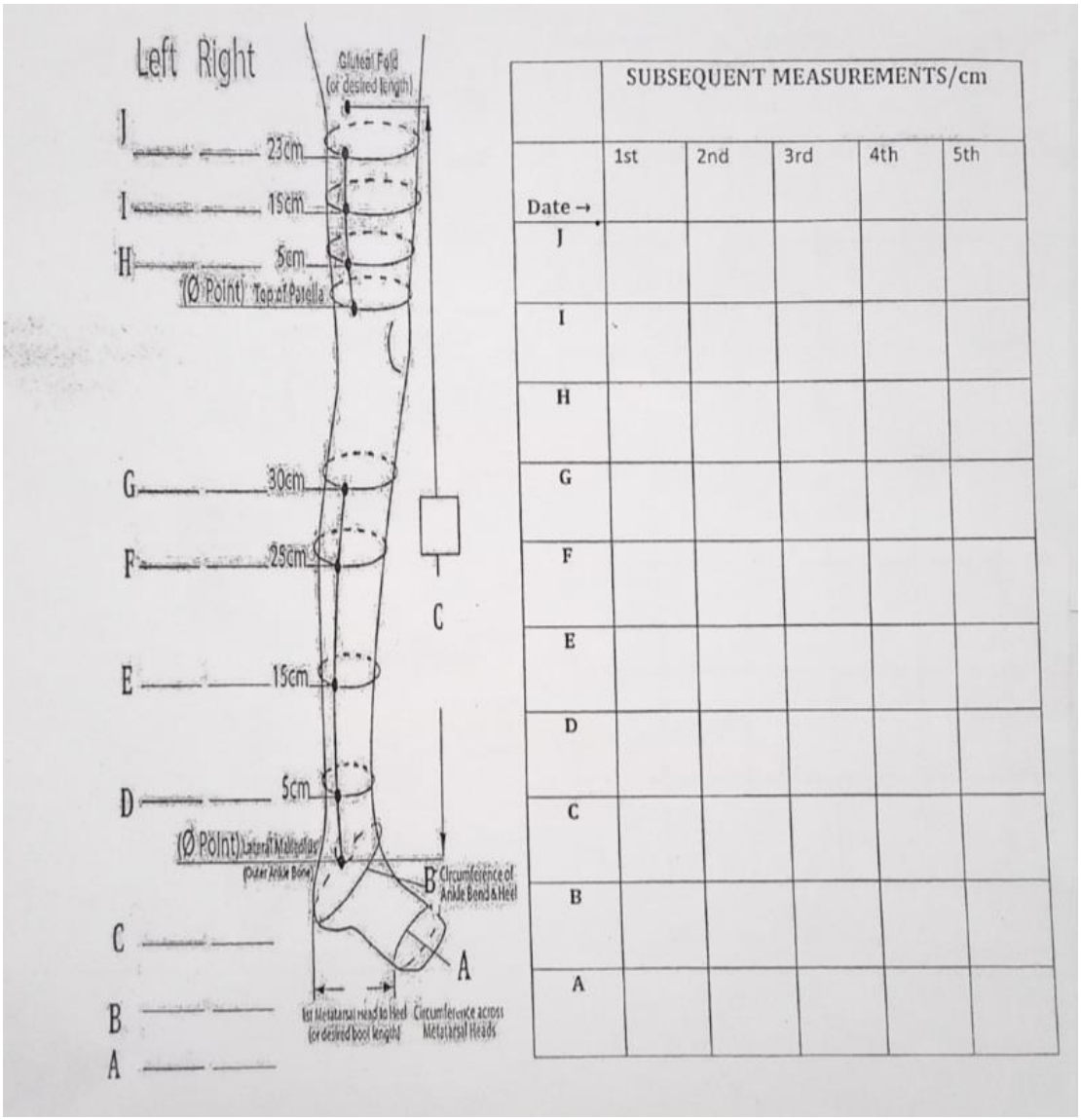
LYPMHOEDEMA MEASUREMENT CHARTS

Figure 1 ***: Measurements for Upper Limb`***



	SUBSEQUENT MEASUREMENTS/ cm				
Date →	1st	2nd	3rd	4th	5th
F					
E					
D					
C					
B					
A					

Figure 2 ***: Measurements for Lower Limb***



	SUBSEQUENT MEASUREMENTS/cm				
Date →	1st	2nd	3rd	4th	5th
J					
I					
H					
G					
F					
E					
D					
C					
B					
A					

4.9 DATA COLLECTION

Data was collected using a case record form and the lymphoedema measurement chart. These were filled by the principal investigator. The forms were coded to ensure full privacy of the participants as well as to reduce bias.

Demographic variables collected included the Age, Sex, Occupation,

The following measurements were taken and recorded on the lymphoedema measurement chart for each participant at the stated specific time of the treatment (research)

a. Limb circumference
b. Limb volume
c. Excess limb volume
d. Change in excess limb volume

Other data collected was the quality of life assessment at the beginning and end of the compression bandaging treatment.

4.10 DATA ANALYSIS

All data was entered in a spreadsheet software, Microsoft Excel version 16.0

Data inputted per participant shall be as follow

- Demography
- Underlying cause of the lymphoedema
- Limb circumference
- Limb volume
- Excess limb volume
- Change in excess limb volume
- Quality of life assessment score

4.11 STATISTICAL ANALYSIS

SPSS statistics software version 25 was used for data analysis. Continuous numerical data was summarized using mean and standard deviation and categorical data with percentages. The primary outcome measures were the change in excess limb volume and change in limb circumference, measured in percentages.

Repeated measure analysis of variance (ANOVA) was used to see the difference in the primary outcome measures within and between groups. P value of < 0.05 was considered statistically significant.

Limb circumference measurements were used to calculate the limb volume for both affected and unaffected limb. The difference in circumference and volume measurements were calculated and from that the change and percentage change in limb circumference and volume obtained for analysis.

LYMQOL for upper and lower limb were used in assessing the quality of life of patients. Patients answered the questionnaire and the scoring per the response was calculate by dividing the total mark by the number of questions answered. The smaller the score obtained, the better the quality of life.

4.12 DESSERMINATION OF RESULTS

The dissertation was completed and presented to the Ghana College of Surgeons as part fulfilment for the award of the fellowship in Plastic Surgery. After submission to the college the dissertation will be presented to the National Reconstructive Plastic Surgery and Burns Centre, Korle Bu Teaching Hospital.

The results will also be submitted to the Ghana Medical Journal and any other journal for publication. Results will also be presented at relevant seminars.

4.13 ETHICAL CONSIDERATIONS

1. Participation in the study was voluntary
2. Written informed consent was obtained from all participants

3. Participant privacy was ensured throughout the entire research period
4. Withdrawal from the study was possible at any point in time.
5. The participants did not bear any extra cost than they would usually bear from routine lymphoedema treatment
6. The research in no way delayed patient treatment
7. Participants were not exposed to any harm or invasive procedures during the study

4.14 PERSONNEL

The Principal investigator for this study was responsible for;

- Data collection
- Clinical examination to ascertain eligibility criteria of the participants
- Measurement and recording of limb circumference, volume and excess volume as well as administration of the quality of life assessment tool/questionnaire.
- Data entry and data analysis

Also assisting with the research were be two trained physiotherapists at the Physiotherapy Department of the National Reconstructive Plastic Surgery and Burn Centre. They were responsible for;

- Manual lymphatic drainage prior compression bandage application
- Application of the compression bandages for the participants

To minimize bias they randomly attended to the participants as and when they reported for their twice weekly physiotherapy sessions.

5 RESULTS

5.1 DEMOGRAPHICS

The study population consisted of 23 patients with unilateral extremity (limb) lymphoedema. Surprisingly all the patients were females. The age distribution of the research participants is shown in the figure below (fig 3). Their mean age was 48.61 years.

