INCORPORATING PELVIC FLOOR EXERCISES IN COMPLETE DECONGESTIVE THERAPY FOR FEMALES WITH LOWER EXTREMITY LYMPHEDEMA, WITH AND WITHOUT GENITAL INVOLVEMENT, TO IMPROVE VOLUMETRIC AND QUALITY OF LIFE OUTCOMES

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

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BY

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To the Dean of the Graduate School:

I am submitting herewith a dissertation written by Shelley Smith DiCecco entitled, "Incorporating Pelvic Floor Exercises in Complete Decongestive Therapy for Females With Lower Extremity Lymphedema, With and Without Genital Involvement, to Improve Volumetric and Quality of Life Outcomes." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Physical Therapy.

Katy Mitchell, PhD, Major Professor

We have read this dissertation and recommend its acceptance:

PT PhD

Director of the School of Physical Therapy

Accepted:

Dean of the Graduate School

DEDICATION

To my husband, Robert DiCecco,
thank you for your love, understanding,
and support over the last several years.

To my parents, Robert and Peggy Smith,
thank you for encouragement, love,
and support for my entire life.

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ABSTRACT

SHELLEY SMITH DICECCO

INCORPORATING PELVIC FLOOR EXERCISES IN COMPLETE DECONGESTIVE THERAPY FOR FEMALES WITH LOWER EXTREMITY LYMPHEDEMA, WITH AND WITHOUT GENITAL INVOLVEMENT, TO IMPROVE VOLUMETRIC AND QUALITY OF LIFE OUTCOMES

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Millions of people are diagnosed with lymphedema, a treatable condition that may be considered disabling to those inflicted. The research available on lymphedema treatment, outcomes from the treatment, and overall the impact the condition has on individuals is significantly limited. There has been little advancement in the standard physical therapy treatment since the 1970s. There is a need for increased attention in the medical community on lymphedema; especially on how the edema is measured, how quality of life is affected, and on possible modifications to the current treatment.

Water displacement is the gold standard for the quantitative documentation of volume of those with lymphedema. A study was completed comparing the gold standard to the truncated cone method and found an excellent relationship between the two methods for lower extremity edema. The study also found excellent intertester reliability with the truncated cone method.

The Quality of Life Index (QLI), a quality of life (QOL) tool, was completed by 20 females with lower extremity lymphedema. The study showed that lymphedema does

impact the overall QOL of females with lower extremity lymphedema as compared to the general population. No difference in the overall QLI scores was found when comparing those with to those without one of the symptoms of interest: pain, urinary incontinence, or sexual dysfunction. The small sample size did provide initial data related to QOL using the QLI. Overall, the study showed a need for the medical community to address QOL when treating lymphedema.

A final study was completed to compare the current Casley-Smith complete decongestive treatment (CDT) method for lymphedema and a modified form of treatment incorporating the pelvic floor muscles. The focus was on volumetric reductions and improvement in quality of life (QOL) for females with lower extremity lymphedema, with and without genital involvement. Ten females participated. All participants showed a reduction in volume and improvement in QLI scores post treatment. The study also showed there was a significant difference in these changes when the control and experimental groups were compared. The modified CDT with the addition of pelvic floor muscle contractions had a greater impact on the volume and QOL changes.

There needs to be additional research in the future with larger populations. This research should not only further investigate the addition of the pelvic floor muscles with CDT for the lower extremities of females; it should also consider different muscle groups that may improve lymphedema in other areas and should look at both genders. Those treating lymphedema should continue to search for additional understanding of the condition and for ways to improve the efficiency and efficacy of treatment.

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CHAPTER I

INTRODUCTION

Around the world, about ninety million people are affected with lymphedema. Lymphedema is often misdiagnosed, mistreated, or not treated at all.[1] Currently, there is no cure for lymphedema, only a variety of treatment methods to reduce the symptoms and manage the condition. Lymphedema occurs when the lymphatic system responsible for collecting interstitial fluid is compromised and the lymphatic flow is altered, resulting in the abnormal accumulation of high protein fluid in the interstitium. Lymphedema is classified as a low-flow, high protein edema. The term "low-flow" refers to the decreased transport capacity of the lymphatic system. This suggests there is some structural or functional impediment to the flow of the lymphatics, and as a result, a high concentration of proteins accumulate in the interstitium.[2,3]

Lymphedema can affect any area of the body. Often articles and textbooks only mention two locations of lymphedema, the upper extremity and/or lower extremity. Genital lymphedema is rarely discussed, especially for females. However, genital lymphedema is associated with at least 10% of the cases of people with lower extremity lymphedema.[4]

Dr. Alexander Van Winiwarter first developed manual "massage" treatment for lymphedema at the end of the 19th century. Dr. Emil Vodder was the first to expand on this concept in the 1930s. Over the years, the "massage" technique and the entire

treatment for lymphedema has been modified by several others.[5(p103)] Different schools for certification have developed from this initial technique, including the Vodder Method, the Casley-Smith Method, the Földi Method, and the Chikly Method. Regardless of the method used, treatment for these patients involves manual lymphatic drainage (MLD) to move the lymphatic fluid to a functioning area, special therapeutic exercises to mimic the action of the lymphatic system, skin care, patient education, compression bandaging to reduce the volume in the involved areas, and concluding with compression garments to maintain the reduction. The goals of therapy are to improve skin condition, to decrease the size of the affected body part, to maintain the reduction with appropriate compression, by using either bandages and/or garments, and to educate the patient on how to manage the condition at home.[2,5]

In the treatment of lymphedema, a therapist will perform volumetric measurements of the involved and un-involved body parts to obtain quantitative data. Quantitative results are valued by health professionals, insurance companies, the practitioner, and patients. The gold standard for obtaining volumetric measurements of a limb is water displacement. Water displacement is not practical to use in most outpatient settings due to the size of the equipment, the amount of water needed and time constraints.[6] Therapists may use girth measurements along the limb at certain boney prominences and compare the involved side to the uninvolved side. The truncated cone method involves using a measuring tape to record girth measurements along the limb at certain distances. Then the volume is calculated using a truncated cone equation.[2] There are limited studies comparing the water displacement of the lower extremity to the

truncated cone method of calculating volumetrics of the lower extremity. Chapter three of the dissertation will compare the truncated cone formula used to quantify volume by lymphedema therapists to the gold standard of water displacement, using participants with and without lower extremity edema.

When treating genital lymphedema it is more difficult to obtain volumetric data. There are fewer bony landmarks to use for repeated measurements. In the case of females, the swelling may be inside the actual vaginal vault and impossible to quantify with a measuring tape. Therefore, one must look to qualitative outcomes to assess the success or failure of treatment.

A quality of life tool addressing all aspects of female genital lymphedema is crucial. This is especially true when investigating common symptoms of female genital lymphedema, such as: sexual dysfunction, urinary dysfunction, pain and the impact of these symptoms on the female's quality of life. An extensive literature search of articles between the years of 1997 and 2008 was completed using the keyword quality of life and grouping it with the following other keywords: lymphedema, swelling, and pelvic floor. Each of the tools found in the literature review was evaluated on whether or not the signs and symptoms related to genital lymphedema (pain, incontinence, and sexual dysfunction) were covered, as well as the reported psychometric properties of the tools. Based on the signs and symptoms reported by individuals with the condition, there was no single tool from the literature review that would completely assess the quality of life for a female with genital lymphedema.

Chapter four will discuss the findings from the literature review for the existing quality of life (QOL) tool, the Quality of Life Index, and describe a new QOL tool for this particular population. Ferrans and Powers developed the Quality of Life Index, a tool that is used to measure the satisfaction and importance of different domains in a person's life. The tool encompasses a person's overall quality of life (QOL) by looking at four separate domains: health/functioning, psychological/spiritual, social/economic, and family. The Quality of Life Index has been found to provide a sense of a person's general quality of life across a wide spectrum of areas in a short amount of time.[7] Since this tool does not completely address the specific symptoms of lymphedema, a second questionnaire, Assessing Quality of Life of Those with Edema was developed by the principal investigator. The Assessing Quality of Life of Those with Edema is designed to assess general health and condition-specific symptoms for this particular population based on the literature.

Appropriate exercises can increase the uptake by the initial lymphatics, increase the pumping of the collecting lymphatics, enhance the joint pumps of the lymphatics, and strengthen the surrounding muscles to prevent a common side-effect of lymphedema, muscle wasting.[2] The current exercises used by certified therapists are sequential and follow the pattern of beginning centrally and progressing to the distal components of the lymphatic system. For lower extremity and genital lymphedema, the customary exercise sequence progresses from the neck, to axillary region, abdomen, inguinal area, and then down the lower extremity. According to Casley-Smith, the exercises should be performed with compression to enhance the muscle pumping, with low exertion to prevent

overloading of the lymphatic vessels. The exercises should be used in conjunction with diaphragmatic breathing to clear the thoracic duct and be completed slowly and rhythmically to follow the pace of the normal lymphatic system.[2] The exercises are designed to facilitate the pumping of the lymphatic fluid by involving self-manual lymph drainage to help move the fluid, as well as to enhance the contraction and relaxation phases of muscle.[2]

The main muscles of the pelvic floor are the Levator Ani (Pubococcygeus, Pubovaginalis, Puborectalis, and Iliococcygeus), the Coccygeus, the Bulbocavernosus, and the Ischiocavernosus.[8] These muscles assist with the support of the pelvic organs, sphincter control of bowel and bladder, sexual response, unloading the spine through intra-abdominal pressure, and assist with pelvic-spinal stability.[9] A contraction of these muscles is called a Kegel, named after Dr. Arnold Kegel.[10] The lymphatics responsible for draining the genitals are intermingled with these muscles.[8] The deep and superficial inguinal nodes are the only nodal groups stimulated with the customary exercise sequence. The genital region for both males and females is drained by multiple groups of nodes, not just the inguinal nodes. To date, there are no documented lymphedema exercise programs which utilize the contraction of the pelvic floor muscles to assist with treating genital lymphedema.

Chapter five involves a study of lymphedema treatment for women diagnosed with lower extremity lymphedema, with or without genital involvement. The study compares the current method of treating this patient population according to the Casley-Smith training with treatment using the current method plus the addition of pelvic floor

exercises. The women of the study were randomly assigned to one of two groups. The study used the previously discussed volumetric measurements and the QOL tools to assess the outcomes of the treatment techniques.

RESEARCH QUESTIONS

1. Will there be a relationship with the intertester reliability of certified therapists, from different certification programs, when they are calculating lower limb volume using the truncated cone formula?
2. Will the lower limb volume calculated with the truncated cone formula be comparable to the volume obtained with water displacement?
3. Will the Quality of Life Index show a difference in QOL for females with lower extremity lymphedema, with and without genital involvement, as compared to the general population without lymphedema?
4. Will the Assessing Quality of Life of Those with Edema tool be able to identify if pain and or other symptoms associated with genital lymphedema impact the quality of life for a female with lower extremity lymphedema, with and without genital involvement?
5. Will the volume and quality of life outcomes be different for females with lower extremity lymphedema with and without genital involvement when using the current method for lymphedema treatment as compared to the current method of treatment with the addition of pelvic floor exercises?

HYPOTHESES

1. There will be no significant correlation among physical therapists certified in different methods when they use the truncated cone formula method to calculate volume on a lower extremity with/without lymphedema.
2. There will be no significant correlation between the truncated cone formula for volumetric measurements and the water displacement volume method of a lower extremity with/without lymphedema.
3. The Quality of Life Index will show no difference in QOL for females with lower extremity lymphedema, with and without genital involvement, as compared to the general population.
4. The Assessing Quality of Life of Those with Edema tool will not be able to describe or identify the impact of pain and or symptoms associated with genital lymphedema on the quality of life for a female with lower extremity lymphedema, with and without genital involvement.
5. The current method of treating lymphedema with the addition of pelvic floor exercises will have no difference in self-reported outcomes for quality of life for females with lower extremity lymphedema, with and without genital involvement, when compared with the use of the current method alone.
6. The current method of treating lymphedema with the addition of pelvic floor exercises will have no difference in the quantitative outcomes for volume reduction for females with lower extremity lymphedema, with and without

genital involvement, when compared with the use of the current Casley-Smith method alone.

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CHAPTER II

REVIEW OF THE LITERATURE

LYMPHATIC SYSTEM

The lymphatic system has been inadequately studied due to the sheerness of the vessel walls and petite size of the collecting vessels preventing conclusive cadaver dissection.[1] The lymphatic system contains pre-lymphatic tissue channels, the initial lymphatics, the pre-collectors, the collectors, and the lymph nodes. The tissue channels are located in the interstitial space, and are a continuous labyrinth of passages in the body.[2] These channels either drain into the initial lymphatics, or act as the initial lymphatics in areas void of lymphatics. The initial lymphatics are located in the dermal layer of the skin and are made of a single layer of endothelium cells. The fluid exchange with the surrounding tissue is through the junctions or gaps. The pre-collectors act as transitional vessels between the initial lymphatics and the collectors. The collectors have fewer junctions for fluid exchange and contain both smooth muscle and elastin in the walls. The collectors contain special units, or lymphangions, with a pump-like valve between each unit. The smooth muscle in the walls acts as a pacemaker for the lymphangions to "pump" fluid along to the next lymphangion.[2] The rate of contractions can be affected by lymph load, a stretch stimulus, temperature, medication and pressure.[2] Along the lymphatic vessels are encapsulated accumulations of lymphatic tissue, or lymph nodes.[31] The lymph nodes filter the lymph of antigens and debris.[2] The lymph

continues along through the vessels until reaching the thoracic or the right lymphatic duct. The fluid in these ducts will eventually return to the venous system via the right and left subclavian veins.[2]

The genital lymphatic system of males and females follows the above general principles. There are unique differences between males and females, due to anatomical differences, in vessel layout and in the pattern of lymph node filtering of the genital region. The genital region in both sexes has multiple pathways for drainage of each component of the genital region. (Figure 1) The lymph nodes draining the genitals also contain lymph fluid from the surrounding abdominal, pelvic and upper leg regions. The ureter in both genders drains into several nodes, including the kidney, the lateral aortic, intermediate lumbar, common iliac, and the internal iliac nodes. The male and female bladders drain into either the internal iliac nodes or the external lymph nodes. The urethra and the internal iliac nodes will both drain into the external iliac nodes.[1,4-6]

In males, the epididymis, ductus deferens, and seminal vesicles are drained initially by a superficial capillary plexus.[1,4-6] The male's testis, prostate, glans penis, the skin of the scrotum, and the skin of the penis are drained by the superficial capillary plexus, and the deep interstitial plexus, which travel to the superficial and deep inguinal nodes respectively. The inguinal nodes drain into the external iliac nodes and join lymph fluid from additional vessels of the superficial ductus deferens, the posterior prostate, the glans penis, and the superficial and deep seminal vesicles. The dorsal portion of the prostate is carried via the lateral sacral nodes into the internal iliac nodes. The internal iliac nodes process the lymph fluid from the external iliac nodes, the lateral sacral nodes,

and lymph vessels of the prostate, and the deep and superficial seminal vesicles. This lymph fluid flows into the common iliac nodes and then into the intermediate lumbar, preaortic and lateral aortic nodes. Lymph vessels from the superficial and deep testis also drain into the intermediate lumbar, preaortic and lateral aortic nodes.[1,4-6]