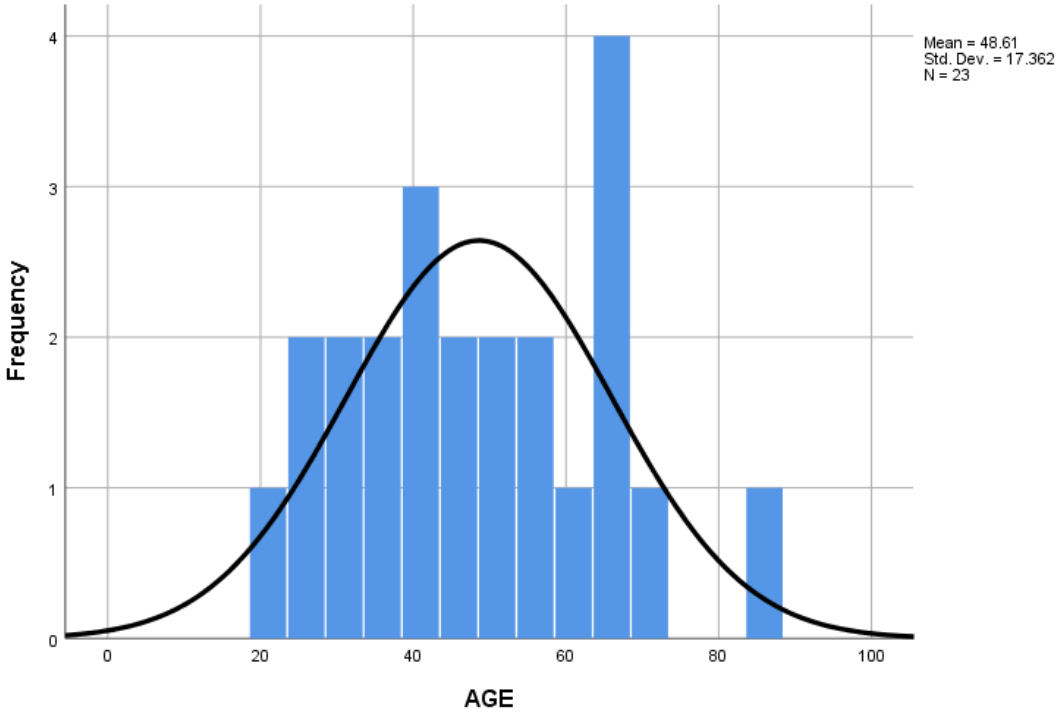


Figure 3 : Age distribution of participants

The mean age for the inelastic compression bandage group (Group A) was 42.8years and that for the elastic compression group (Group B) was 53.9 years as shown in Table 1. Comparing the mean age for the two groups showed that the difference was not statistically significant (p-value = 0.128).

Table 1: Mean age between groups

	Mean (±SD)	t-test	p-value
Group A	42.8 (±18.3)	-1.58	0.128
Group B	53.9(±15.3)		

SD= Standard deviation; Group A = inelastic compression bandage, Group B = elastic compression bandage

Table 2 shows the occupation of the patients who took part in the survey. The highest being 34.8% each for both the professionals and artisans. 6 on them were retirees and only 1 person was a student.

Table 2: Occupation of participants

	n	%
Professional	8	34.8
Artisan	8	34.8
Student	1	4.3
Retired	6	26.1

Comparing the difference in the type of occupation for the two research groups, showed there was a significant difference (p-value = 0.012) in terms of the participants' occupation as shown in Table 3 below.

Table 3: Occupation status between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B		
Professional	7 (63.6)	1(8.3)	9.66	0.012*
Artisan	2(18.2)	6 (50.0)		
Student	1(9.1)	0(0.0)		
Retired	1(9.1)	5(41.7)		

* P-value<0.05-statistically significant; Group A = inelastic compression bandage, Group B = elastic compression bandage

Table 4. Shows majority of the patients 12 (52%) have had some form of tertiary education, 8(34.8%) secondary education and the least 3 (13%) had basic education

Table 4: Level of education of participants

	n	%
Basic	3	13.0
Secondary	8	34.8
Tertiary	12	52.2

Also comparing the level of education between the 2 groups showed there was a significant difference (p-value = 0.015) in their level of education as shown in Table 5.

Table 5: Level of education between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B		
Primary	1(9.1)	2(16.7)	7.66	0.015*
Secondary	1(9.1)	7 (58.3)		
Tertiary	9(81.8)	3(25.0)		

* P-value<0.05-statistically significant; Group A = inelastic compression bandage, Group B = elastic compression bandage

Most of the patients 21(91%) were staying in Greater Accra Region and the remaining 2(9%) were from the Volta Region.

Of the total number of participants in the study only 4 (17%) had co-morbid conditions. Two of the participants had hypertension, one had asthma and the last one diabetes.

5.2 LYMPHOEDEMA CHARACTERISTICS

The following characteristics relating to the diagnosis and condition of the patients were assessed.

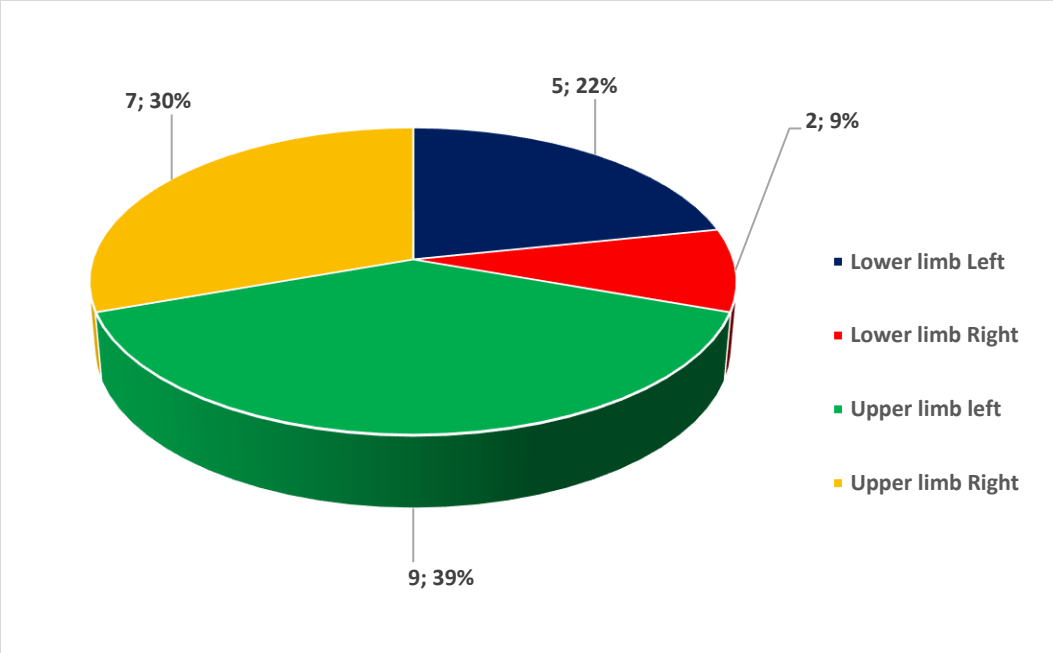


Figure 4 Part of body involved

Figure 4 is a Pie chart representing the specific body extremity affected by the lymphoedema (abnormal limb). Out of the 23 patients, 9 (39%) of them had the condition affecting their left upper limb and the least 2 (9%) had it affecting their right lower limb. 5 (22%) and 7(30%) had the lymphoedema involving their left lower limb and right upper limb respectively. In terms of upper limb versus lower limb; 16 (69%) had it affecting their upper limb against 7(31%) in the lower limb.

Comparing the body extremity affected between the two research group showed no significant difference (p = 0.506) between them as shown in Table 6.

Table 6: Part of body affected between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B		
Lower limb left	3(27.3)	2(16.7)		

Lower limb Right	2(18.2)	0 (0.0)	3.00	0.506
Upper limb left	3(27.3)	6(50.0)		
Upper limb Right	3 (27.3)	4(33.3)		

Group A = inelastic compression bandage, Group B = elastic compression bandage

Figure 5. Shows the distribution of the age of the patient at which the diagnosis of lymphoedema was made. The mean age at which patients were diagnosed was 46.26 years.