In females, the ovaries have a capillary plexus, while the uterus and uterine tubes have mucous, muscular, serous and subserous plexuses.[1,4-6] The vagina contains plexuses in the mucosa and the muscular layers. The superficial and deep inguinal nodes collect fluid from the lower section of the uterine tube, the lower section of the vagina, the labia majora, labia minora, and the body and fundus of the uterus. The inguinal nodes join lymph fluid from the cervix, the clitoris, the cervicovaginal region, and the body and fundus of the uterus in the external iliac nodes. The lateral sacral nodes receive lymph fluid from the cervix and then join the external iliac nodes in the internal iliac nodes. The internal iliac nodes also process lymph fluid from the cervicovaginal region, the middle region of the vagina, the lower section of the uterine tube, the cervix, and the body and fundus of the uterus. This lymph fluid all drains into the sacral lymph node with extra lymph vessels from the cervix. The cervix also has lymph vessels which drain into the common iliac nodes and the lateral sacral nodes. The sacral lymph nodes continue on to the common iliac nodes. The lumbar preaortic and the lateral aortic nodes collect lymph fluid from the common iliac nodes and the ovaries, the uterine tube and the body and fundus of the uterus. The ovaries, fallopian tubes, and the uterus also will drain into the superficial and deep inguinal nodes.[1,4-6]

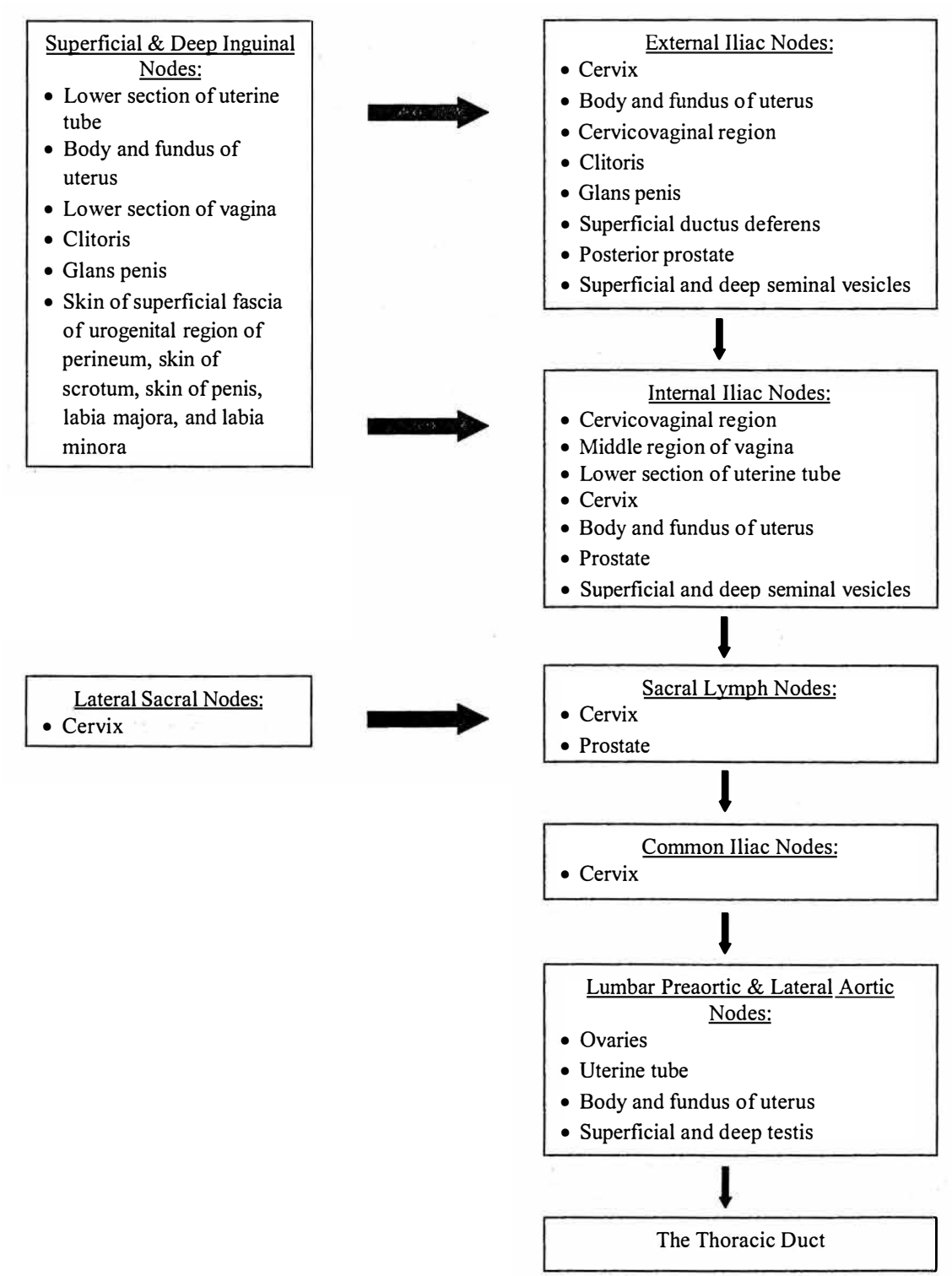


Figure 1. Lymph node drainage of genital region

LYMPHEDEMA

Lymphedema occurs when the system is over-taxed by some mechanism and substances begin to accumulate in the interstitium.[7] The volume in the tissues must increase by 30% before the excessive accumulation of fluid in the interstitial space is detected clinically.[7] Lymphedema is classified as a low out-flow, high protein edema.[2] This means there is some structural or functional limitation to the flow of the lymphatics and a high level of proteins accumulate in the interstitium as a result. Structural causes of this can include: decreased size or number (hypoplasia) of tissue channels, or initial lymphatics; excessively larger or malformed collectors with incompetent valves (hyperplasia); incompetent valves and/or walls in the initial lymphatics; a decreased number, or obstruction of collectors; or fibrotic, blocked, or excised lymph nodes. Functional reasons for lymphedema are lack of variation of tissue pressure; spasms, paralysis, decreased contraction of collectors; or increased lymph in an adjacent area.[2] The dysfunction of the lymphatic system allows protein to accumulate in the tissues. Protein is hydrophilic and draws extra fluid out of the tissues.[2] The protein can be a stimulus for chronic inflammation, infection, increased temperature, and fibrosis of the tissues.[8] Also, metabolic exchange slows down, tissue nutrition decreases, and metabolites accumulate in the tissues. As the fluid continues to increase, the pressure will eventually cause the initial lymphatics to collapse, and the collectors to decrease contractions until the collectors become fibrotic. The affected tissue has decreased oxygen and nutrients and has an increased healing time.[2] The skin can have noticeable changes such as dry or flaky skin, hair loss, thickened skin secondary to accumulation of

keratin (hyperkeratosis), fibrosis of the skin and subcutaneous tissue, dilation with fibrosis of the upper dermal lymphatics (papillomatas), a proliferation of lymph vessels at the surface (lymphangion), discoloration, skin folds, lymphorrhea (leakage of lymph fluid through the skin), distortion of the natural contours of the involved body part and loss of mobility.[2,8]

There are two main categories of lymphedema, primary and secondary. Primary lymphedema is when the cause is inherent in the individual and may or may not be apparent at birth. Primary can be a result of heredity, or a birth anomaly. If the damage is not obvious at birth (congenital), it will usually present later in life with a sudden trigger or gradually as the system is overtaxed.[2] The sudden trigger can be trauma, infection, or even puberty. Primary lymphedema is more often in the lower extremities and in females.[8] Primary lymphedema exclusively in the genital region is rare, more often it accompanies lower extremity lymphedema. Absent or decreased number of lymphatics, or functional failure, are the underlying cause of primary genital lymphedema.[9]

Secondary lymphedema is the result of an outside factor which reduces lymphatic drainage in an area.[2] The most common cause of secondary lymphedema is filariasis.[10] Approximately one hundred and twenty million people in over eighty countries are inflicted with filariasis.[10] Filariasis occurs when a human is infected by a mosquito carrying the parasitic worm larvae.[10,11] The most common strand of the parasite is the Wuchereria Bancrofti, followed by the Brugia Malayi, and the Brugia Timori.[3,10,11] After penetrating the skin, the larvae travels to the lymphatics, where the larvae will grow into mature adult worms.[3,10,11] The adult worms can live ten years or longer in the lymph

nodes.[11] The female worm produces microfilariae and releases them to circulate in the bloodstream of the host.[11] The worms cause the main lymphatic channels to dilate, destroy the valves, block lymphatic flow, and damage the endothelium lining of the vessels.[8,10-12] If the damage is significant enough, lymphedema will develop in the affected areas.[11] The genitals are more often involved with secondary lymphedema, and most frequently as a result of filariasis.[9]

Other causes of secondary lymphedema can include: surgery, radiation, trauma, paralysis, allergic reactions, metastases, chronic venous insufficiencies, self-mutilation, lipoedema, AIDS, benign growths, post thrombophlebitic syndrome, and/or infection.[2,8,9] In the western section of the world, secondary genital lymphedema is typically caused by trauma, surgery, and cancer treatments.[9] Researchers believe genital lymphedema may be more common in males than female due to the effects of gravity on the anatomy.[9]

Signs and Symptoms of Lymphedema

Regardless of the initial cause of the lymphedema, the clinical symptoms are similar. Patients often complain of a feeling of fullness or pressure, "bursting" pain, "puffiness," feeling of pins or needles, increased warmth of the affected areas, redness or swelling, decreased mobility, lymphorrhea, chronic infections, skin changes, and/or aching pain of the involved areas.[2,8,9,13]

In genital lymphedema, the swelling can involve only part or the entire genital region. Excessive swelling of the genitals can hinder sexual activities, and urination for both males and females.[9] For males the swelling can cause impotency or pain with erections, and is emotionally and functionally disabling.[9,14] In females, sexual activity is

usually decreased from either pain or decreased libido from the lymphedema. Patients with genital lymphedema often complain of a "dragging, heavy or bursting sensation" in the genitals.[9] The skin of the genitals can thicken, begin to flake, and develop papillomatas. Since the genitals are usually warm and moist with multiple folds, bacterial infections are common in genital lymphedema.[9]

TREATMENT OF LYMPHEDEMA

Management of lymphedema involves both prevention and treatment. Prevention involves identifying patients at risk for secondary lymphedema and educating these patients on methods to possibly decrease the chance of developing lymphedema. Patients diagnosed with any cancer, especially with lymph node excision and/or those undergoing extensive surgeries with incision of multiple lymph vessels or removal of lymphatic tissues should be educated on proper prevention methods, for these patients are considered to be high risk for developing lymphedema. Treatment for lymphedema includes medications, dietary management, pain management, compression pumps, complex (or complete) decongestive therapy, compression garments, and surgeries.[2,7-9,14]

Medications

Pharmacologic therapy for lymphedema has not proven beneficial and may actually contribute to adverse reactions.[7] Some medicines that have been prescribed for lymphedema include: diuretics, anticoagulants, selenium, pantothenic acid, pyridoxine, hyaluronidase, benzo-pyrones (coumarin), and antibiotics.[7,8,15]

Diuretics are ineffective for the treatment of lymphedema.[8] Diuretics remove excessive fluids from the tissues, but not protein. The increased osmotic pressure from

the accumulated proteins will continue to draw out fluid into the interstitial spaces.[2,16] Diuretics can actually increase the fibrosis of tissues.[7]

Selenium in the form of sodium selenite can decrease radical oxygen production, and lower the lymphedema volume in the tissue. The studies on the effects of selenium have been lacking in objective measures and significant outcomes.[15] Micke et al performed a study on twelve patients with arm edema and thirty-six patients with head-and-neck edema.[17] The participants received a form of selenium over four-six weeks. At the end of the study, 83.3% of the patients with arm edema and 65% of the patients with head-and-neck edema had substantial reductions in edema. The study did not find any adverse reactions in any of the forty-eight participants. Micke et al did state, "little is known about the basic pharmacologic mechanisms by which selenium reduces edema."[17]

Benzo-pyrones are controversial in their effect on lymphedema. Benzo-pyrones are thought to decrease chronic lymphedema by stimulating the macrophages and decreasing the stagnant protein in the involved body part.[2,15] The proteolysis in the tissues leads to a reduction in osmotic pressure, edema, fibrosis, and diminishes the suitable environment for bacterial growth.[2] In a study by Casley-Smith et al in 1993 coumarin (a type of benzo-pyrone) was shown to decrease fluid accumulation, decrease size of the extremity and decrease the discomfort associated with lymphedema.[18] Another study by Casley-Smith and colleagues, using coumarin involved a randomized, double-blind, placebo-controlled crossover study on thirty-one participants with upper extremity lymphedema secondary to cancer and twenty-one participants with lower extremity lymphedema from various causes.[19] This study showed a reduction in volume, fibrosis,

and skin temperature of the participants. The participants in this study also reported a decrease in feelings of pain, tightness, tension, and heaviness.[19] Coumarin has been found to have significant side effects, including hepatic toxicity, and is currently not available in most countries.[7] A study by Loprinzi et al[20] on one hundred and forty women with lymphedema secondary to breast cancer found, "coumarin did not alleviate lymphedema and that coumarin-related hepatotoxic effects were more common than has previously been reported." The study had hepatotoxic effects in 6% of the women in the study as compared to the usually reported 1%.[2,18-20]

Anticoagulants and antibiotics should only be used if the patient is prone to, or currently has either a thrombosis or an infection respectively.[7] Hyaluronidase is used to decrease hyaluronic acid, or hyaluronan, a hydrophilic substance which may be a stimulus for an inflammatory response. Pantothenic acid and pyridoxine also are prescribed to improve the swelling.[7]

Dietary Management

The main focus with dietary management should be weight. Increased weight will add stress to an already over-taxed lymphatic system.[9] Obese patients with primary lymphedema have an increased risk of genital lymphedema secondary to the added pressure of the oversized abdomen on the groin.[9] A study of two hundred and fifty-one women with surgical treatment for breast cancer found that women with a body mass index (BMI) $\geq$ 26 had an increased risk of developing lymphedema.[21] Another study was completed on twenty-one women with breast cancer-related lymphedema and weight loss as a form of treatment. This study found decreased arm volume in the women with

weight reduction.[22] A diet low in proteins will not decrease the amount of proteins in the tissues, and should be avoided to prevent tissue damage.[2]

Pain Management

Lymphedema can be a painful condition. As the swelling decreases, the pain a patient experiences should also decrease. Until then, a person's pain should be controlled with the aid of nonopioid or opioid analgesics, relaxation techniques, adjuvant medicines (tricyclic antidepressants, corticosteroids, anticonvulsants or local anesthetics), and/or transcutaneous electrical nerve stimulation (TENS).[7,23] Patients with genital lymphedema may need to wear a jock strap or spandex shorts to decrease the pain from gravity on the genitals.[9]

Pumps

There have been two main types of compression pumps used in the treatment of lymphedema, single-chamber and multichamber pumps. The older pumps were single-chamber and provided an intermittent, nonsegmental compression to the entire limb at one time. Healthcare providers against the pump insist that this type of compression, especially the single-chamber pump, can lead to an increase in limb edema, damage the existing lymphatic system, cause the person to develop genital or trunk edema, and contribute to the development of a fibrotic band at the top of the limb.[8,16,24]

The multichamber pump can be a standard sequential or gradient sequential system, with the gradient being the most common in current treatments. The chambers are arranged in an overlapping pattern and compress in a distal to proximal direction.[16,25]

The idea behind these types of pumps is to mimic the hands of the therapists performing the manual lymph drainage.[25,26]

One such pump, the Lympha-Press®, has applied pressures reaching 110 mm Hg in the upper extremity and up to 150 mm Hg in the lower extremity.[25] A study was conducted on fourteen patients with upper extremity lymphedema using the Lympha-Press®.[25] The study provided two weeks of treatment with the pump, ten hour long sessions, with volumetric measures taken before and after treatments. The study found a significant difference between the pre and post volumes on the first and fourth days only. The study recommends the use of the Lympha-Press® in conjunction with manual lymphatic drainage.[25]

A complaint about the pumps by those treating lymphedema is that the pumps do not cross into the trunk effectively. Another multichamber pump trying to address this concern is the Flexitouch®.[26,27] The Flexitouch® uses a light compression to the involved limb and to portions of the ipsilateral trunk. A survey study was conducted on one hundred and fifty-five patients with lymphedema with a home Flexitouch®.[26] A survey was completed prior to initiation of the Flexitouch® and during the maintenance phase of the Flexitouch's protocol. Less than 50% of the participants used the Flexitouch® per the prescribed protocol, yet 90% of the participants reported, "that they were satisfied with the Flexitouch® system."[26] Another study used the Flexitouch® on ten patients with unilateral breast cancer-related lymphedema. The study involved a crossover between the use of the Flexitouch® and self-administered massage. Each participant was randomly assigned to the order of treatments. The study found a significant ($p=0.007$) reduction in

volume after the use of the Flexitouch® in both groups, and no significant difference after massage.[26]

According to the expert opinion of Casley-Smith, the Lymphoedema Association of Australia, and other healthcare providers, pumps should only be used in a supervised setting with a certified lymphedema therapist in conjunction with manual lymph drainage.[8,16,28,29] Rockson supports the use of pumps in conjunction with manual lymphatic drainage in order to clear the trunk for the involved limb.[24] Petrek et al's article states, "[multichamber pumps] can force protein-rich edema fluid toward the shoulder, an area already congested, but not, however, through the axillary blockage; lymphedema involves the whole quadrant of the ipsilateral trunk, the area that the obstructed axillary channels would normally drain."[16] If the trunk of a patient with lower extremity lymphedema is not "cleared" first with manual lymph drainage, the use of the pump can increase genital lymphedema.[8] A study by Boris et al, found a high incidence of genital edema in patients using a pump for lower extremity lymphedema as compared to patients with lower extremity lymphedema who did not use a pump.[30] The study compared patients retrospectively and did not consider other contributing factors for the incidence of genital lymphedema with the patients other than the use of the pump.

Complete Decongestive Therapy

Complete Decongestive Therapy (CDT) for lymphedema is a treatment option originating in Europe.[16] The approach focuses on the concept of the entire body being involved with the treatment of lymphedema. The treatment can be divided into two phases. The first phase includes skin care, manual lymph drainage (MLD), low-stretch

multilayer bandaging, and exercises. The second phase is the maintenance section for the patient to continue at home and includes skin care, MLD, bandaging at night, compression garments during the day, and exercises.[16]

The patient education portion of both phases consists of extensive skin care and precautions for decreasing the prevalence of future recurrence of symptoms of lymphedema.[2,16] Skin care is especially important with genital lymphedema. The lymphrea leaks onto the skin of the genital tissue and increases the patients' occurrence of secondary bacterial infections.[3] Skin care is an inexpensive treatment, and is especially beneficial in third world countries with lymphedema from filariasis, where treatment options and compliance to therapy is limited. Skin care with acidic soaps lowers the pH of the skin making the environment not conducive for bacterial growth.[12]

Manual lymph drainage (MLD) is a complex sequence of manual strokes designed to reduce the swelling by removing lymph fluid and proteins in an affected area to functioning collateral lymph vessels.[2] The technique is thought to stimulate the lymph vessels to increase contraction rate, thereby, channeling the fluid to adjacent functioning lymphatics.[16] The MLD can also decrease the fibrotic tissue in the area.[2] A study by Andersen et al[31] investigated forty two women with upper extremity swelling and compared standard therapy (garment, skin care, exercise) and standard therapy with MLD. The women in the control group who felt they were not receiving full therapy were allowed to switch groups after three months. There was no significant difference between the two groups in volume reduction or subjective symptoms. All the patients had minor, acute (less than 15 months) lymphedema.[31] A study by Stalker in 2001 surveyed seven

patients after discharge from CDT to assess the effects of CDT on reduction of limb volume, pain, skin changes, mobility, quality of life, appearance, fitting of clothing, and in ROM.[32] There was an eighty-six to one-hundred percent improvement in all categories. However, the study had a very small sample size and was entirely subjective.[32] Kessler et al[33] performed a study on twenty-three subjects after hindfoot surgery. The subjects were divided into two groups; one received standard physical therapy intervention and the other received standard physical therapy intervention with manual lymph drainage. The study found that the subjects that received MLD along with standard physical therapy intervention showed a significant decrease in edema as compared to those not receiving MLD.[33]

During therapy, the reduction in edema from the MLD is complimented with the use of compression, bandages and garments, and special exercises to be performed daily while wearing the compression. Földi's Textbook of Lymphology[4] defines compression as "the pressure that is exerted on the tissues covered by a compression device (stocking or bandage) and on the blood and lymph vessels in those tissues." The compression bandages are used after each MLD session to maintain and enhance fluid reduction. Compression garments are used to maintain the reduction of the limb. The compression can enhance the "muscle pump" of the involved limb, can protect the limb from trauma, and can prevent over stretching of the skin from pressure.[34] Compression can possibly decrease the likelihood of trauma to the limb from insect bites, lacerations, and burns.[23,35] A study of twenty patients with leg lymphedema and nine healthy controls found a 50 ml and 60 ml reduction respectively after only two hours of bandaging.[36] Brorson found a

"sudden marked increase in arm volume" in six patients with upper extremity lymphedema after removing the compression garments for one week at the one year mark after liposuction.[35] The increase was reversed when the patients reapplied the garments.[35] Compression is not always suitable for those with edema. Those that are too weak to don the compression, are unable to physically manipulate the body into a position to don the garments and those with abnormal shaped limbs are limited in the type and amount of compression on the limb.[37] According to Harris et al[23] "Patients may be noncompliant with using compression garments because the garments are unsightly, uncomfortable, difficult to put on and expensive."

Performing exercises while wearing compression can enhance the decongestion of the lymphedema.[4] The compression can, "increase the uptake of fluid into the initial lymphatics and improve the pumping action of the lymph collectors."[38] A study by Havas et al[39] using scintography to monitor lymph flow with exercises found, "a consistent three- to sixfold increase in the clearance rates due to muscle contractions."

Surgery

Surgery may be successful if performed by an experienced surgeon, but in some CDT clinicians' opinions surgery generally has a low long term success rate.[8] It is thought that surgery may often result in the increase of lymphedema, and possibly make CDT treatment more difficult.[8] Surgery can be divided into the two categories of physiological and reduction.[16] Physiological surgery is an attempt to restore normal lymphatic functioning by connecting the involved area to an area with normal

lymphatics. Reductive or debulking surgery is the removal of the tissue and excess fluid to reduce the lymphedema.[16]

Physiological surgery, also known as microsurgery, aims "to restore lymphatic flow to the limb either by reconstruction of lymphatic channels or by bridging lymphedematous tissue to areas with normal lymphatics, usually by direct microsurgical anastomosis of several lymphatics to veins."[16] Lymphangioplasty, omental and pedicle flaps, myocutaneous flap, microlymphatic-venous anastomosis (LVA), and lymphatic grafting are all forms of physiological procedures.[4,40] According to Zuther, "the surgical attempts to increase the transport capacity of the lymphatic system have failed."[38] The studies conducted on this type of procedure have contained small samples, no long term results, and most show some edema recurrence.[41]

Debulking or reduction/resection surgeries aim to reduce the lymphatic fluids and tissue. This form of surgery is not highly specific and can further compromise the lymphatic system by removing or damaging other lymphatic vessels.[4,38] A common debulking surgery for scrotal/penis lymphedema is the Charles procedure. A study by Modolin et al[42] performed a modified Charles procedure, "which consists of the excision of the affected skin followed by scrotoplasty and midline suture simulating the scrotal rahpe."[49] The study was completed on seventeen patients with lymphedema of the penis and scrotum. The results at six years post surgery showed only one reoccurrence of edema due to underlying disease. The study also stated the patients had a "remarkable improvement in quality of life", yet did not administer or state standard questions to assess quality of life.[42] Complications from the Charles procedure can include:

hematoma, necrosis, poor wound healing, edema, development of condylomata or wart-like growths, ulcers, infections, papillomas, and thickening of the skin.[4,40] Currently, there is not a similar surgery for females with genital lymphedema.[43]

Liposuction and amputation are also included in the debulking category.[4,40,41] Liposuction "removes the suprafascial fatty tissue and destroys any remaining intact lymph collectors; lymphatic microcirculation is significantly disturbed."[38] Brorson states that liposuction, unlike complete decongestive therapy, can remove the hypertrophic adipose tissue that is often found in those with chronic lymphedema of at least stage II.[35] The removal of this adipose tissue and the extra fluid from the lymphedema could help explain the decrease in cellulitis episodes he has found in his patients. The fluid reduction decreases the "proteinaceous fluid, which may potentiate bacterial overgrowth," and the adipose tissue removal can decrease "colonized" bacteria.[35] Brorson does require his patients to wear constant compression after liposuction to help maintain the reductions.[35]

Lasers

A relatively new treatment option for lymphedema is the low level lasers. According to Carati et al[44] the benefits for postmastectomy lymphedema are seen due to the laser, "...treating the surgical scars associated with postmastectomy lymphedema (PML) and in treating the brawny edema that often develops in lymphedematous limbs." Carati et al[44] performed a study on sixty-one participants with postmastectomy lymphedema, twenty-eight in the control group and thirty-three in the "active" group. The study found two cycles of the low level laser, "to be effective in reducing the volume of the affected arm, extracellular fluid, and tissue hardness in approximately 33% of patients

with postmastectomy lymphedema at 3 months after treatment."[44] A study by Kaviani et al[45] using low level laser with women status post mastectomy found a greater decrease in volume measurements in the laser group than the control group until the final measurements at week twenty-two. The control group did report a greater decrease in pain from week twelve through week twenty-two. The entire study was over a twenty-two week period with treatments or placebo during weeks 1-3 and 12-14 and measurements at weeks 3, 9, 12, 18, and 22.[45]

VOLUME

Need for Measurements

In 1986, the American Physical Therapy Association's (APTA) Board of Directors acknowledged the need for the field of physical therapy to improve the "state of measurement in physical therapy."[46-48] According to the APTA, measurements can "classify and describe patients, plan treatments, predict outcomes, document the results of treatments, and determine when to refer patients to other practitioners."[47] The APTA notes that while the field of physical therapy has grown significantly, measurement techniques to quantify the treatment techniques have not advanced as drastically. The insurance industry is trying to reduce reimbursement in all healthcare fields, and physical therapy is no exception. Insurance companies require documentation on the "efficacy and cost-effectiveness" of services. The APTA realizes the importance of improved documentation, involving measurements of "high quality," in order to guarantee continued payment by insurances for physical therapy services.[47]

Current Forms of Measurement

Physical therapists, in general, measure a patient's swelling on initial evaluation and subsequent visits to document the extent of the injury and the progress of therapy. Water displacement, or volumetric measurement, is considered to be the gold standard for measuring a limb's volume.[49] However, water displacement is not practical to use in an outpatient setting. The equipment has to be large enough to hold an edematous extremity, needs a water source, becomes heavy once filled, is time consuming, and a patient needs to be able to submerse in the water. Water displacement methods cannot be used to measure the patient's swelling if there is an open wound, incisions, or significant skin irritation, all of which can be common with lymphedema.[2,38,49-51] Therefore, water displacement is not typically used in documenting volume in physical therapy when treating lymphedema.

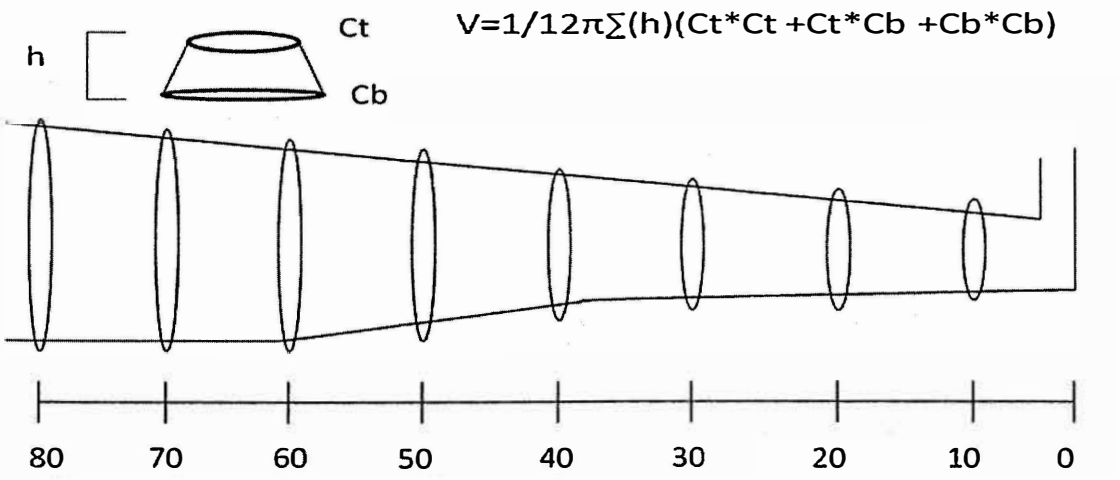
The Casley-Smith method for treating lymphedema uses the truncated cone formula to objectively measure initial swelling and reduction from treatment. The method for the leg involves measuring the foot at the metatarsophalangeal joints (MTP) and the least ankle (smallest part of the ankle directly superior to the malleoli), then measuring from this point up the leg every ten centimeters for thirteen different measurements. The ten centimeters can be changed at the therapist's discretion if he/she feels the measurements need to be closer or further apart to capture an accurate representation of the leg. For example, with shorter legs, one may not reach the thirteen different points, and longer legs may need additional points. The circumference at each point is documented along with the distance between each measurement. The values are then

inserted into the truncated cone volume formula of $V=1/12\pi\sum(h)(Ct*Ct+Ct*Cb+Cb*Cb)$ to sum the thirteen different conical measurements, where (h) is the length of each segment, (C) is the circumference, (t) is the top of the cone, and (b) is the bottom of the cone.[2] This method of documenting volume is less time consuming than the water displacement, and can be used over open wounds, incisions, and skin irritations.