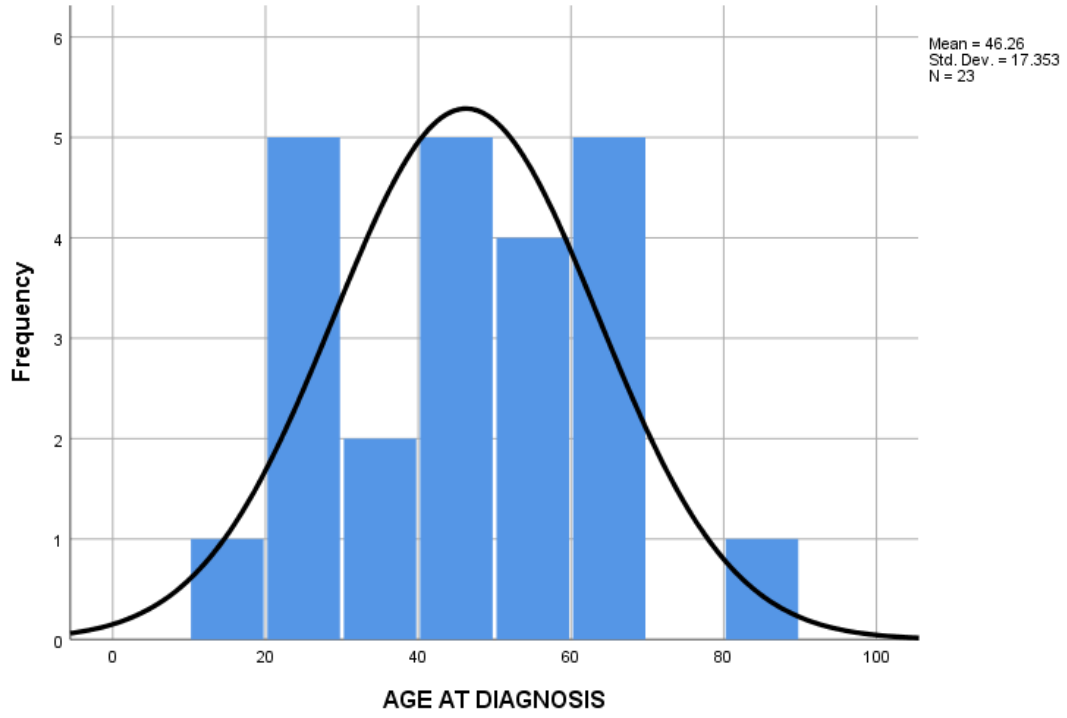


Figure 5 : distribution of age at diagnosis

When comparing the mean age at which patients were diagnosed with lymphoedema for the two groups, there was no statistical difference (p-value = 0.193) as shown in table 7.

Table 7: Mean age at diagnosis between groups

	Mean (±SD)	t-test	p-value
Group A	41.3 (±17.5)	-1.34	0.193
Group B	50.8(±16.6)		

SD= Standard deviation; Group A = inelastic compression bandage, Group B = elastic compression bandage

Figure 6 shows the duration of illness for all the patients, that is how long they have had the lymphoedema prior to they being recruited into the study. 8(35%) have had the lymphoedema for less than a year, 9(39%) have had it for 1 to 4 years and 6(26%) for more than 4 years.

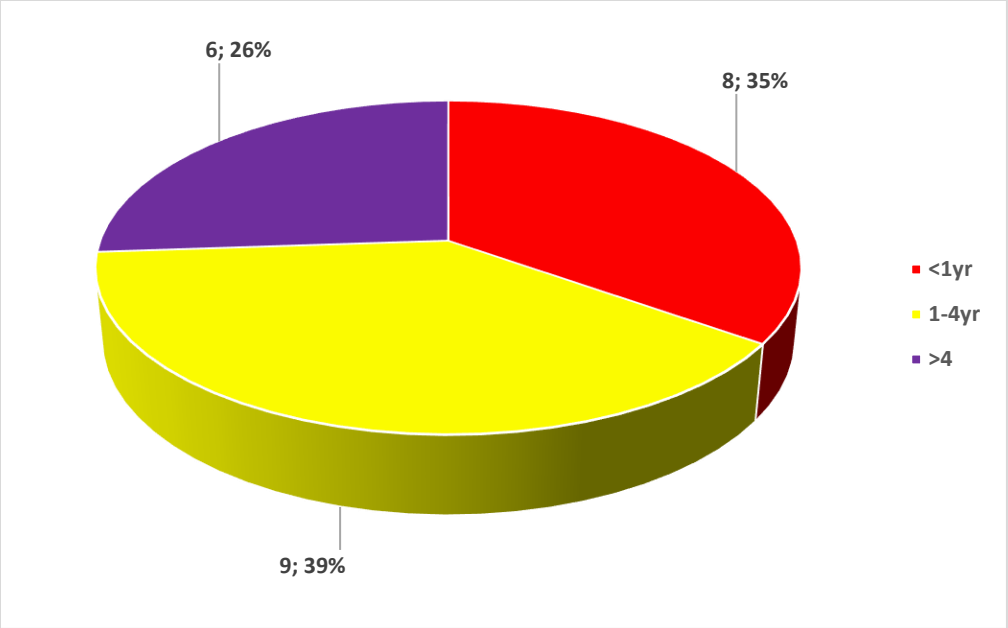


Figure 6 : Duration of Illness

There was no significant difference statistically (p-value = 0.511) when the duration of illness was compared for the two study groups as shown in Table 8.

Table 8: Duration of illness between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B		
< 1 year	5(45.5)	3(25.0)		
1-4 year	3(27.3)	6(50.0)	1.50	0.511
>4 year	3(27.3)	3(25.0)		

Group A = inelastic compression bandage, Group B = elastic compression bandage

Of the total number of participants for this study, 4(17%) of them has had some form of treatment for their lymphoedema. 2 out of the 4 had used compression garment at some stage, 1 of them had some form of compression bandage therapy and the last one massage therapy by a physiotherapist. However these were more than 6 months prior to be recruited for the study (part of the inclusion criteria).

Table 9: Cause of lymphoedema

	N	%
Primary	**4**	**17.4**
Secondary		
Infection	2	8.7
Malignancy	8	34.8
Radiotherapy	5	21.7
Surgery	3	13.0
Others (postpartum)	1	4.3
Total for secondary	**19**	**82.6**

Table 9 shows the underlying cause of the limb lymphoedema for all the participants. 4 (17%) of them had primary lymphoedema and 19 (83%) had secondary lymphoedema.

Of those who had secondary lymphoedema, 16 of them were due to a malignancy and its associated treatment. 2 were due to infection (filariasis) and 1 had developed lymphoedema after her pregnancy.

The commonest malignancy attributed to the cause of lymphoedema in this study was breast cancer.

Comparing the underlying cause of the limb lymphoedema for the two groups showed there was no significant difference (p-value = 0.423) between the two groups. As shown in Table 10 below

Table 10: Cause of lymphoedema between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B		
Primary	2(18.2)	2(16.7)		
Infection	2(18.2)	0(0.0)	6.89	0.423
Malignancy	3(27.3)	5(41.7)		
Radiotherapy	1(9.1)	4(33.3)		
Surgery	2(18.2)	1(8.3)		
Others	1(9.1)	0(0.0)		

Group A = inelastic compression bandage, Group B = elastic compression bandage

Associated symptoms

Aside the symptom of unilateral limb swelling, the study also looked at other symptoms associated with limb lymphoedema. Pains, heaviness, altered sensation, skin changes, joint discomfort and reduced mobility in the affected limb were the other symptoms assessed in this study.

A total of 17 (74%) of the patients had pains in the affected limb and 6 (26%) had no pains associated with the limb swelling. Table 11 shows the distribution of those with and without pains in the two study groups and their corresponding percentage within each group. 7(63.6%) of those in Group A had pains and 10 (83.3%) in Group B also had pains as part of their symptoms.

However comparing the two groups, there was no statistical significant difference (p-value = 0.371) between them in terms of pains as a symptom

Table 11: Symptoms of pain between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B	1.16	0.371
Yes	7(63.6)	10(83.3)		
No	4(36.4)	2(16.7)		

Group A = inelastic compression bandage, Group B = elastic compression bandage

15(65%) of the patients had heaviness in the affected limb as part of their symptoms and 8(35%) had no heaviness in the affected limb. Table 12 shows the group distribution of heaviness as a symptom and any statistical significant difference between them. 6(54.5%) of those in Group A had heaviness in the affected limb, likewise 9(75%) of those in Group B. Comparing the presence of heaviness in the affected limb for both group showed there was no statistical significant difference (p-value = 0.400) between the two groups as shown in Table 12

Table 12: Symptoms of heaviness between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B	1.07	0.400
Yes	6(54.5)	9(75.0)		
No	5(45.5)	3(25.0)		

Group A = inelastic compression bandage, Group B = elastic compression bandage

A total of 6 (26%) of the patients had altered sensation in the affected limb and 17 (74%) had no altered sensation associated with the limb swelling. Table 13 shows the distribution of those with and without altered sensation in the two study groups and their corresponding percentage within each group. 2(18.2%) of those in Group A had altered sensation and 4 (33.3%) in Group B also had altered sensation as part of their symptoms.