The difference between the truncated cone and the cylinder methods is the formula used to calculate the volume. The truncated cone volume is calculated with the formula, $V=1/12\pi\sum(h)(Ct*Ct+Ct*Cb+Cb*Cb)$, and the cylinder volume is calculated with the formula $V=1/4\pi\sum(L)(C^2)$. In these formulas, (h) is the length of each segment, (C) is the circumference, (t) is the top of the cone, (b) is the bottom of the cone, and (L) is the length of the segment (Figure 2).[2,51] Some clinicians feel the extremities most resemble multiple cylinders, while others feel that multiple truncated cones reconstruct a limb.[49] A study by Pani et al[52] on severe, grade II, filarial edematous legs found that even though the water displaced volume was consistently larger than the conical volumes, the values had a significant correlation, $r=0.92$ with $p\leq 0.0005$. He felt, "not only could volume of edema be calculated by circumference measurements, but the simple measurement of average circumference difference between the affected and normal limb accurately reflected the volume of actual edema."[52] This study used the entire foot in both the water displaced volumes and the calculated volumes. This study only assessed swelling due to filarial infection.[52] Sitzia compared only the truncated cone and the cylinder volumes and found the cylinder method always underestimated the volume when compared to the truncated cone method. This research did not compare either method to

water displacement volumes.[53] There needs to be a proven method of objectively recording a patient's lower leg, including the foot, to justify therapy and document the patient's progress with the lymphedema therapy.

Volume of a Truncated Cone



Volume of a Cylinder

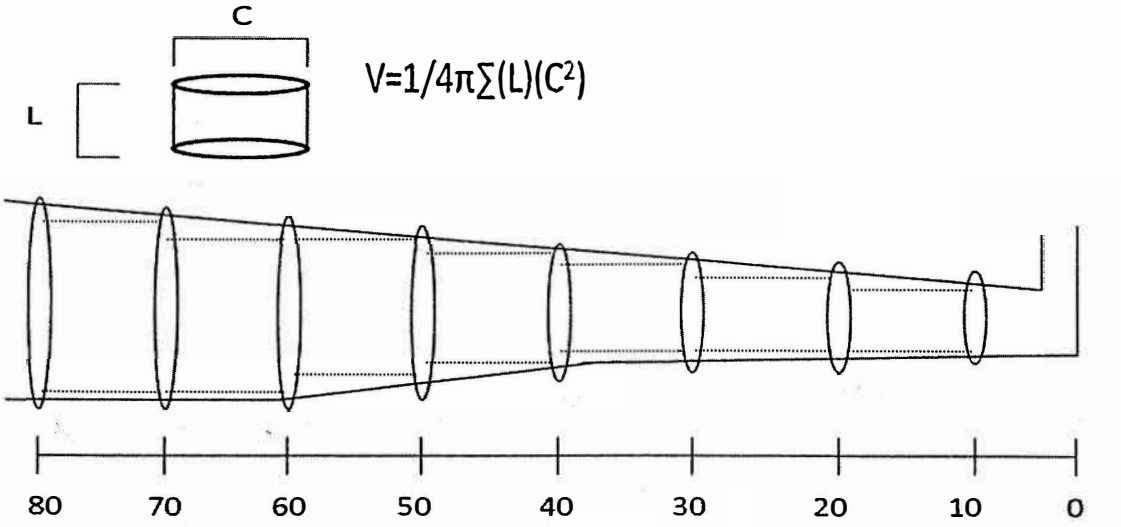


Figure 2. Calculating the volume of a truncated cone and a cylinder as depicted by Casley-Smith

Casley-Smith J, Casley-Smith JR. Modern Treatment for Lymphoedema 5th edition. Adelaide, Australia. Henry Thomas Laboratory. 1997.

QUALITY OF LIFE[1]

The term "health," was defined by the World Health Organization in 1946 as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."[54] Ferrans and Powers define QOL as "a person's sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her."[55] The health community is beginning to fully grasp the importance of the subjective components' impact on overall outcomes. Thus, QOL measurement tools to quantify these subjective aspects are being developed for multiple patient populations. Crosby et al[54] sites Gotay and Moore's[56] thoughts on why quality of life measurement tools are key when researching any of these four aspects of healthcare: "1) when patients have a chronic illness and need palliative care; 2) treatments are expected to be equivalent in efficacy, but one offers a QOL benefit; 3) a new treatment shows a small benefit that is offset by QOL deterioration; or 4) treatments differ in terms of short-term efficacy, but the overall failure rate is high."

The definition for female sexual dysfunction was developed by The American Foundation of Urologic Disease in 1998. Sexual dysfunction encompasses a person's sexual desire, sexual arousal disorders, orgasmic disorders, and sexual pain disorders. The conditions must be severe enough to cause personal distress for a woman.[57] There are noticeable similarities when comparing the signs and symptoms of female genital lymphedema and the actual definition of sexual dysfunction. According to Rosen et al,[58]

[1] The Quality of Life section is part of a previously published article: "Quality of Life Tools and Their Relevance for Females with Genital Lymphedema." Copyright Clearance is in Appendix A

"in spite of the high prevalence which appears to surpass that of male sexual dysfunction, less attention has been paid to the sexual problems of women." They also state there are few studies on the underlying causes of female sexual dysfunctions and the available treatments for the dysfunctions.[58] The purpose of the review was to determine if a current tool was available to assess QOL for females with genital lymphedema.

The review of literature revealed twelve QOL tools that may be considered for use with the client population with genital lymphedema. Each tool was evaluated by content and available psychometric literature. Five of the outcome measures were found to have limited evidence with this particular search, so will only be discussed briefly at the end of this section.

Quality of Life Index (QLI)

In 1984, Ferrans and Powers developed the Quality of Life Index (QLI) to measure the satisfaction and importance of different domains in a person's life. The tool focuses on a person's overall QOL, and four separate domains: health/functioning, psychological/spiritual, social/economic, and family. The generic version has two sections with 33 questions each, for a total of 66 questions. The first section focuses on how "satisfied" one is with different aspects of his/her life. The second section questions how "important" each of the previous aspects are to the individual. The participant rates each question on a 1-6 point scale, with 1 being "very dissatisfied" and 6 "very satisfied."[55] The questions are divided into five areas for scoring. The areas are: total quality of life, health and functioning subscale, social and economic subscale,

psychological/spiritual subscale, and family subscale. The points for areas are calculated using a statistical program, which weights the questions and provides the resulting score. This tool has been adapted for several different disorders, and also for the population at large.[55] Due to its versatility, the QLI has been utilized in multiple studies and has demonstrated acceptable reliability and validity. The studies have shown the tool to have internal reliability with an alpha ranging from 0.73-0.99 and temporal/test-retest reliability ranging from r=0.72-0.87. Concurrent validity for the QLI overall score ranged from r=0.61-0.93 when compared to the Campbell, Converse, and Rodgers' measure of life satisfaction; and content validity was established after extensive literature review and a high rating on the Content Validity Index, which is based on experts' ratings of item relevance.[55] The tool has shown the ability to adapt to different medical conditions, while maintaining validity and reliability.[59-63]

A study by Rannestad et al[64] was conducted using the QLI for "women suffering from gynecological disorders." The study compared adult women undergoing a benign hysterectomy with a random sample from the general population of similar ages. The study showed the women post-hysterectomies to have the lowest score in the domain on health/functioning and the highest score in the family domain. There was no statistical difference in the two groups for overall QOL. The study attributed this to "the marked stability of one's generic QOL despite various occurrences in the course of a lifetime."[64]

The QLI can provide an excellent sense of a person's general quality of life across a wide spectrum of areas in a short amount of time.[55] The disadvantage of this tool for the specific population of females with genital lymphedema is that there are only a few

questions addressing the actual symptoms associated with this condition. There is one question on pain and one on sexual function in each section. There are no questions on incontinence or urinary dysfunction.

SF-36 Health Survey

The SF-36 Health Survey is a short multi-purpose tool, which consists of 36 questions. The SF-36 has an "eight-scale profile of scores as well as a summary of physical and mental measures."[65] The dimensions of physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health are computed using standardized procedures with the higher scores representing a more positive view of one's health status. The thirty-six questions cover a person's subjective feelings pertaining to health, functional abilities, and mental state. The questions for the scale are from a one hundred and forty-nine question tool, the Functioning and Well-Being Profile. The internal reliability and test-retest reliability both "exceed .80" and the tool has been shown to have both content and construct validity."[65-67]

Sherman et al[68] conducted a three-arm, randomized placebo-controlled, double-blinded study on post-menopausal women with coronary heart disease. This was the only study found for the SF-36 in the current search with any relevance to the population of interest. All of the participants were enrolled in an estrogen replacement and atherosclerosis trial. The study found the women reporting "chest pain, gallbladder disease, hypertension, not currently taking cholesterol medication, and less social support" to have lower scores on the SF-36 than the women that did not receive estrogen replacement in the control group.[68]

Overall, the SF-36 appears to be an excellent tool. The disadvantage of the SF-36 for investigating the effects of genital lymphedema is the lack of questions addressing actual symptoms of the condition. There are no questions on sexuality or urinary dysfunctions. Pain, however, is addressed in two of the questions in this tool. The main focus of the tool's questions is on a person's ability to perform functional aspects of daily living including walking, climbing stairs, and on the person's emotional/mental status. Since a person may still be able to walk without limitation from incontinence, heavy sensations in the genital region or some of the other symptoms associated with genital lymphedema, this tool may not be valid for the population of females with genital lymphedema.

Female Sexual Function Index (FSFI)

Rosen et al[58] developed the Female Sexual Function Index (FSFI), a "multidimensional self-report instrument for assessing the key dimensions of sexual function in women." This tool examines the following six domains: desire, arousal, lubrication, orgasm, global satisfaction and pain. There is an overall composite score, as well as a score for each domain. In a study using participants previously diagnosed with female sexual arousal disorder (FSAD) and age-matched controls, the tool was found to have high test-retest reliability with a correlation coefficient of $r=0.79-0.86$ which was significant at $p\leq0.001$, an internal consistency $\alpha=0.89-0.97$, and discriminate validity with significant mean differences between the two groups in each domain at $p\leq0.0001$.[58] Speer et al[69] used the FSFI to study the sexual dysfunction experienced by individuals following breast cancer. The desire, arousal, lubrication, orgasm and painful intercourse

domains were shown to be the most problematic, showing significantly lower scores in all areas ($p<0.001$) for individuals following breast cancer when compared to sexually healthy women without breast cancer.[69]

A disadvantage of the FSFI is that the person has to have been sexually active within the last four weeks to be able to answer any of the questions with a score other than "0." The tool does not ask for an explanation of why a person has not been sexually active within the last month. The three questions on pain mainly relate to pain one would experience during or after intercourse. There are no questions on urinary dysfunction. With genital lymphedema, sexual dysfunction is not the only symptom and may not always be a factor. The tool is detailed and may be offensive or embarrassing to some women due to the content.

Incontinence Quality of Life (I-QOL)

The Incontinence Quality of Life (I-QOL) tool consists of 22 questions with values for answering each question ranging from 1 (not at all) to 5 (extremely). The points from each question are summed, and the total score is converted to a 100 point scale, with lower scores indicating a larger impact of incontinence on daily life.[70]

Kinchen et al[70] performed a cross-sectional study on women with incontinence. The women had all been previously diagnosed with incontinence by the National Family Opinion (NFO) World group survey. The results of the I-QOL showed that about 50% of women with urinary incontinence sought treatment. The women were likely to seek treatment only when they felt the incontinence impacted their QOL. The length of

symptoms, the perceived severity and the likelihood of noticeable leakage were found to be significant ($p \leq 0.05$) for those who chose to seek treatment.[70]

The disadvantage of using only the I-QOL for assessing QOL with genital lymphedema is that the questions are related only to the impact of incontinence in females. There are no questions addressing pain in this tool. There is one question on sex as it relates to fear of urination during intercourse. While incontinence can be associated with genital lymphedema, it may not be the only or the most debilitating symptom.

Pelvic Floor Distress Inventory (PFDI)

The Pelvic Floor Distress Inventory (PFDI) is a 46-question tool, which includes portions of three other QOL assessment tools: the Urinary Distress Inventory (UDI), the Colorectal-Anal Distress Inventory (CRADI), and the Pelvic Organ Prolapse Distress Inventory (POPDI). The tool was developed to assess women's distress over the symptoms associated with pelvic floor dysfunction. For each question, the patient answers the degree to which he/she is affected by the symptom on a 1 (not at all) to 4 (quite a bit) scale. The question asks about a particular symptom and how much that symptom "bothers" the participant. The questions assess urinary dysfunctions, bowel dysfunctions, pressure, heaviness, prolapse, and abdominal discomfort. There is a short form of the tool consisting of 20 questions.[71-74]

A study by Barber et al[71] used the PFDI on women diagnosed with a pelvic floor disorder at the Duke University Medical Center. The study compared the results of the PFDI and another tool, the Pelvic Floor Impact Questionnaire to a complete physical examination. The study found the PFDI to have good internal consistency ($\alpha=0.88$) and

test-retest reliability reported as an ICC of 0.87. According to the study the PFDI, "serves the role of both a symptom inventory and a measure of the degree of bother and distress caused by the broad array of pelvic floor symptoms."[71]

Bradley et al[73] completed a study using the PFDI to assess the association of lifestyle factors in pelvic floor disorders and the occurrence of women deciding not to seek care for symptoms of pelvic floor disorders. The study modified the PFDI to a yes/no type answer for each question. The PFDI was administered to two hundred and ninety-seven women enrolled in the Women's Health Initiative (WHI) Hormone Replacement Therapy Clinical Trial at a mid-western site, excluding those currently seeking treatment for pelvic floor disorders. The study found women with higher body mass indices had increased urgency with related incontinent symptoms, those with a history of smoking had symptoms of "pelvic heaviness and fecal urgency," and those drinking coffee had "urinary obstructive symptoms, including a weak urinary stream and difficulty emptying the bladder."[73] The most prevalent symptom (51.2%) of the women not seeking medical attention was stress urinary incontinence.[73]

The disadvantage with the original PFDI is the length. The short form of this questionnaire does address this disadvantage. Also, this tool does not include all the symptoms associated with female genital lymphedema. There are only two pain questions on the short form, one is associated with flatulence and the other is for general lower abdominal pain. There are no questions on sexual dysfunction on the short form.

Pelvic Floor Impact Questionnaire (PFIQ)

The Pelvic Floor Impact Questionnaire (PFIQ) is a 93-question tool focused on the impact of pelvic floor symptoms on a person's quality of life. The tool contains three scales with 31 questions each, the Urinary Impact Questionnaire (UIQ), the Colo-Rectal-Anal Impact Questionnaire (CRAIQ), and the Pelvic Organ Prolapse Impact Questionnaire (POPIQ). The questions relate to the impact of bladder, bowel and vaginal symptoms on a person's QOL and are scored from 1 (not at all) to 4 (quite a bit).[70-73] According to Barber et al[71] "the PFIQ assesses areas more traditionally associated with health-related quality of life by measuring the degree to which bladder, bowel, or vaginal symptoms affect the daily activities, relationships, and emotions of women with pelvic floor disorders."[71-74]

Wren et al[74] performed a study on women surgically treated for pelvic organ prolapse and urinary incontinence. The study used multiple tools to assess quality of life in this population. This cross-sectional study was conducted by phone with initial and 2-week follow-up interviews. The study found most of the tools, including the PFIQ to have test-retest reliability of $r > 0.60$, internal consistency reliability of $\alpha \geq 0.6$, and a validity of $p < .001$ for moderate-to-severe incontinence level when the scores were compared to the PFDI.[74]

Barber, Walters and Bump performed a study on the short form of the Pelvic Floor Impact Questionnaire, the PFIQ-7.[72] This study also included the PFDI-20 tool. A subset regression analysis was performed to determine which items best predicted the score for each subset. After the items were selected for the test, face and content validity were

assessed by an expert panel. The new short forms of the tools were administered to 45 females at an urogynecology clinic with pelvic floor disorders. The tools were administered to the participants twice preoperatively and at the third and sixth months postoperatively. The PFIQ-7 had a moderate responsiveness (ES=0.67, SRM=0.63) and excellent discrimination for change in symptoms (c=0.88).[72]

The disadvantage of the PFIQ tool is that "bladder, bowel and vaginal symptoms" are not clearly defined in the scale. The original tool is too long to administer frequently in a clinical setting with ninety-three questions. Again, the short form does correct for this shortcoming. Like many others, this tool does not address all the symptoms associated with genital lymphedema.

Pelvic Muscle Exercise Self-Efficacy Scale (PMSES)

Broome[75] developed the Pelvic Muscle Exercise Self-Efficacy Scale (PMSES) based on the theories of Albert Bandura. Broome references Bandura[76] and his extensive work on self-efficacy, especially in the physical health area in her research. Broome's research follows portions of Bandura's theory on the impact of self-efficacy on physical health, which has three sections. First, self-efficacy can impact a person's stress levels, thereby influencing the immune system. Second, a person's belief on how a treatment option works will affect the person's attitude and participation in the treatment. Finally, a high self-efficacy can help prevent a condition from becoming worse.[75]

Broome wanted to develop a tool that would assess a female's belief in pelvic floor exercises designed to improve her condition in order to predict outcomes following treatment for incontinence.[75,77] The PMSES scale consists of 23 questions based on the

confidence of the individual to complete pelvic floor contractions in different settings and the individual's confidence in the effectiveness of the exercises to prevent urine loss with different exercises. The questions are scored on a 0-100 point scale in intervals of ten.[75,77,78] Scores of at least 66 show high self-efficacy, scores of 33-65 show moderate self-efficacy, and scores below 33 are indicative of low self-efficacy.[75,78]

A study by Broome in 1999 had one hundred and fifteen community-dwelling females with complaints of urinary incontinence over the age of fifty and twenty females from a continence clinic complete the PMSES. Each subject completed the PMSES before and after treatment of pelvic muscle exercise for urinary incontinence. The study found internal consistency reliability for the tool to be α=0.97, and test-retest reliability of r=0.72. The content validity of the PMSES was determined by having experts in the areas of self-efficacy and urinary incontinence examine the questions. The study was unable to assess concurrent validity due to the lack of a comparable tool.[75]

The disadvantage of the PMSES is that the only symptom assessed is urinary incontinence. There are no questions relating to pain or sexuality in the tool. The questions mainly focus on the confidence one feels in being able to perform pelvic floor exercises in different situations. Currently, pelvic floor exercises are not a standard aspect of lymphedema treatment. Shu-Yueh Chen criticized the tool in his article, saying "the Broome PMSES is not necessarily suitable for Taiwanese women given that the concept of self-efficacy is culture-dependent."[79] The tool was only evaluated using Caucasian and African-American women with urinary incontinence. Other races have not been examined with this tool.

Other QOL Measurement Tools

The following tools are available for use, yet lack significant supporting literature for assessing the validity and reliability of the tools across different medical populations.

RAND-36. The RAND-36 item health survey is a short form of the Medical Outcomes Study's (MOS) Functioning and the Well-being Profile. The survey is divided into four physical and four mental subscales with a 0-100 range for each subscale. There are two questions on pain and the others all relate to a person's ability to perform functional activities of daily life. The RAND-36 has the same questions as the SF-36, yet is scored differently.[80] The RAND-36 has been found to have an internal consistency of α=0.75 for the subscales.[72,81] The only symptom addressed by the RAND-36 dealing with the symptoms associated with female genital lymphedema is pain.

Fecal Incontinence Quality of Life Scale (FIQL). The Fecal Incontinence Quality of Life Scale (FIQL) is a forty-one question tool developed to assess the alteration of dietary habits, behavioral adaptations, and the psychological state of people diagnosed with fecal incontinence. The tool has two questions relating to avoidance and lack of sexual activity due to fear of fecal incontinence. There are no questions relating to pain or urinary dysfunction. A study by Rockwood et al[82] compared fifty-five people with fecal incontinence to the control group of seventy-two people with non-incontinent gastrointestinal problems. The FIQL was found to have internal consistency of α=0.70, and convergent validity of r=0.28-0.65 as compared to SF-36.[82]

Profile of Female Sexual Function (PFSF). The Profile of Female Sexual Function (PFSF) is a thirty-seven item tool developed to measure sexual desire and

sexual function of women that are post-menopausal. The tool has seven subscales, sexual pleasure, sexual desire, responsiveness, arousal/orgasm, sexual self image, sexual concerns, and disinterest.[83] There are no questions in this tool on pain or urinary dysfunction. A study by McHorney et al[83] compared three hundred and twenty-seven oophorectomized females diagnosed with hypoactive sexual desire disorder to two hundred and fifty-five females in a non-oophorectomized control group. The study involved participants from the United States, Australia, Europe and Canada. The study showed the PFSF to have good internal consistency and test-retest reliability with α=0.79-0.96 and an ICC of 0.52-0.90 respectfully.[83] There are only questions related to sexuality on this questionnaire, none addressing pain or incontinence.

Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire (PISQ). The Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire (PISQ) was developed to assess sexual function in women previously diagnosed with pelvic organ prolapse or urinary incontinence. The tool consists of three domains: behavioral/emotive, physical, and partner-related. The original tool has thirty-one questions. There are questions relating to pain, urinary dysfunction, bowel dysfunction, sexual dysfunction, orgasms, impotency, premature ejaculation, and other details relating to sexuality.[84,85] A study was performed on one hundred and eighty-two women from the University of New Mexico Hospital. The study found the tool to have an internal consistency score for all domains to range from α=0.43-0.86, and for the entire tool to be 0.85. The test-retest reliability for the domains ranged from κ=0.56-0.93.[84]

A short form was developed with only twelve questions from a regression analysis of the long form's thirty-one questions.[85] A study was performed by Wren et al[74] on eighty-eight women one year after surgical procedures for pelvic floor disorders. The study found the short form to have a test-retest reliability of κ=0.79 and internal consistency of α=0.36.[74]

Disadvantages

The primary disadvantage of all of these tools is the lack of research available on the tools using the limited keyword search. Like most of the previous tools, these tools do not address all of the symptoms associated with lymphedema and/or genital lymphedema. Most of the tools only focus on one symptom or condition. In the case of the PSIQ, the questions may be offensive or embarrassing to some females and several of the questions focus on the partner having sexual dysfunctions.

CONCLUSION

After an extensive review of the literature for lymphedema, treatments, qualitative measurements and QOL tools, it is evident that there is a substantial lack of research on genital lymphedema. There is not a sufficient study on using the truncated cone method of volumetric measurements for lower extremities for quantifying edema. There needs to be a study comparing the gold standard of water displacement with the truncated cone method on lower extremities. Currently, there also is not an adequate method to evaluate the QOL of females with genital lymphedema. There needs to be a study to determine the QOL of females with lower extremity and/or genital lymphedema. A tool needs to be developed that targets the specific symptoms known to exist with genital lymphedema,

especially in females. This tool could be used in conjunction with a general QOL tool to provide a thorough qualitative assessment of this patient population. Lastly, there are no articles found on specific treatment techniques for persons with genital lymphedema. The CDT method as it currently exists may not be the best for reducing edema and improving QOL in females with genital lymphedema. A study needs to be performed comparing the current CDT method and an altered method to see which produces the most desired effect for this population. The conclusion after this literature review is at a minimum there needs to be at least three studies: one on volumetrics, one on QOL tools, and one on possible alternative treatment options for females with lower extremity and/or genital lymphedema.

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CHAPTER III

INTERTESTER RELIABILITY AND CRITERION VALIDITY OF THE TRUNCATED CONE FORMULA FOR MEASURING LOWER EXTREMITY VOLUME

A paper to be presented for publication

INTRODUCTION

Lymphedema occurs when the lymphatic system is compromised and lymphatic flow is altered, resulting in accumulation of interstitial fluid.[1,2] The first manual "massage" treatment for lymphedema was developed at the end of the 19th century, and then expanded on in the 1950s by Dr. Emil Vodder. The "massage" technique and the entire treatment for lymphedema has been modified by several others.[3] These modifications have led to the development of different training courses, including the Vodder method, the Casley-Smith method, the Földi method, and the Chikly method. During the training process for all of the methods, participants are trained to use either the cone or cylinder method to calculate extremity volume.

According to the *Guide to Physical Therapy Practice*, all physical therapists should measure a patient's edema on initial evaluation and during subsequent visits to document the extent of the impairment and progress of therapy.[4] Water displacement, or volumetric measurement, is considered to be the gold standard for measuring a limb's volume.[5] Studies by Smyth et al, DeVore, Hamilton, and Waylett-Rendall all have shown the volumetric measurements to be accurate with an error of +/- 1% for reproducibility.[6-8]

However, water displacement of the lower extremity is not typically used in the assessment of those with lymphedema.[3,5,9,10]

The methods therapists choose to measure lower extremity edema can differ. Simple girth measurements are usually taken at boney prominences and/or a documented distance from these prominences. Some clinicians feel the extremities most resemble multiple cylinders, while others feel that multiple truncated cones are best to represent a limb.[5] Both the truncated cone formula and the multiple cylinder formula use multiple measurements along the edematous limb to calculate the volume.

Sukul et al[11] compared water displacement volumes to the truncated cone volumes, and also compared water displacement volumes to the cylinder volumes for the calf portions of the study participants; the foot measurements were not included. The authors found the amount of water displaced and the cylinder formula produced interchangeable results; however, this was not found when comparing water displacement with the truncated cone volume.[11] A study by Stranden calculated the truncated cone volume of the leg from the malleoli to the knee and compared it with the water displacement volume of the entire lower extremity, including the foot. This study found the truncated cone volumes to be 11% larger than the water displacement measurements.[12] Sitzia compared the truncated cone and cylinder volumes for the upper extremity and found the cylinder method consistently produced a smaller volume when compared to the truncated cone formula.[13] There needs to be a reliable and valid method of objectively recording a patient's lower leg, including the foot, to justify the need for therapy and to document the patient's progress with the lymphedema therapy.

The purpose of this study was to compare the truncated cone formula for volume measurement with the gold standard of water displacement for measuring volume in those with and without lower extremity lymphedema. The null hypotheses for this study were 1) there will be no significant relationship among physical therapists certified in different methods using the truncated cone formula method to calculate volume on a lower extremity with/without lymphedema, and 2) there will be no significant correlation between the truncated cone formula for volumetric measurements and the water displaced volume method of a lower extremity with/without lymphedema.

METHODS AND MEASURES

IRB approval was obtained from Texas Woman's University and BenchMark Physical Therapy prior to the start of the data collection (Appendix B). The investigators were all licensed physical therapists. Those measuring for the truncated cone formula had completed advanced training in lymphedema from one of the following schools: Vodder, Casley-Smith, and/or Chikly. Prior to the arrival of participants, all investigators underwent a review of the procedures and were given time to practice the techniques.

The study was completed on a sample of convenience to obtain 30 participants with either previously diagnosed or symptoms of lower extremity edema and 30 participants without a diagnosis or symptoms of lower extremity edema (control). Inclusion criteria for participation included males and females of all races from the age of 18 years to 65 years. The participants were recruited from a private outpatient clinic and included patients, employees, and local residents. The protocol for both the control and the participants with edema was the same.

Regardless of group, each participant signed informed consent and completed a medical questionnaire prior to participating in the study (Appendix C). The participants were also offered an informative brochure on the treatment and causes for lymphedema. The participant was then taken to the first examination area. Therapist (A) reviewed the medical questionnaire and examined the legs of the participant for the following: open wounds or open incisions, and skin irritations. If any of the conditions were found, or if the legs were too large by visual inspection to be lowered into the water displacement apparatus, the participant would have been removed from the study. For participants with edema, the leg with edema was used for testing. If the participant had edema in both legs, then the therapist would randomly select a leg for measurement. The therapist also randomly selected the leg to be measured for those without any previous edema. The water in the container was at room temperature, 70˚, and the container was filled to the drainage spout as directed by the manufacturer. Therapist (A) slowly lowered the leg into the Baseline® Volumetric Edema Gauge system (13in L X 6in W X 24in H) and recorded the water displaced measurement for the lower extremity (Appendix D).[14] Therapist (A) then marked on the participant's calf the top level of the water prior to removing the extremity.

The participant's leg was then thoroughly dried off, and the participant was escorted to either exam room two or three. The second therapist (B) then measured for the truncated cone formula, the same lower extremity, from the metatarsophalangeal (MTP) joints to the drawn line from therapist (A). Therapist (B) measured the foot at the MTPs, the mid arch of the foot, the least ankle, or the smallest portion of the ankle, and

then measured proximally in 6 cm increments to the drawn line. If the top measurement was not 6 cm from the previous, the actual cm length was documented and adjusted to the actual interval measurement in the data equation. A technician recorded the measurements for the therapist (Appendix E). The third therapist (C) then repeated the exact process used by therapist (B). Therapist (C) was one of the three physical therapists (with various advanced training backgrounds).

The values obtained from therapist (B) and (C) were then inserted into the truncated cone volume formula of $V=1/12\pi\sum(h)(Ct*Ct+Ct*Cb+Cb*Cb)$, where (h) is the length of each segment, (C) is the circumference, (t) is the top (proximal portion) of the cone, and (b) is the bottom (distal portion) of the cone.[10] The calculated volumes were then documented for each participant.

Data Analysis

Pearson product moment correlation coefficients (2-tailed test, $p\leq0.005$) were used to determine the relationships between the volumes obtained with the water displacement and the truncated cone method. The standard p-value of $p\leq0.05$ was divided by the number of tests (10) that were conducted to decrease the chance of a type-I error. This modified the p-value, or significance level, to $p\leq0.005$. Power analysis was calculated for the Pearson product moment correlations. Intraclass correlation coefficients, ICC(2,1), were calculated to measure the intertester reliability.

RESULTS

Sixty participants were eligible and 57 completed the study. Two control and one edematous participants' data were removed prior to data analysis. These outliers were removed due to data entry errors with the water calculations.