However comparing the two groups, there was no statistical significant difference (p-value = 0.640) between them in terms of altered sensation as a symptom as shown in Table 13

Table 13: Symptoms of altered sensation between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B	0.68	0.640
Yes	2(18.2)	4(33.3)		
No	9(81.8)	8(66.7)		

Group A = inelastic compression bandage, Group B = elastic compression bandage

7(30%) of the patients in the study had skin changes in the affected limb as part of their symptoms and 16(70%) had no skin changes in the affected limb. Table 14 shows the group

distribution of skin changes as a symptom and any statistical significant difference between them. 3(27.3%) of those in Group A had skin changes in the affected limb whiles 4(33.3%) of those in Group B also had skin changes. Comparing the presence of skin changes in the affected limb for both group showed there was no statistical significant difference (p-value = 1.000) between the two groups as shown in Table 14.

Table 14: Symptoms of skin changes between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B	0.100	1.000
Yes	3(27.3)	4(33.3)		
No	8(72.7)	8(66.7)		

Group A = inelastic compression bandage, Group B = elastic compression bandage

A total of 12 (52%) of the patients had joint discomfort in the affected limb and 11 (48%) had no joint discomfort associated with the limb swelling. Table 15 shows the distribution of those with and without joint discomfort in the two study groups and their corresponding percentage within each group. 4(36.4%) of those in Group A had joint discomfort and 8 (66.7%) in Group B also had joint discomfort as part of their symptoms.

However comparing the two groups, there was no statistical significant difference (p-value = 0.150) between them in terms of joint discomfort as a symptom as shown in Table 15.

Table 15: Symptoms of joint discomfort between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B	2.21	0.150
Yes	4(36.4)	8(66.7)		
No	7(63.6)	4(33.3)		

Group A = inelastic compression bandage, Group B = elastic compression bandage

10 (43%) of the patients in the study had reduced mobility in the affected limb as part of their symptoms and 13(57%) had no such symptom in the affected limb. Table 16 shows the group distribution of reduced mobility in the affected limb as a symptom and any statistical significant difference between them. 4(36.4%) of those in Group A had reduced mobility in the affected limb whiles 6(50.0%) of those in Group B also had reduced mobility. Comparing the presence of reduced mobility in the affected limb for both groups showed there was no statistical significant difference (p-value = 0.680) between the two groups.

Table 16: Symptoms of reduced mobility between groups

	Group; n (%)		Fisher Exact test	p-value
	Group A	Group B	0.434	0.680
Yes	4(36.4)	6(50.0)		
No	7(63.6)	6(50.0)		

Group A = inelastic compression bandage, Group B = elastic compression bandage

5.3 LIMB CIRCUMFERENCE MEASUREMENTS

The circumference was measured for both the unaffected and affected limb at specific points and the values added up for each participant. Table 17 shows the mean circumference of the unaffected limb for both groups. The mean circumference for those in Group A was 180.39 (±26.17)cm and those in Group B was180.73 (±13.31)cm. Comparing the mean circumference for the two groups showed no statistical significant difference between them (p-value = 0.960)

Table 17: Mean circumference of unaffected limb between groups

	Mean (±SD) cm	t-test	p-value
Group A	180.39 (±26.17)	-0.039	0.960
Group B	180.73(±13.31)		

SD= Standard deviation; Group A = inelastic compression bandage, Group B = elastic compression bandage

Table 18 shows the mean circumference of the affected limb prior to compression bandaging treatment. The mean circumference of the affected limb for those in Group A was 203.24(±34.37) cm and that for those in Group B was 206.21(±17.65) cm. Comparing the mean circumference of the affected limb for both groups showed there was no statistical significant difference (p-value = 0.794) between them.

Table 18: Mean circumference of affected limb pre-treatment between groups

	Mean (±SD) cm	t-test	p-value
Group A	203.24(±34.37)	-0.26	0.794
Group B	206.21(±17.65)		

SD= Standard deviation; Group A = inelastic compression bandage, Group B = elastic compression bandage

Figure 7 is a line graph showing the mean percentage change in the circumference of the affected limb for both groups prior to treatment and 4 weeks & 8 weeks respectively during compression bandaging treatment. For Group A the pre-treatment mean percentage change in limb circumference was 12.7% and the mean percentage change at 4 weeks and 8 weeks during treatment was 10.4% and 8.1% respectively.

For Group B the pre-treatment, 4 weeks and 8 weeks mean percentage change in limb circumference were 14.3%, 8.5% and 6.4% respectively. There is no statistical significant

difference between the two groups in terms of the mean percentage change in limb circumference (p-value = 0.861).

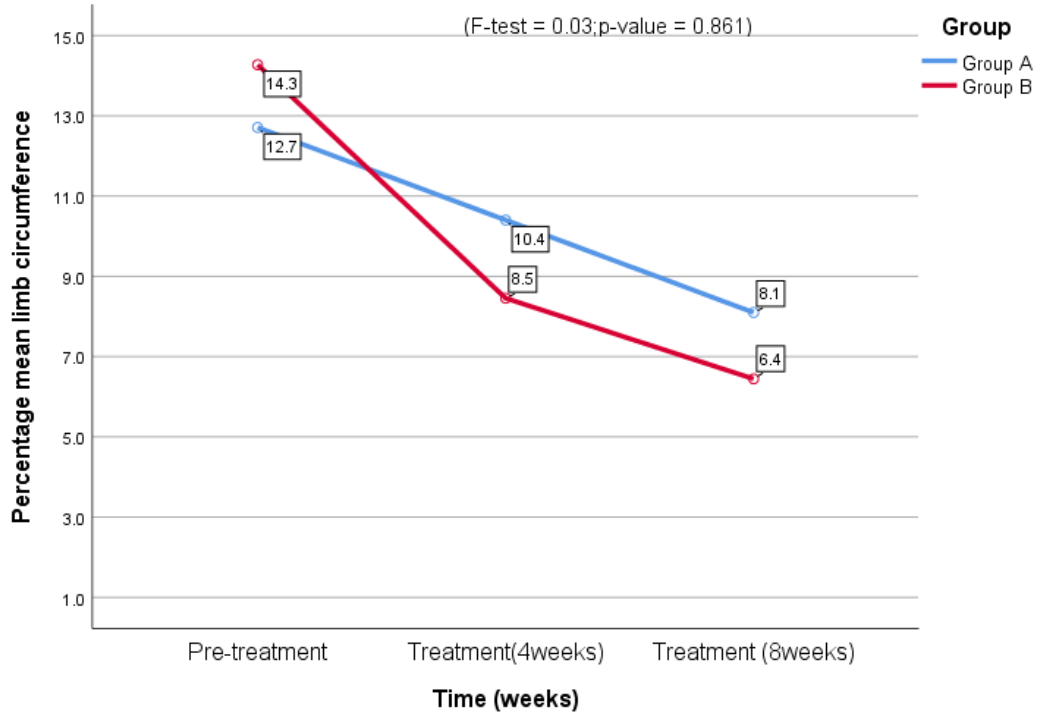


Figure 7 : Mean percentage change in limb circumference

5.4 LIMB VOLUME MEASUREMENTS

Table 19 shows the mean volume of the unaffected limb for both groups. The mean volume for those in Group A was 2500.43 (±1145.51) cm^3 and those in Group B was 2663.48 (±684.13097) cm^3 Comparing the mean volume for the two groups showed no statistical significant difference between them (p-value = 0.680).

Table 19: Mean volume of unaffected limb between groups

	Mean (±SD) cm^3	t-test	p-value
Group A	2500.43 (±1145.51)	-0.42	0.680
Group B	2663.48(±684.13097)		

SD= Standard deviation; Group A = inelastic compression bandage, Group B = elastic compression bandage

Table 20 shows the mean volume of the affected limb prior to compression bandaging treatment. The mean volume of the affected limb for those in Group A was 3275.53 (±1772.83) cm^3 and that for those in Group B was 3487.72(±719.84) cm^3. Comparing the mean volume of the affected limb for both groups showed there was no statistical significant difference (p-value = 0.706) between them.