The age of the participants ranged from 19-65 years, with a control group average age of 50.0 years with a standard deviation of 15.9 years and the edematous group average of 42.1 years with a standard deviation of 10.6 years. There were 17 control males, 13 control females, 8 edematous males and 22 edematous females. Of the edematous group, 10 had previously been diagnosed with lymphedema. The remaining 20 had other causes for the lower extremity edema. The most common two health conditions for the participants in both groups were heart conditions and diabetes.

Multiple correlations were calculated from the data. (Table 2, Figure 3, and Figure 4) The truncated cone volumes were calculated two ways, the full method used the entire lower leg, and the short method removed the foot portion. Overall, the results for intertester reliability range, for the full and short calculations, was $r=0.93\text{-}0.95$, $r^2=0.86\text{-}0.90$ and the results for the same comparisons of water displacement and the truncated cone method range was $r=0.94\text{-}0.97$, $r^2=0.86\text{-}0.92$. The power analysis for all the correlations ranged from 0.86 to greater than 0.995, except for when comparing the control group's water volume with the truncated cone volume from therapist C the power was 0.33. The high statistical power supports a minimal chance of not rejecting a false null hypothesis, or a Type II error. Intraclass correlation coefficient, ICC(2,1), for the intertester reliability was 0.95 for full calculations for both groups, and for the short

calculations was 0.93 for the control and 0.94 for the edematous. These results supported rejection of the first null hypothesis for no relationship with intertester reliability among therapists using the truncated cone to calculate volume of the lower extremity with/without lymphedema. The correlation between water displacement and the truncated cone method ranged from r=0.94-0.96, and r^2=0.86-0.92. These results supported rejection of the second null hypothesis for no significant correlation between the truncated cone and water displacement methods for volume calculations of a lower extremity with/without lymphedema.

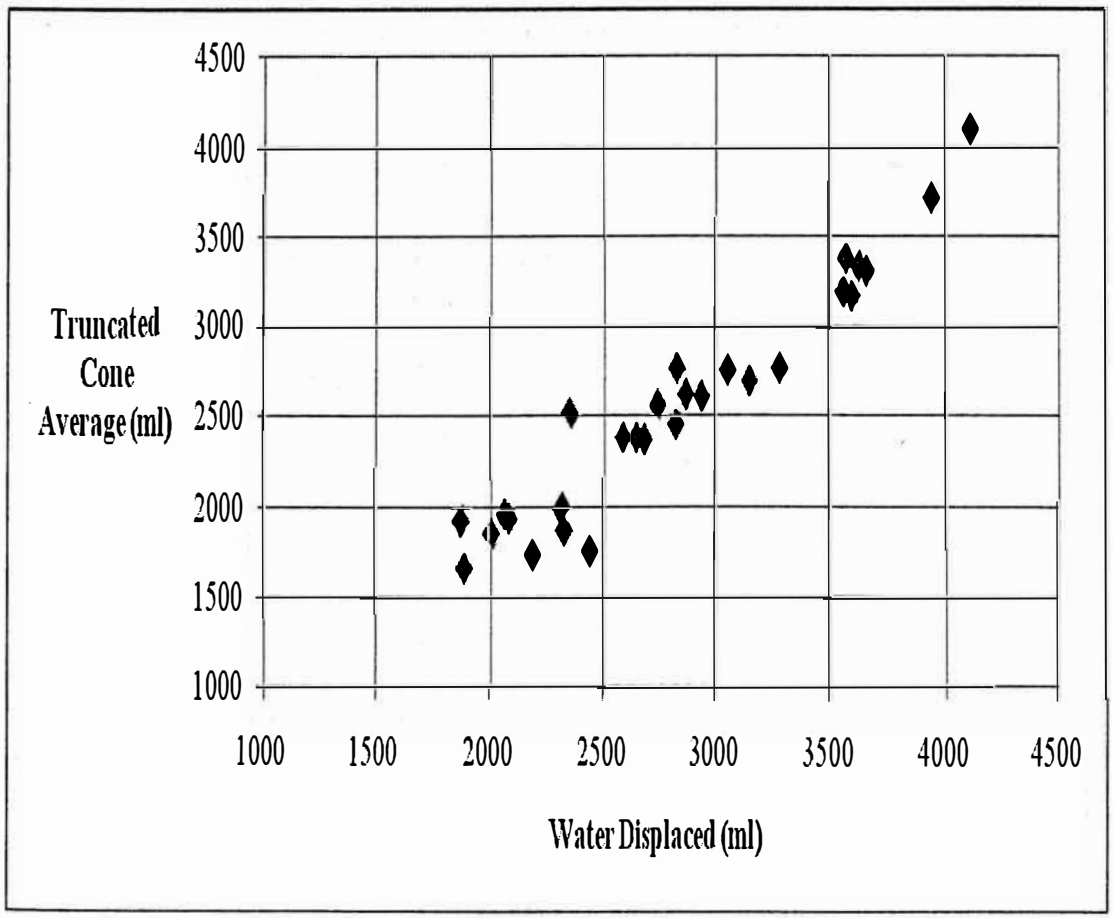

Figure 3. Correlations using participants without edema between water volume and avg truncated cone volume of (B) and (C) (r=0.96)

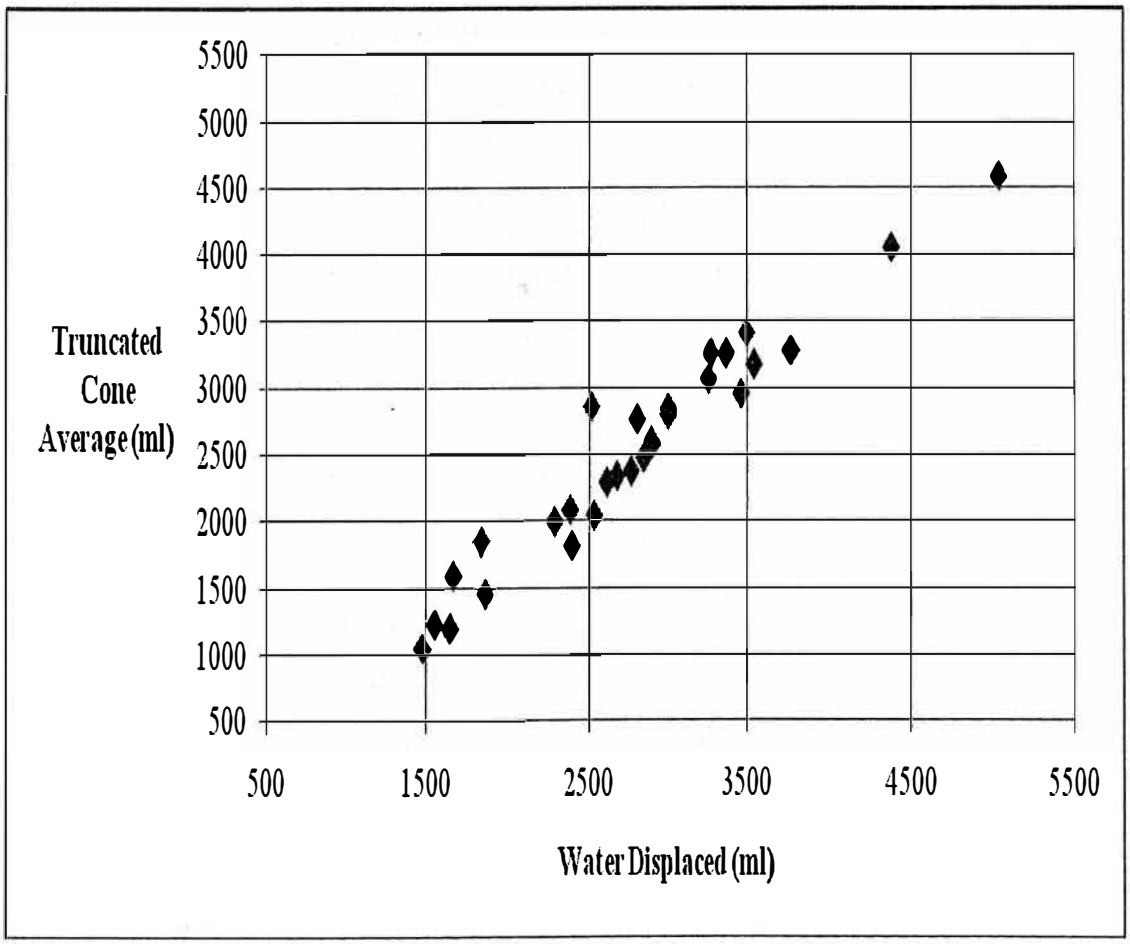

Figure 4. Correlations using participants with edema between water volume and avg truncated cone volume of (B) and (C) (r=0.97)

Table 1. Statistical Results Using Pearson Correlations (2-tail tests) ($p \leq 0.005$) and Intraclass Correlation Coefficients

	Control (r)	Control (ICC)	Edematous (r)	Edematous (ICC)
Water Volume and Truncated Cone Volume for the Full Lower Leg of Therapist(B)	r=0.96		r=0.96	
Water Volume and Truncated Cone Volume for the Full Lower Leg of Therapist (C)	r=0.94		r=0.96	
Truncated Cone Volumes for the Full Lower Leg of Therapist (B) and Therapist (C)	r=0.95	ICC=0.95	r=0.95	ICC=0.95
Water Volume and Truncated Cone Volume for the Full Lower Leg Average of Therapist (B) and (C)	r=0.96		r=0.97	
Truncated Cone Volumes for the Lower Leg Minus the Foot (Short) of Therapist (B) and Therapist (C)	r=0.93	ICC=0.93	r=0.94	ICC=0.94

DISCUSSION

In this study the correlations between the water displacement volumes and the calculated volumes with the truncated cone formula ranged from r=0.95-0.97 and r^2=0.90-0.94. In other similar studies, the correlation ranges were r=0.93-0.99 and r^2=0.88-0.98.[5,9,15] In general, correlations in health sciences greater than r=0.75 is considered to be good to excellent.[16,17] Therefore, this study found there to be an excellent correlation between the gold standard of water displacement for volumetric measurements and the truncated cone method for volume measurements regardless of the lymphedema training of the physical therapist.

This is important, for water displacement is not typically used in documenting lower extremity volume in outpatient clinics. There are several reasons for this; the equipment must be large enough to hold an edematous lower extremity, a water source is required, the device is heavy once filled, the method is time consuming, and the lower extremity must be submersible. Also, water displacement methods cannot be used to measure the patient's edema if there is an open wound, incisions, or significant skin irritation, all of which commonly occur with lymphedema.[3,5,9,10]

The intertester reliability of the physical therapists using the truncated cone formula for measuring lower extremities with and without edema in this study was r=0.95, r^2=0.90. In other similar studies, the range was r=0.97-0.99, r^2=0.94-0.98.[5,9] This study found there to be excellent intertester reliability for physical therapists using the truncated cone formula for calculating volume of lower extremities. Intraclass correlation coefficients for the intertester reliability ranged from 0.93-0.95. According to Portney and

Watkins, "for most clinical measurements, reliability (ICC) should exceed 0.90 to ensure reasonable validity."[16] The ICC values for this study were all greater than 0.90, so there is good consistency with the measurements among the different therapists.

This study used three physical therapists that had completed different lymphedema courses, Vodder, Casley-Smith, and Chikly for therapist (C). This is important, for the measurements for the least ankle were calculated differently by the therapists. The Vodder-trained therapist measured the distance from the MTP to the least ankle on the dorsum of the foot, and the other 3 therapists measured the least ankle to the floor. This was not standardized in the study to see if the different method would impact the results. A correlation was calculated between the volumes from the investigators (B) and (C) with the foot subtracted out of the values. (control $r=0.93$, $r^2=0.88$; swollen $r=0.94$, $r^2=0.86$). Even though the comparison of truncated cone volume for therapist (C) did have the lowest power for the correlation; a Type II error was not committed, for the null hypothesis was rejected. So, using two different techniques for measuring the least ankle did not significantly impact the results.

Limitations of the Study

There were three limitations of this study involving the water displacement method. One limitation may have lead to an increase in the amount of water displaced. When the participant's leg was lowered or removed from the gauge, if the participant shifted any, additional water could have poured out of the gauge. The second limitation may have lead to a decrease in the amount of water displaced. If the participant sat too far back on the table this would not allow the calf to fully submerge in the gauge. The third

limitation involved the marking of the water level on the participant's calf. The wet lower extremity made drawing the line difficult and the line may have shifted slightly or have been marked incorrectly on the skin.

The limitation with the truncated cone method involves the pressure applied by the therapist while determining circumference measurements. The pressure used with the measuring tape was not monitored during the study. The therapists may have applied different amounts of pressure to the measuring tape, which would have changed the circumference values. Also, the method for measuring the least ankle was not standardized in the study for the therapists.

There were two limitations of the entire study relative to the generalizability of the results. The study only measured the calf portions of legs. The upper extremities and the entire lower extremities were not measured in this study. Also, the sample was of convenience, and may not have represented the entire population.

The recommendation from this study is that the truncated cone measurement technique to quantify edema in patients with lower extremity symptoms is comparable with the water displacement method. The benefits of this finding include: 1) provides the patient and the therapist with information on the progress of the current treatment, 2) provides therapists with a practical method to calculate volume to improve communication among healthcare providers for the patient and 3) provides quantifiable evidence for the need of services to insurance companies. Future research could include expansion on the truncated cone measurements to include other body parts. More expansive research could be conducted to assess if therapists certified by different

schools differ in their accuracy with volumetric measurements using the truncated cone technique. These findings could be used in future studies investigating the effects of current and future treatment techniques.

CONCLUSION

Truncated cone measurements have an excellent relationship with water displacement in determining volume of a lower extremity with lymphedema. Therapists trained in lymphedema treatment (regardless of training method) have excellent intertester reliability using the truncated cone method for measuring the volume of a lower extremity with lymphedema. Using the truncated cone method in diagnosis and treatment with lymphedema can help with determining the extent of involvement, especially with unilateral edema, improve communication on the patient with other health professionals, support claims and improve communication with insurance companies, document progress with treatments and will be useful in future research on lymphedema.

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CHAPTER 4

QUALITY OF LIFE TOOLS AND THEIR RELEVANCE FOR FEMALES WITH GENITAL LYMPHEDEMA

A paper to be presented for publication

INTRODUCTION

Secondary or acquired genital lymphedema can be caused by trauma, surgery, and treatments for various cancers, especially when the inguinal lymph nodes are affected.[1,2] In genital lymphedema, the swelling can involve only part or the entire genital region. General symptoms of lymphedema can include: lymphorrhea (leakage of lymph fluid through the skin), skin changes such as dry or flaky skin, hair loss, thickened skin secondary to accumulation of keratin (hyperkeratosis), fibrosis of the skin and subcutaneous tissue, dilation with fibrosis of the upper dermal lymphatics (papillomatas), a proliferation of lymph vessels at the surface (lymphangion), and discoloration.[1,3] The symptoms of thickened skin, flaky skin, and papillomatas are especially common with lymphedema in the genitals. The multiple folds and the warm and moist environment of the genitals can increase risks of bacterial infections.[2]

Patients with lymphedema often complain of a feeling of fullness or pressure, pain, parasthesias, increased warmth of the affected areas, redness or swelling, decreased mobility, lymphorrhea, chronic infections, and/or skin changes.[1,3,4] Those with genital lymphedema also may complain of a "dragging, heavy or bursting sensation" in the genitals.[2] Excessive swelling of the genitals has been found clinically to hinder sexual

activities, decrease libido, be emotionally disabling, hinder urination, and cause pain in the genital region, especially with intercourse.[2,5] Genital lymphedema is not mentioned in the literature as often as the other forms of lymphedema. This is especially true when investigating the specific symptoms of sexual dysfunction, urinary dysfunction, and pain and the impact of these symptoms.