Table 20: Mean volume of affected limb pre-treatment between groups

	Mean (±SD) cm^3	t-test	p-value
Group A	3275.53 (±1772.83)	-0.38	0.706
Group B	3487.72(±719.84)		

SD= Standard deviation; Group A = inelastic compression bandage, Group B = elastic compression bandage.

Figure 8 is a line graph showing the mean percentage change in the volume of the affected limb for both groups prior to treatment and 4 weeks & 8 weeks respectively during compression bandaging treatment. For Group A the pre-treatment, 4 weeks and 8 weeks mean percentage change in limb volume were 28.51%, 21.00% and 13.72% respectively.

For Group B the pre-treatment, 4 weeks and 8 weeks mean percentage change in limb volume were 34.42%, 24.72% and 22.27% respectively. There is no statistical significant difference

between the two groups in terms of the mean percentage change in limb volume (p-value = 0.504).

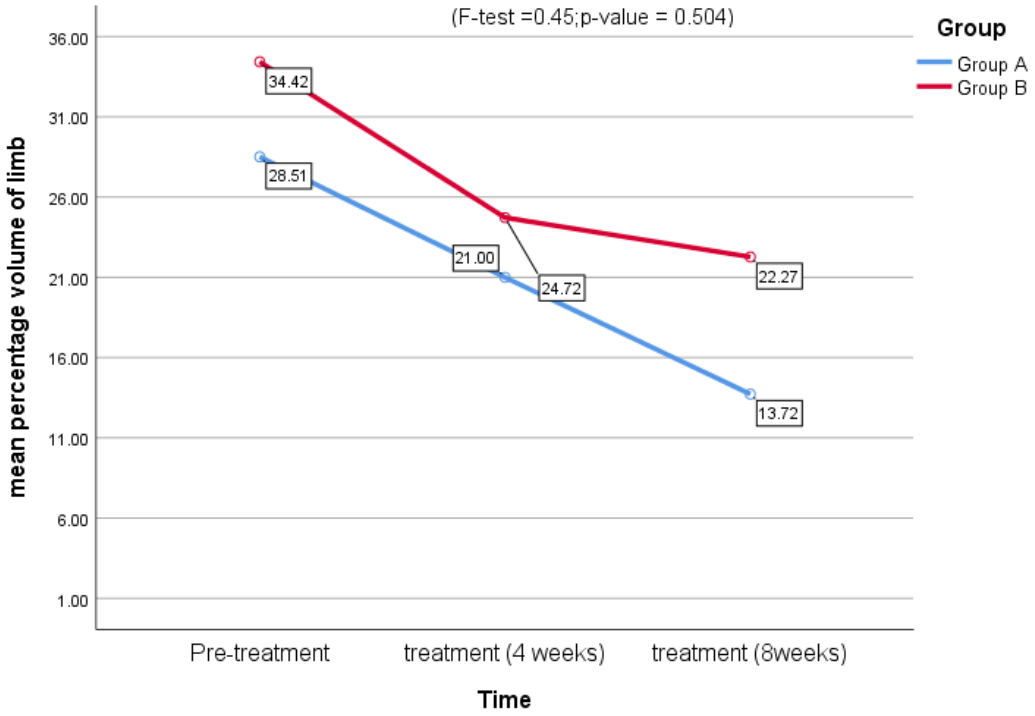


Figure 8 : Mean percentage change in limb volume between groups

5.5 QUALITY OF LIFE ASSESSMENT

Table 21 shows the overall quality of life assessment for all the participants of this study. The mean of the quality of life assessment before compression bandage was 1.8 (±0.6) and that after compression bandage treatment was 1.2(±0.2). There is a statistically significant difference between the quality of life before compression bandaging treatment and the quality of life after treatment (p-value < 0.0001).

Table 21: Overall quality of life

	mean (±SD)	t-test	p-value
QoL before treatment	1.8 (±0.6)	5.11	<0.0001*
QoL after treatment	1.2(±0.2)		

* P-value<0.05-statistically significant

Table 22 shows a comparison of the quality of life before and after treatment within each study group and also the quality of life between each group before treatment and then between each group after treatment. For Group A the quality of life before and after treatment were 1.6 (±0.5) and 1.30(±0.2) respectively. For Group B the quality of life before treatment and after treatment were 1.9(±0.6) and 1.2(±0.2) respectively. There was no statistical significant difference when the quality of life was compared across the two groups both before treatment (p-value = 0.236) and after treatment (p-value = 0.231).

However there was statistical significant difference in the quality of life compared within each group before and after treatment. For Group A (p-value = 0,021) and that for group B was (p-value = 0.001).

Table 22: Quality of life within and groups

	Group , mean (±SD)		t-test	p-value
	Group A	Group B		
QoL before treatment	1.6 (±0.5)	1.9(±0.6)	-1.22	0.236
QoL after treatment	1.30(±0.2)	1.2(±0.2)	-1.23	0.231
	p-value : 0.021	p-value : 0.001		

SD= Standard deviation; Group A = inelastic compression bandage, Group B = elastic compression bandage

6 DISCUSSION

6.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANT

A total of 23 participants were enrolled for this study. The study population was a middle aged one with a mean age of 49 years, which correlates with data from other studies like that by Hacard et al who had a mean of 58 years for 30 patients who had lymphoedema and the study was comparing change in skin thickness and volume change(99). D.H Keast et al publication on lymphoedema impact and prevalence international study: The Canadian Data; in the *Lymphatic Research and Biology*, also had more than 90% of participants being older than 45 years(100). There was no statistically significant difference in the mean age of participants in the two groups.

All the participants in this study were female, which at first looked strange compared to a lot of data that puts the female to male preponderance at 3.5 to 5:1. However a research by S.M Dean et al 2018 (The clinical characteristics of lower extremity lymphoedema in 440 patients), concluded that the collective cohort was more likely to be female (71.1%, $P < 0.001$)(101). Whiles the research by Hacard et al had 24 out of the 30 (80%) participants being females(99). The high female ratio could also be explained by the fact that one of the commonest causes of lymphoedema in Ghana is from breast cancer and its related treatment. And out of 100 patients with breast cancer only 1 is a male patient. Making it highly unlikely for a male patient to be diagnosed with breast cancer related lymphoedema.

In terms of the occupation of the participants, majority 7 (63.6%) of those in the inelastic bandage group were professionals, whiles majority 6 (50%) of those in the elastic group were artisans. The difference in occupation for the two groups was statistically significant (p-value = 0.012). A further look into the nature of the work of these participants may be necessary to see if that may affect the treatment outcome as prolonged standing or sitting or less inactivity has a direct link to the worsening of the limb swelling. This may skew the results in a particular way.

For the level of education majority of participants 12(52.2%) have had some form of tertiary education. But of this number 9 of them were in the inelastic bandage group and only 3 were in

the elastic bandage group. Rather majority of those in the elastic bandage group 7 have had some form of secondary education. This difference in the level of education is statistically significant (p-value = 0.015). Considering the nature of limb lymphoedema and the fact that there is no known cure and the challenge of compliance to the time consuming and cost involving Complete Decongestive Therapy (CDT) treatment, a better understanding of the condition is necessary for a successful treatment outcome.

This therefore makes it necessary to factor good patient education in the treatment of lymphoedema to ensure good compliance and treatment outcome. As much as possible this must be in a language and manner that will be clearly understood by patients.

6.2 LYMPHOEDEMA CHARACTERISTICS

16 (70%) out of the 23 participants had the limb lymphoedema affecting the upper limbs with 7 (30%) having it affecting their lower limbs. In terms of laterality, 14 (61%) had it affecting the left limbs and 9 (39%) had it involving the right limb.

Worldwide lymphoedema involves the lower limb more than the upper limb(102). And this is justified by the fact that the commonest cause of lymphoedema worldwide is Lymphatic filariasis and this involves more of the lower limb than any other part of the body(103). Contrary, this study had 70% of the participants with upper limb involving as against 30% with lower limb involvement. This could probably be due to the fact that KBTH is a referral centre and hence the higher likelihood of receiving referrals for malignancies which tend to be the leading cause for upper limb lymphoedema. Whiles patient with filariasis are mostly handled at the district or regional hospitals and the added advantage of programs directed at eradicating filariasis. The Mass drug administration (MDA) with Ivermectin and Albendazole strategy initiated in 2001 – 2006 in all 98 endemic districts was crucial in reducing the prevalence of filariasis(104).