Quantitative results are valued by health professionals, insurance companies, the practitioner, and patients. In the treatment of lymphedema involving a limb, a therapist will perform volumetric measurements of the involved and un-involved body parts to obtain quantitative data. However, when treating genital lymphedema, this data is often more difficult to obtain. There are fewer boney landmarks to use for repeated measurements. In the case of females, the swelling may be inside the actual vaginal vault and impossible to quantify with a measuring tape. Using the water displacement method is also not appropriate with genital lymphedema. A therapist would need a container large enough to submerge the entire lower half of a person to capture any external genital edema volume. There are no studies stating if the water displacement method is able to capture the external genital volume, nor are there any studies regarding volumetrics of the internal vaginal vault for females with edema. Thus, when treating genital lymphedema, one must look for other methods, like qualitative outcomes, to assess the success of treatment.

Medical research in the area of quality of life (QOL), also known as health-related quality of life (HRQOL), has become more prevalent in recent years, instead of solely focusing on objective outcomes of the particular medical condition.[6,7] A person's medical

condition not only involves the objective, or pathological component, but also is impacted by subjective symptoms.[7] According to Bardwell et al,[8] "HRQOL is essential to identify women in need of psychosocial interventions and also as a key criterion in evaluating treatments." A quality of life tool addressing all aspects of female genital lymphedema is crucial.

A review of the literature was completed to determine if there was an existing tool capable of showing the impact genital lymphedema can have on a female's quality of life.[2] The review identified twelve total QOL tools that may be considered for use with the client population with genital lymphedema. Genital lymphedema has multiple symptoms associated with the condition. Construct validity was established for genital lymphedema based on the three symptoms of pain, sexual dysfunction (mainly pain with intercourse), and incontinence. The twelve tools were evaluated on assessment of the three symptoms. Table 2 shows the results of this analysis and the other statistical results of the tools based on this search.

[2] The review of literature and Table 2 is part of a previously published article: "Quality of Life Tools and Their Relevance for Females with Genital Lymphedema." Copyright Clearance is in Appendix A

Table 2. Comparison of Reviewed QOL Tools in a Limited Keyword Search as They Relate to Genital Lymphedema

Tool	Main Condition Assessed	# of Items	Construct Validity for Genital Lymph-edema	Internal Reliability	Test-Retest Reliability	Content Validity	Sensitivity to Change
QLI	Health Status	66	2/3	Yes	Yes	Yes	Yes
SF-36	Health Status	36	1/3	Yes	Yes	IE	Yes
FSFI	Sexual Function	19	2/3	Yes	Yes	IE	IE
I-QOL	Urinary Incontinence	22	2/3	IE	IE	IE	IE
PFDI	Pelvic Floor dysfunction	46	2/3	Yes	Yes	IE	IE
PFIQ	Pelvic Floor dysfunction	93	vague in symptoms	Yes	Yes	Yes	IE
PMSES	Urinary Incontinence	23	1/3	Yes	Yes	IE	IE
RAND-36	Health Status	36	1/3	Yes	IE	IE	IE
FIQL	Fecal Incontinence	41	1/3	IE	IE	IE	IE
PFSF	Sexual Function	37	1/3	Yes	Yes	IE	IE
PISQ	Sexual Function	31	3/3 related to sexual function only	Yes	Yes	Yes	Yes
PISQ-12	Sexual Function	12	3/3 related to sexual function only	Yes	Yes	IE	Yes

- The QLI, SF-36, and the FIQL all had other statistical analysis available for these tools not mentioned in the chart from the available articles
- The construct validity for genital lymphedema is based off the tools having questions pertaining to pain, sexual dysfunction, and incontinence
-The statistical analysis for the internal reliability, test-retest reliability, content validity, and sensitivity to change was performed in reviewed studies with a different population than the one of interest for this article.
-The content validity and sensitivity to change is based off of available information from the reviewed articles with the limited keyword search.
-IE: Insufficient evidence based on reviewed articles from limited keyword search

When looking at the tools by condition, it is obvious several of the tools primarily focus on one aspect (Table 2). The Incontinence Quality of Life (I-QOL) and the Pelvic Muscle Exercise Self-Efficacy Scale (PMSES) focus on urinary incontinence, while the Fecal Incontinence Quality of Life Scale (FIQL) is for fecal incontinence. The Female Sexual Function Index (FSFI) and the Profile of Female Sexual Function (PFSF) are to be used on women with sexual dysfunction. Incontinence, pain and sexual dysfunction can all be involved with genital lymphedema. Having a separate tool for each aspect can be time consuming for the participant completing the tools and for the investigator scoring the tools, especially when more than one symptom is present.

There are tools which focus on the general aspects of overall pelvic floor dysfunction relating to urinary and bowel problems, which would solve the problem of multiple tools. The PFDI and the PFIQ tools look at multiple aspects of urinary dysfunctions, bowel dysfunctions, and prolapse. There are no questions relating to sexual function or pain in the genital region in either of these tools. A person's primary complaints with the genital lymphedema may be pain and subsequently sexual dysfunction.

There are tools that are designed to assess a person's general health. Using one of these tools could help expand the narrow scope of symptoms covered in the more specific tools. The three tools for health related quality of life are the RAND-36, the SF-36, and the QLI. The QLI has the most direct questions relating to sexual function. All three tools' questions on pain are extremely vague. While these tools do address a wider array of symptoms, they still do not cover every aspect associated with genital lymphedema.

It is clear following this review that the statistical data for most of the tools is lacking. Seven of the tools have two or fewer supporting psychometric results in the literature. Four of the tools have support from at least three different statistical analyses, and have been used in more studies. However, the QLI and the SF-36 each have numerous studies and statistical data to support the tools' ability to assess quality of life across a wide variety of health conditions other than lymphedema.

The QLI, while not developed for lymphedema, addresses the most of the desired symptoms to be assessed for those with genital lymphedema. The tool was, "designed to measure QOL in both ill and healthy individuals."[9] There are no previous studies on the QLI involving any form of lymphedema; so unfortunately, there are no scores for comparisons

The purpose of this study was to explore the quality of life (QOL) domains as measured by the QLI for females with lower extremity and/or genital edema. The null hypotheses for this study were 1) the Quality of Life Index will show no difference in QOL for females with lower extremity lymphedema, with and without genital involvement, as compared to the general population, and 2) the Assessing Quality of Life of Those with Edema tool will not be able to describe or identify the impact of pain and or symptoms associated with genital lymphedema on the quality of life for a female with lower extremity lymphedema, with and without genital involvement.

METHODS AND MEASURES

IRB approval was obtained from Texas Woman's University and Dekalb Medical Center prior to the start of the data collection (Appendix F). Edema was considered as the abnormal accumulation of fluid, which also can be diagnosed as lymphedema. The definition was vague to account for those not formally diagnosed with lymphedema. Currently, there is no tool available to address QOL for this particular population. This study used an existing QOL questionnaire, the Quality of Life Index by Ferrans and Powers, to assess overall quality of life.[7] This tool consists of four subscales, health and functioning (HF), psychological/spiritual (PS), social and economic (SE), and the family subscale (FS). The tool has 66 questions in total, 33 on satisfaction and 33 on importance of the different aspects of life. The questions are on a six point scale from "Very Dissatisfied" to "Very Satisfied." The total QOL score with the QLI can range from 0-30; with a higher score representing a higher perceived QOL.[7] This tool has been cited in over two hundred studies and has been found to have internal consistency reliability with alpha ranges from 0.73-0.99 for the entire tool and 0.63 to 0.96 for the subscales.[7]

The second questionnaire, Assessing Quality of Life of Those with Edema (Appendix G), was a newly developed questionnaire designed to assess general health and condition-specific symptoms for this particular population. This questionnaire was developed by the principal investigator. This is the first study using this tool.

The informed consent/cover letter and the two questionnaires were posted on Survey Monkey.[10] Survey Monkey is an online tool for the purpose of developing "professional online surveys." Survey Monkey helps with designing the surveys,

collecting the responses and analyzing the data. The site has options for collecting anonymous responses. This particular study chose the option to not save the email address of the participant.

The Lighthouse Lymphedema Network (LLN) is a non-profit organization located in Atlanta, Georgia.[11] The organization's goal is, "to educate, promote awareness and provided support for lymphedema patients, the medical community, family and caregivers, insurance companies, the general public, and lymphedema support groups."[11] While the majority of those on the mailing (standard and email) lists for the organization are from the local area, there are also national and international persons involved with the organization. The principal investigator is an active part of the organization and is on the board.

The LLN included a brief description of the principal investigator and the study in the fall newsletter for 2009 and on the LLN's website. This newsletter was sent to everyone on the mailing list and was available at a LLN sponsored lymphedema conference in the fall of 2009.

There was no way to tell by the names on the mailing list the sex of the individual, the participant's age, or what body part(s) was involved. A person's spouse or family member may be the actual name on the mailing list. For this particular study, only female subjects over the age of eighteen years that could read and understand English were included. There was no exclusion by race. There is a question on age and another question on location of the edema on the second questionnaire. If the participant entered an age under eighteen, then the questionnaires for that participant would have been

excluded from this and all future studies. Any male participants and/or participants that listed no edema in the lower extremity and/or genital region were excluded from this particular study. The data from the excluded questionnaires, of those over the age of eighteen, may be analyzed and used in future QOL studies. For this reason, the word "female" was not used in the study title to encourage males to also complete the questionnaires.

After the participant read the cover letter explaining participation in the study, the participant was asked to consent to involvement by completing the anonymous questionnaires. The total time involved was generally around fifteen minutes to complete the questionnaires. The participant selected to submit the responses at the completion of the questionnaires.

The potential risks for the participants completing the questionnaires could have been possible embarrassment and/or anxiety with the sensitive/personal questions on the symptoms and sexuality. If the participant became too uncomfortable, he/she could have discontinued at any time without penalty. The participant may have been concerned with a possible loss of confidentiality with the completion of the questionnaires. This risk was minimized by not having any identifying information on the questionnaires and having the participant complete the questionnaires online. Only the principal investigator had access to the answers for the individual questionnaires.

Data Analysis

The collected data was analyzed using Excel and SPSS. The QLI overall and subscale scores were computed by weighting the satisfaction responses with the

importance responses in Excel per instructions provided by Ferrans and Powers.[7] Descriptive statistics were computed for the QLI subscales, the overall QLI score, and the symptoms of interest, pain, urinary incontinence, and pain with intercourse. The overall and subscale QLI scores were compared using a labeling system created in a previous study by Yamada.[12] Due to the small sample size and the data not having a normal distribution, the non-parametric Mann-Whitney two-tailed U tests were performed comparing the overall QLI score with the presence of pain, urinary incontinence, and pain with intercourse. The alpha for the Mann-Whitney tests was set at α=0.05. A two-tailed t-test was also performed comparing the overall QLI score from the current study with the overall QLI score from a previous study on the general population of older females. The alpha for this t-test was set at α=0.01 to increase the protection against a type I error of incorrectly rejecting the null hypothesis. Power analysis was assessed for both the Mann-Whitney U tests and the t-test.

RESULTS

Forty-two people completed the questionnaires. Only female participants at least eighteen years of age with lower extremity, with and without trunk involvement, were analyzed. There were twenty participants meeting the above criteria. The average age of the participants was 51 years, with a range of 30-75. Eighteen women were Caucasian, one was African-American, and one was unknown. There were eleven that were married, seven single and two widowed. Complete Decongestive Treatment (CDT) had been completed by sixteen; there was one unknown, and three with no previous history of CDT. Only five participants reported current pain from the edema with an average of 3.8

and a range of 2-10 on a 0-10 point visual analog pain scale. Ten of the women reported pain with intercourse (50%). Urinary incontinence was reported by seven women (35%). There were only two participants with current or a history of genital involvement. The average length of time the condition of edema was present was 12.28 years with a range of less than 1 year to 41 years. Several other health conditions or co-morbidities were reported (Figure 5), with previous surgeries the highest (55%), diabetes (40%), depression (35%), hypertension (25%), constipation (25%), cancer (15%) and heart disease (5%).

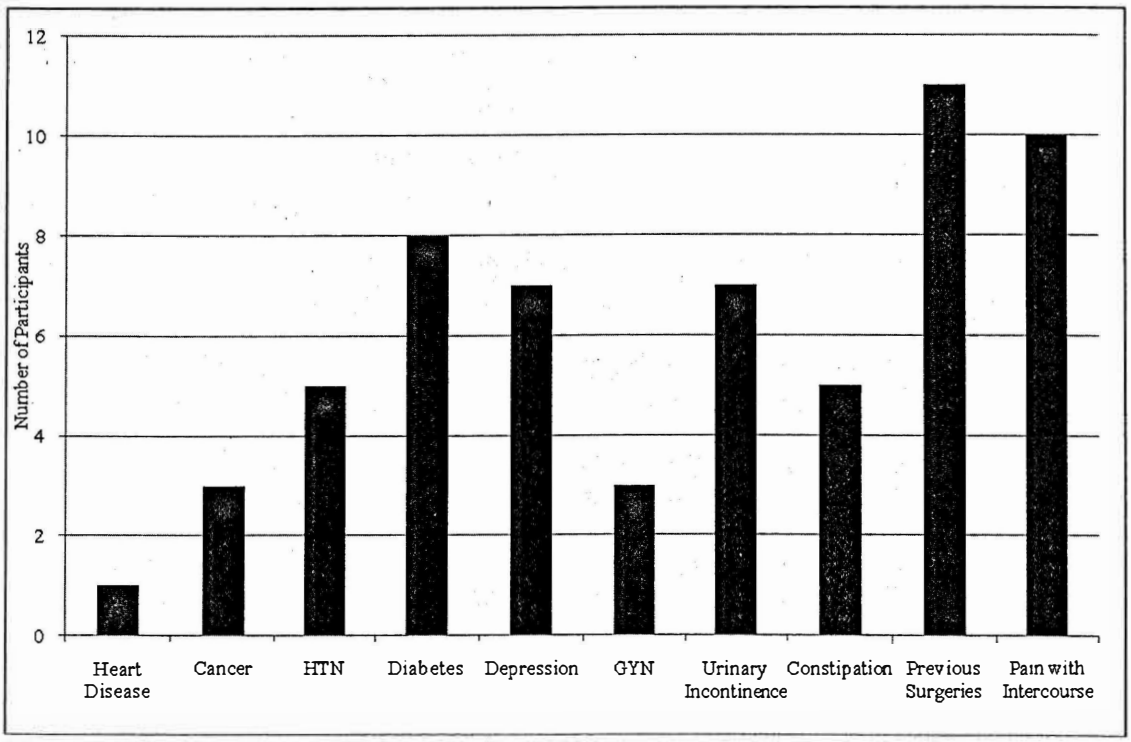

Figure 5. Health conditions and co-morbidities of participants

The overall score and the subscales scores were calculated for the twenty participants. The average overall QLI score was 19.6, with a range of 6.83-29.21, and

standard deviation (SD) of 6.04. The confidence interval for the overall QLI is 16.78-22.43. The breakdown of the overall QLI and each subscale for the descriptive statistics of mean, range and SD are in Table 3.