It is worth noting that despite an increase in breast cancer public awareness, a significant number of breast cancer patients still present with late disease. Late presentation increases the risk of developing lymphoedema of the upper limb(105).

The most likely reason for lymphoedema being more common on the left limbs would be due to the much complex lymphatic system which has the lower limbs, the abdomen and left side of the chest all draining through a much elaborate lymphatic network compared to the right side draining only the right half of the chest. Hence the less likelihood of damage occurring on the right side.

Breast cancer is also more common in the left breast than the right as shown by many studies(106). The left breast is 5% - 10% more likely to develop cancer than the right breast. Reasons for this is still unknown. Hence the higher the chance of developing left upper limb lymphoedema compared to the right upper limb.

The mean age at diagnosis for the study was 46.3 years. The mean age was 41.3 (±17.5) years and 50.8 (±16.6) years for the inelastic bandage group and elastic bandage group respectively. There was no statistical significant difference between the groups in terms of age at which lymphoedema was diagnosed. This is comparable to other studies like that by Aykut Soyder et al; 2014, who studied 101 cases of breast cancer patients that had surgery and were followed for 12 months to see if they will develop lymphoedema(107). 7 (6.9%) 0ut of the 101 patients developed lymphoedema with a mean age of 52 ±10 years. A similar study by Yan-Fei et al; 2021 for the prevalence of breast cancer – related arm lymphoedema over a 10 year period. 49% of his study population (n = 866) later developed lymphoedema with a mean age of 52.27 ± 9.38 years(108).

The duration of illness (limb lymphoedema) of this study compared between the two groups showed no statistical significant difference (p-value = 0.511). However a higher number of those in the inelastic bandage group 5(45.5%) has had the lymphoedema for less than a year, whiles 6 (50.0%) of those in the elastic bandage group has had the lymphoedema between 1 to 4 years. Of the total number of participants in the study only 4 had received some form of treatment for the limb lymphoedema. 2 of them had used compression garments, 1 had some form of compression bandaging and the last massage of the affected limb. These treatments had occurred more than 6 months prior to them being enrolled into this study. Compliance to treatment is one of the key challenges affecting treatment outcomes particularly in the conservative management of

lymphoedema(109). Since lymphoedema has no known cure and its management is life long, good compliance is required to reduce signs and symptoms and also reduce the development of complications. Therefore it becomes necessary to find out why theses 4 patients had stopped their previous treatment and address any such factor that might influence their current treatment.

Out of the study population, 4 (17.4%) had primary lymphoedema and 19(82.6%) had secondary lymphoedema. This is in variance with the Lymphoedema Impact and Prevalence International (LIMPRINT) study that was developed by the International Lymphoedema Framework in 2016(100). From the Canadian data; out of a study population of 68 patients, only 7.35% had primary lymphoedema ant the rest 92.65% had secondary lymphoedema. However a similar LIMPRINT core tool survey by Vaughan Keeley et al; 2019 with a larger study population (n = 8140), conducted in 9 specialist lymphoedema service centres in 4 countries (United Kingdom, France, Italy and Turkey) had similar results as this study. 17.5% of patients had primary lymphoedema and 82.5% had secondary lymphoedema(110).

The most common cause of secondary lymphoedema for this study population was malignancy. 8 (34.8%) of the participants had their lymphoedema from malignancy, 5 (21.7%) from radiotherapy and 3(13%) from surgery relating to malignancy. In effect malignancy and its associated treatment accounted for 16 (70%) of the underlying aetiology of the limb lymphoedema in this study, 2(8.7%) from infection and 1 (4.3%) being postpartum lymphoedema. There was no statistical difference in the aetiology of the lymphoedema for the participants in both study groups (p-value = 0.423). The aetiology of lymphoedema in this study is similar to that from other studies. Shallwani et al 2017; observed in their study that 81% of participant had cancer related lymphoedema and 19% had lymphoedema not relating to cancer(111). Tiwari et al 2003; also observed in their study that the common causes of secondary lymphoedema were malignancy (including metastatic disease), trauma and recurrent infection(112).

From this study radiotherapy was observed has been a relevant risk factor or cause of secondary lymphoedema in cancer patients. Aykurt Soyder et al also observed this in their study. They concluded that in patients with unilateral breast cancer, in terms of lymphoedema development, no significant difference ($p>0.05$) was determined among age, BMI, chemotherapy, post-operative seroma or infection, mastectomy or breast conserving surgery. However they observed

a significant difference ($p < 0.05$) between risk factors like axillary dissection, number of positive lymph nodes, radiotherapy and tumour(107). However Hemnati et al 2013; had a different observation in their study. Number of metastatic lymph nodes and BMI were associated with the development of lymphoedema in patients with invasive breast cancer, whiles type of surgery, excised nodes, size of tumour, presence of metastasis, radiotherapy and chemotherapy had no association with the incidence of lymphoedema.

Aside having unilateral limb swelling as their main symptom, this study also observed other associated symptoms, namely pains in 17 (74 %) of the participants, 15 (65%) had heaviness in the affected limb, 12(52%) had joint discomfort, 10(43%) with reduced mobility in the affected limb, 7 (30%) with skin changes and 6(26%) of participants with altered sensation in the affected limb. Comparing these associated symptoms for the two groups showed no statistical significant difference (p-value > 0.05). It was therefore observed that more than 50% of the study participants had pains, heaviness and joint discomfort. Other studies showed similar symptoms and percentage ranges. Kayo Togawa et al 2021 observed that the mean number of lymphoedema symptoms reported by participants (breast cancer related lymphoedema patients; n = 97) was 4.0 (± 1.8) and the most common self-reported symptoms were heaviness (52%), numbness (47%) and tightness (45%)(113). Likewise Mei R. FU et al 2015 also observed in their study the following symptoms in breast cancer related lymphoedema patients; arm tightness (71.4%), arm heaviness (71.4%), arm firmness (69%), arm arching (61.9%), tingling sensation (59.5%), limited arm movement (57.1%) and arm tenderness (52.4%)(114).

6.3 LIMB CIRCUMFERENCE MEASUREMENTS

The mean circumference of the unaffected limb for participants in each study group were 180.39 (± 26.17) cm and 180.73 (± 13.31) cm for the inelastic bandage group and the elastic bandage group respectively. There was no statistical significant difference between the two groups (p-value = 0.960). The mean circumference of the affected (lymphoedema) limb before starting the compression bandaging treatment, for the two groups were 203.24 (± 34.37) cm and 206.21 (±17.65) cm respectively. There was also no statistical significant difference between the two groups (p-value = 0.794).

The treatment outcome was to assess the rate at which the circumference of the affected (lymphoedema) limb would decrease using the unaffected (normal) limb as a reference. For participants in the inelastic bandage group the mean percentage change in limb circumference were 12.7%, 10.4% and 8.1% before treatment, 4 weeks of treatment and 8 weeks of treatment respectively. The same measurements for those in the elastic bandage group were 14.3%, 8.5% and 6.4%, before treatment, 4 weeks of treatment and 8 weeks of treatment. The rate of decrease in the limb circumference for those in the elastic bandage group was higher (better outcome) than those in the inelastic group. However there was no statistical significant difference (p-value = 0.861) in the decrease of limb circumference for the two study groups.

6.4 LIMB VOLUME MEASUREMENTS

The mean volume of the unaffected limb for participants in each study group were 2500.43 (± 1145.51) cm^3 and 2663.48 (± 684.13) cm^3 for the inelastic bandage group and the elastic bandage group respectively. There was no statistical significant difference between the two groups (p-value = 0.680). The mean volume of the affected (lymphoedema) limb before starting treatment, for the two groups were 3275.53 (± 1772.83) cm^3 and 3487.72 (±719.84) cm^3 respectively. There was no statistical significant difference between the two groups (p-value = 0.706).

The mean percentage change in limb volume for the affected limb using the unaffected limb as reference for the inelastic bandage group were 28.51%, 21.0% and 13.72% before treatment, 4 weeks of treatment and 8 weeks of treatment respectively. The same measurements for those in the elastic bandage group were 34.42%, 24.72% and 22.27%, before treatment, 4 weeks of treatment and 8 weeks of treatment. The rate of decrease in the limb volume was however higher for those in the inelastic bandage group (better outcome) than those in the elastic group. However there was no statistical significant difference (p-value = 0.504) in the decrease of limb volume for the two study groups.

It is worth noting that limb volume measurement are more reliable in assessing lymphoedema improvement than circumference measurements, though the earlier is derived from the later aside other modalities. Mosti et al 2013; made similar observations when they compared bandages (short stretch bandaging) and double stockings(elastic) for the initial therapy of venous oedema. Volume reduction after 1 week was equal in both groups 12.8% and 13%. After 2

weeks (group A = 17% vs group B = 16.2%) and 4 weeks (group A = 17.3% vs group B = 17.0%)(115).

6.5 QUALITY OF LIFE ASSESSMENT

The mean overall quality of life (QoL) assessment for all the participants of this study were 1.8 (±0.6) and 1.2 (± 0.2) before compression bandaging treatment and after treatment respectively. There was a statistical significant difference ($p < 0.0001$) between QoL before treatment and after treatment. Comparing the quality of life using ANOVA between the two bandage groups showed no statistical significant difference. Therefore compression bandaging in treating limb lymphoedema gives a better outcome in terms of quality of life, whether inelastic or elastic compression bandage is used.

6.6 STUDY LIMITATIONS

Limitations to this study include small sample size, fewer physiotherapy sessions by participants than required, strict compliance to bandaging at home by participants as well as cost implications to participants.

Sufficient sample size is necessary in drawing valid conclusions and as such a larger sample size gives a much more precise results. Due to constraints from time available to conduct this research as well as meeting submission deadline, 23 participants were recruited in all. In the future a similar study with more participants may be necessary to see if similar or different results would be observed.

Each participant was to have once a week physiotherapy session for eight weeks. A few of the participants either missed some sessions or were unable to report on the exact review day given. These were mostly due to time inconvenience or financial constraints.

Appropriate application of the bandage for at least 8 hours a day throughout the week was key to ensuring the effectiveness of the compression therapy. However it was difficult to monitor how well participants complied with this directive.

One of the key challenges in lymphoedema management is cost involved. As much as this study tried to reduce this component of the treatment, by subsidizing the cost, a few participants defaulted in coming for the physiotherapy sessions. Most were due to cost of transportation in and out of the hospital and even the reduced amount involved. Securing adequate research funding would have been appropriate to ensure the study was completely free and as such help to overcome such a limitation.

7 CONCLUSION

Limb Lymphoedema is highly associated with malignancies especially breast cancer and its related treatment modalities. Patients with limb lymphoedema aside the obvious limb swelling also have multiple associated symptoms. Despite not having a cure, limb lymphoedema can be successfully managed with compression bandaging. Both elastic and inelastic compression bandages when used will result in reduction of the limb swelling, improve on other symptoms and offer patients a better quality of life. However factors such as level of education and occupation of the patients need special consideration in their management plan.

8 RECOMMENDATIONS

In the near future health care providers must look at establishing lymphoedema specialist management centres throughout the country, at least one centre per region. These centres can be initially started within the regional hospitals and later with adequate resources and finances they can be built as facilities on their own. These centres will have doctors, nurses, physiotherapists and other supporting health care personnel specially trained in the management of lymphoedema.

Public health education on the causes and management of lymphoedema must be intensified especially among high risk patients. This should be done in a very simple way and in a language they can easily understand as well as getting regular feedback from them.

Health Policy makers must consider making the conservative treatment of lymphoedema free by including it in the National Health Insurance Scheme. This will positively affect patient compliance and treatment outcome.

9 APPENDIX

9.1 CASE RECORD FORM

CASE RECORD FORM

Patient Code …… Folder Number……

A. DEMOGRAPHICS

1. Age ……
2. Gender …….
3. Height (m)……..
4. Weight (Kg) ……
5. BMI (Kg/m²) ……
6. Occupation ……
7. Level of Education ……

   None [ ] Primary [ ] Secondary [ ] tertiary [ ]
8. Residential address ……..
   a. Area/ Town ……..
   b. Region ……
9. Co-morbid conditions……

   ……

B. LYMPHOEDEMA CHARACTERISTICS

1. Which part of your body has lymphoedema /swollen
   a. Upper limb Right [ ] Left [ ]
   b. Lower limb Right [ ] Left [ ]
2. Age at diagnosis ……. Duration……...
3. Previous Treatment: Yes [ ] No [ ]
   a. if Yes, please specify type ……...
   b. Duration …….

4. Cause
    a. Primary [ ]
    b. Secondary [ ]
        I. Infection [ ]
        II. Surgery [ ]
        III. Trauma [ ]
        IV. Malignancy [ ]
        V. Radiotherapy [ ]
        VI. Others [ ] Please Specify……..

5. Family History of lymphoedema Yes [ ] No [ ]
    a. If yes specify …….

6. Associated Symptoms. (Tick as many as apply)
    a. Pains [ ]
    b. Heaviness [ ]
    c. Altered sensation [ ]
    d. Skin changes [ ]
    e. Joint discomfort [ ]
    f. Reduced mobility [ ]

9.2 CONSENT FORM

TITLE: A Comparative Clinical Study on efficacy of elastic and inelastic Compression Bandages in the treatment of Limb Lymphoedema.

Department: National Reconstructive Plastic Surgery & Burns Centre (NRPS & BC)

Hospital: Korle Bu Teaching Hospital, Accra. Ghana.

Principal Researcher: Dr. Nathaniel Tetteh

Supervisors: Mr. A. B. Paintsil; Dr. Edem Anyigba

Introduction: This is a research which will involve voluntary participation of patients with limb lymphoedema. This research seeks to compare 2 different types of bandages for compression bandaging in the treatment of limb lymphoedema, to determine the better option.

After reading the information of this research, the decision is yours whether to be part of it or not. You will not be denied good quality of care if you decide not to take part.

Procedure: You will be randomly placed in one of two groups of the research (Elastic Group & Inelastic Group). Participants in each group will undergo 2 layer compression bandaging for 8 weeks with twice a week physiotherapy session.

Before treatment is started each participant will have measurements (circumference and volume) taken of both affected and contralateral/unaffected limb. These measurements will subsequently be taken every 2 weeks up to the end of the 8 weeks.

The change in circumference and volume of the affected limb will be determined at the end of the research. This together with the Quality of Life (QoL) Assessment during the treatment will be used as a measure of the effectiveness of both treatment options.

Participants will also be required to alert the researcher of any unwanted side effects experienced during the research period.

Additional Costs: Participants will not be required to incur any additional cost aside the usual hospital cost of treatment for lymphoedema. Any extra cost will be borne by the researcher.

Benefits: From this research, we will have information on which compression bandage is more effective and has a better patient compliance in the treatment of limb lymphoedema by compression bandaging. It will also serve as a standard for limb lymphoedema treatment at the NRPS & BC.

Confidentiality: All information recorded in the Case Record Form and any other information pertaining to your participation in this research will be strictly confidential. The form will not bear your name but a code and will only be handled by the researcher and reviewers.

Withdrawal from the Research: You have the right to withdraw from the study at any time by simply informing the researcher. This will in no way affect the best available care for you lymphoedema management. The researcher also has the right to withdraw you from research, if it is in your best interest.

CONSENT

I have read and understood the information on the consent form and all my concerns have been duly addressed. I hereby freely consent to be part of this research.

Name of participant	Signature	Date
Name of person conducting consent	Signature	Date

9.3 LIMB MEASUREMENTS FORMS

9.3.1 UPPER LIMB

LYMPHEDEMA MEASUREMENT CHARTS –

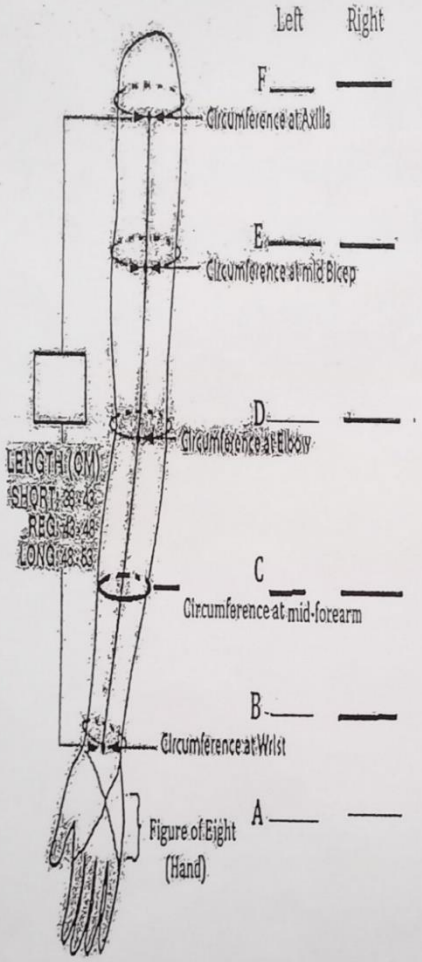
UPPER LIMB

Name of Patient: Sex: Age:

Rater/ Therapist:

Date:

[Baseline]



	SUBSEQUENT MEASUREMENTS/ cm				
Date →	1st	2nd	3rd	4th	5th
F					
E					
D					
C					
B					
A					

9.3.2 LOWER LIMB

LYMPHEDEMA MEASUREMENT CHARTS –

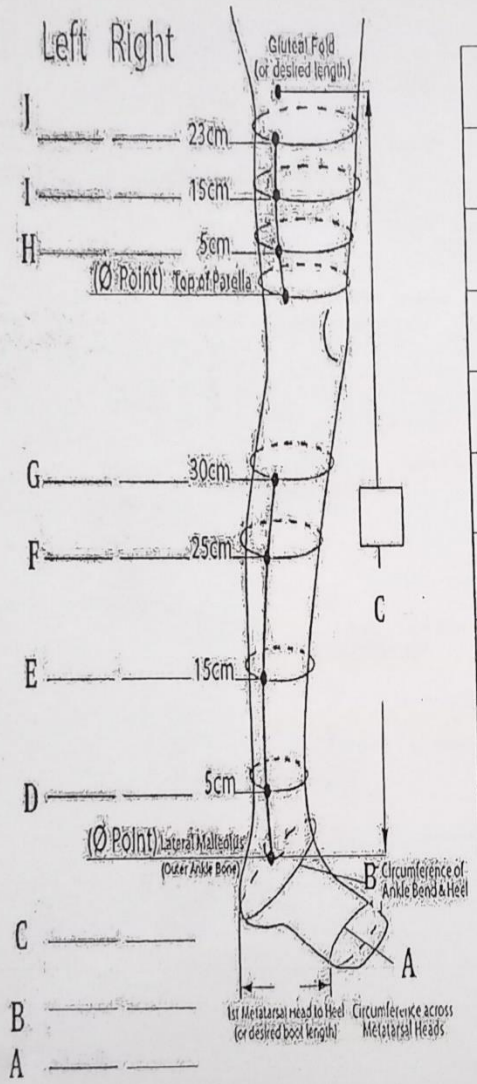
LOWER LIMB

Name of Patient: Sex: Age:

Rater/ Therapist:

Date:

[Baseline]



	SUBSEQUENT MEASUREMENTS/cm				
Date →	1st	2nd	3rd	4th	5th
J					
I					
H					
G					
F					
E					
D					
C					
B					
A					

9.4 QUALITY OF LIFE ASSESSMENT FORMS (LYMQOL)

9.4.1 UPPER LIMB

LYMQOL ARM-Scoring System
Lymphoedema Quality of Life Tool

The score for the individual responses are given below. If the item is not scored and left blank or not applicable this is scored with a 0. Domain totals are calculated by adding the individual scores and dividing the total by the number of questions answered. (If >50% of questions per domain are not answered this cannot be calculated and =0).
The four domains and their corresponding questions are: Function 1 (a–h), 2, 3;
Appearance 4, 5, 6, 7, 8; Symptoms 9, 10, 11, 12, 13, 14; and Mood 15, 16, 17, 18, 19, 20.
Overall quality of life (Q21) is scored as the value marked by the patient, between 0–10.

(1) How much does your swollen arm affect the following daily activities?	Not at all	A little	Quite a bit	A lot
a) occupation	1	2	3	4
b) housework	1	2	3	4
c) combing hair	1	2	3	4
d) dressing	1	2	3	4
e) writing	1	2	3	4
f) eating	1	2	3	4
g) washing	1	2	3	4
h) cleaning teeth	1	2	3	4
(2) How much does it affect your leisure activities/social life?	1	2	3	4

Please give example(s) of this.

(3) How much do you have to depend on other people?	1	2	3	4
(4) How much do you feel the swelling affects your appearance?	1	2	3	4
(5) How much difficulty do you have finding clothes to fit?	1	2	3	4
(6) How much difficulty do you have finding clothes you would like to wear?	1	2	3	4
(7) Does the swelling affect how you feel about yourself?	1	2	3	4
(8) Does it affect your relationships with other people?	1	2	3	4
(9) Does your lymphoedema cause you pain?	1	2	3	4
(10) Do you have any numbness in your swollen arm?	1	2	3	4
(11) Do you have any feelings of 'pins and needles' or tingling in your swollen arm?	1	2	3	4
(12) Does your swollen arm feel weak?	1	2	3	4
(13) Does your swollen arm feel heavy?	1	2	3	4
(14) Do you feel tired?	1	2	3	4
In the past week	1	2	3	4
(15) Have you had trouble sleeping?	1	2	3	4
(16) Have you had difficulty concentrating on things, e.g. reading?	1	2	3	4
(17) Have you felt tense?	1	2	3	4
(18) Have you felt worried?	1	2	3	4
(19) Have you felt irritable?	1	2	3	4
(20) Have you felt depressed?	1	2	3	4
(21) (24) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:	1	2	3	4

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

9.4.2 LOWER LIMB

LYMQOL LEG-Scoring System
Lymphoedema Quality of Life Tool

The score for the individual responses are given below. If the item is not scored and left blank or not applicable this is scored with a 0. Domain totals are calculated by adding the individual scores and dividing the total by the number of questions answered. (If >50% of questions per domain are not answered this cannot be calculated and =0).
The four domains and their corresponding questions are: Function 1 (a–f), 2, 3
Appearance 4, 5, 6, 7, 8, 9, 10; Symptoms 11, 12, 13, 14, 15 and Mood 16, 17, 18, 19, 20, 21.
Overall quality of life (Q22) is scored as the value marked by the patient, between 0–10.

(1) How much does your swollen leg affect the following daily activities?

If any items are not applicable, please write N/A in the relevant box(es)	Not at all	A little	Quite a bit	A lot
a) your walking	1	2	3	4
b) your ability to bend, e.g. to tie shoelaces or cut toenails	1	2	3	4
c) your ability to stand	1	2	3	4
d) your ability to get up from a chair	1	2	3	4
e) your occupation	1	2	3	4
f) your ability to do housework	1	2	3	4

(2) Does the swelling affect your leisure activities?	1	2	3	4

Please give example(s) of this.

(3) How much do you have to depend on other people?	1	2	3	4
(4) How much do you feel the swelling affects your appearance?	1	2	3	4
(5) How much difficulty do you have finding clothes to fit?	1	2	3	4
(6) How much difficulty do you have finding clothes you would like to wear?	1	2	3	4
(7) Do you have difficulty finding shoes to fit?				
(8) Do you have difficulty finding socks/tights/stockings to fit				
(9) Does the swelling affect how you feel about yourself?	1	2	3	4
(10) Does it affect your relationships with other people?	1	2	3	4
(11) Does your lymphoedema cause you pain?	1	2	3	4
(12) Do you have any numbness in your swollen arm?	1	2	3	4
(13) Do you have any feelings of 'pins and needles' or tingling in your swollen arm?	1	2	3	4
(14) Does (do) your swollen leg(s) feel weak?	1	2	3	4
(15) Does (do) your swollen arm(s) feel heavy?	1	2	3	4
In the past week	1	2	3	4
(16) Have you had trouble sleeping?	1	2	3	4
(17) Have you had difficulty concentrating on things, e.g. reading?	1	2	3	4
(18) Have you felt tense?	1	2	3	4
(19) Have you felt worried?	1	2	3	4
(20) Have you felt irritable?	1	2	3	4
(21) Have you felt depressed?	1	2	3	4
(22) (24) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:	1	2	3	4

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

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