Table 3. Descriptive Statistics of Overall QLI and Subscales

Statistic	Health/ Functioning Subscale (HF)	Family Subscale (FS)	Social/ Economic Subscale (SE)	Psychological/ Spiritual Subscale (PS)	Overall QLI
Mean (SD)	18.24 (6.45)	19.36 (5.67)	21.09 (7.89)	20.02 (6.10)	19.60 (6.04)
Minimum	4.42	5.40	2.50	3.57	6.83
Maximum	28.96	30.00	29.38	28.93	29.21
Confidence Interval (95.0%)	15.23-21.26	16.71-22.01	17.39-24.78	17.17-22.88	16.78-22.43

A previous study by Dunn et al[13] established labels for the QLI, in an effort to standardize the scoring. The labels created by Dunn were: 25-30 good QOL, 20-25 moderate QOL, 15-20 fair QOL, and 10-15 poor QOL.[13] These four labels were divided into five labels in a study by Yamada et al, 0-5 very poor QOL, 6-11 poor QOL, 12-17 regular QOL, 18-23 good QOL, and 24-30 very good QOL.[12] Since there was no previous study on lymphedema with the QLI, the principal investigator decided to use labels to categorize the results. The scale used by Dunn leaves a large range of scores in the lowest category; whereas, the labels created by Yamada are more evenly spread throughout the entire range of possible scores.[12,13] This study decided to use the labels by Yamada due to this wider range of the categories. Using these labels, the frequency

distribution of the results from the twenty participants had a majority of the scores in the "good" QOL range (Table 4).

Table 4. Frequency Distribution of the 20 Participants for the QLI and the Subscales

	HF		FS		SE		PS		QLI	
	#	%	#	%	#	%	#	%	#	%
Very Poor (0-5)	1	5%	1	5%	2	10%	1	5%	0	0%
Poor (6-11)	3	15%	1	5%	1	5%	1	5%	4	20%
Regular (12-17)	3	15%	5	25%	2	10%	4	20%	2	10%
Good (18-23)	11	55%	10	50%	4	20%	9	45%	11	55%
Very Good (24-30)	2	10%	3	15%	11	55%	5	25%	3	15%

With further analysis of the participants and the category labels, there seemed to be an age difference in perceived QOL (Figure 6). The participants in their forties had the lowest scores as a group, with all 18.0 or below; yet, the participants in their seventies had the only "very good" scores for two of the subscales (FS and SE). The participants in their seventies also had the lowest score of all the age groups for the HF subscale.

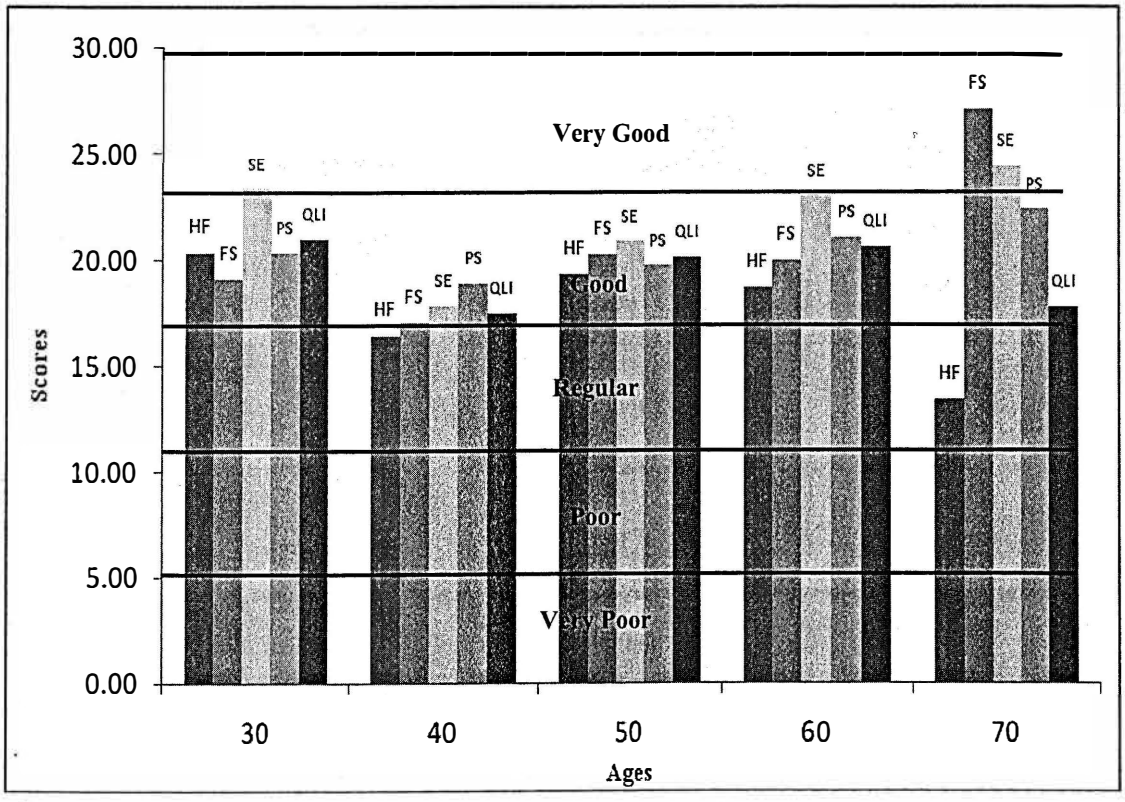

Figure 6. Distribution of QLI and Subscale Scores by age of the participant
(HF) Health/Functioning, (FS) Family Subscale, (SE) Social/ Economic, (PS) Psychological/ Spiritual, (QLI) Overall QLI

The overall QLI score was compared, using the Mann-Whitney two-tailed U tests, with the presence of pain, urinary incontinence, and pain with intercourse. The Mann-Whitney was used instead of a standard t-test due to an inability to assume the parametric requirements of normality and homogeneity of variance. The alpha was $\alpha=0.05$ for each of the tests. The results of the tests are in Table 5. The power analysis for the three tests was low, with a range from 0.16-0.31. The p-values for all three tests were not significant (p-values greater than the value of alpha) and the chance of incorrectly accepting the null hypothesis was low. Therefore, the null hypothesis of the Assessing Quality of Life of

Those with Edema tool not being able to identify the impact of symptoms associated with lymphedema cannot be rejected.

Table 5. Mann-Whitney U Tests for Symptoms Associated with Lymphedema

		N	Mean	Median	p-value
Pain	No Pain	6	22.64	22.26	0.24
	Pain	14	18.3	21.62	
Incontinence	No Incontinence	13	20.83	21.13	0.44
	Incontinence	7	17.32	22.11	
Pain with Intercourse	No Pain with Intercourse	10	21.04	21.61	0.53
	Pain with Intercourse	10	18.16	21.62	

A previous study was completed by Nesbitt and Heidrich[22] on the QOL of women sixty-four and older. This study was used to obtain baseline scores on the QLI for the general population. The actual raw data for the study was not available, so the overall QLI mean (23.54), standard deviation (3.64), and number of participants (137) were used to perform a two-tailed t-test with unequal variances. Due to the lack of raw data, the alpha was set at 0.01 to increase the protection against a type I error. There was a significant difference in the QLI scores for the general population (M=23.54, SD=3.64) and the QLI scores for females with lower extremity lymphedema (M=19.60, SD=6.04); t(155)=2.83, p=.005. This t-test had a corresponding power of 80%. Therefore, the null

hypothesis on the QLI showing no difference in QOL for females with lower extremity lymphedema, with and without genital involvement, as compared to the general population was rejected.

DISCUSSION

Quality of life studies are increasing across multiple diagnoses including: continuous ambulatory peritoneal dialysis (CAPD), venous ulcers, chronic illness, heart conditions, and especially cancer.[12-18] Currently, there has been no previous study on QOL as it relates to those with lymphedema. The goal of this study was to explore the effect lymphedema may have on a person's QOL.

Seventeen, 85%, of the twenty participants had other health conditions or co-morbidities. Surgery was the most common at 55% of the participants. There were no additional questions to determine if the surgery was associated with the lymphedema, either as the start of the edema or as an attempt to treat the edema. Diabetes was associated with 40% of the participants. Several previous studies have found higher body mass indexes (BMI) and obesity to correlate with lymphedema.[19-21] There were no additional questions on type of diabetes, BMI, or weight of the participant. Depression was present in 35% of the participants. Additional information on the depression was not elicited from the questionnaires. It is unknown if the depression directly relates to the lymphedema. One of the factors evaluated when searching for a QOL tool, was limiting the time needed to complete the tool. If additional questions were added to expand the information on the health conditions or co-morbidities, the time associated with

completion of the tool would increase. This may also decrease the participant's willingness to participate or complete the tool.

The health and functioning subscale had the lowest mean score. This section has the most questions, thirteen, of all the subscales. The questions are on the satisfaction the participant has with his/her own health, ability to care for oneself, sex life, pain, recreational life, and on one's future. This subscale also encompasses all of the symptoms of interest for the current study. The participants in their seventies in this current study had the lowest score of all the age groups in this subscale, 13.4. As one ages, he/she may have developed more co-morbidities and lost some functional independence. A study by Jordan and Delunas on participants with cancer found QOL scores increased with age and attributed this to a diagnosis of cancer may be more "devastating" to the younger person.[16] Lymphedema in the leg can hinder a person's ability to ambulate and complete hygiene, especially of the lower limbs. This could be more problematic to those in their seventies. The study by Jordan and Delunas did not mention where the cancer was located in the participants.[16] It is reasonable to suggest that those with chronic health conditions would have the lowest satisfaction with their current health status.

The family subscale had the second lowest mean score. The family subscale has five questions and asks how satisfied the person is with the emotional support from the family, the health of the family, the happiness of the family, the person's children, and the person's spouse/lover/partner. As stated by Dunn, "living with individuals with a chronic illness has a major impact on spouses."[13] In the current study, the average on the

FS of those married was 21.0 as compared to 17.4 for the non-married participants. This lack of a supporting spouse/partner could explain the lower score for the FS subscale.

The Mann-Whitney U tests showed no difference for all of the symptoms of interest in the medians of the QOL scores. For all three symptoms the mean of those without the symptom was always larger, by at least 2.83 points, than those with the symptom. This suggests that a future study with a larger sample size may be needed to further assess how symptoms associated with lymphedema can impact the QOL of the individual.

The focus of this study was on the quality of life of females with lower extremity lymphedema. Males and those with lymphedema in other areas were not included in any of the data analysis. Pain, a symptom of interest in the current study, is an acknowledged symptom for all lymphedema, regardless of gender or location of the edema. Including the results from all forty-two participants that completed the questionnaires may have shown a difference with the Mann-Whitney U test for pain.

This study did not administer the questionnaires to a group of participants without lymphedema to obtain "general population" scores. The QLI reports the study by Nesbitt and Heidrich to represent general population QLI scores.[22] The t-test, even with a more stringent alpha of 0.01, provided evidence that there was a difference in the current populations' QLI scores and those from the previous study. The mean QLI score of the general population is significantly higher than females with lower extremity lymphedema, with and without genital involvement. A study involving participants with

lymphedema and those without lymphedema that were age and gender matched would be beneficial further explore the impact lymphedema may have on the QOL.

Overall, the study did show that lymphedema can impact a person's QOL. The exact symptoms associated with lymphedema that impacts the QOL decline was not identified. This study will hopefully increase interest in further research on lymphedema in general, QOL associated with lymphedema, and on treatment outcomes of those with lymphedema.

Limitations of the Study

The main limitation of this study was the sample size. The study utilized Survey Monkey and required the participants complete the questionnaires on a computer. The hope in using a computer-assisted approach was to reach more participants. Asking potential participants to type in the web address to complete the study may have limited participation. With mailing or physically handing the questionnaires to a participant, as was done in several of the studies mentioned previously, there may have been a greater number of responses. The person may have skimmed over the informed consent and thought the study was going to be too time consuming and not beneficial to them personally.

Another limitation is this study only analyzed female participants with self-reported lower extremity lymphedema. Males and those with other locations of lymphedema were not considered in the data analysis. There is also the risk of inaccurate responses and/or bias with self-reported questionnaires. The small sample size and the

lack of diversity in race, gender, and location of lymphedema will limit inferences to the general population and those with lymphedema.

CONCLUSION

Quality of life is important in all aspects of healthcare and is growing in interest. Addressing all aspects of a patient's life that can be impacted by a medical condition is important. The knowledge of a person's QOL should help guide the individualized course of treatment. This study has provided some general baseline scores of QOL using the QLI, but the scores need further testing to confirm the reliability and validity for individuals with lymphedema. This study has shown the need for future research in the area of lymphedema. This study has also shown that practitioners treating lymphedema need to be aware of a person's QOL and consider QOL in the treatment of lymphedema. Due to the time commitment involved in treating lymphedema, a therapist has the most contact with the patients and could possibly have the most impact on addressing and improving the quality of life.

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CHAPTER V

A COMPARISON OF TREATMENT TECHNIQUES FOR FEMALES WITH LOWER EXTREMITY LYMPHEDEMA WITH AND WITHOUT GENITAL INVOLVEMENT

A paper to be presented for publication

INTRODUCTION

Lymphedema is a chronic inflammatory disease that can not only physically impact a person; it can also hinder them socially, emotionally and mentally. The altered lymphatic system can cause changes to the subcutaneous tissues, the dermis, and can physically alter the involved parts.[1,2] Lymphedema is the accumulation of high protein fluid in the interstitium due to a mechanical compromise of the lymphatic system. This structural or functional alteration of the lymphatic system can be primary, present at birth, or secondary, acquired later in life. The resultant edema can affect any area of the body and both genders.[3,4] Information in medical studies, medical books, and journals about lymphedema and these physical changes has slowly increased over the years.

There has been little change in treatment options for those with lymphedema since Dr. Emil Vodder first expanded on Dr. Alexander Van Winiwarter's techniques in the mid 1900s.[1] The different schools of certification (Vodder, Casley-Smith, Földi, and Chikly) all instruct their therapists in the Complete Decongestive Therapy (CDT) method. To obtain quantitative outcomes during CDT a therapist will complete volumetric measurements. The Casley-Smith method uses the truncated cone method of taking circumference

measurements along the limb and entering the circumference and distance into a formula to obtain actual volume. The formula is: volume=h*(Ct*Ct+Ct*Cb+Cb*Cb)/12*Π, where h=height, C=circumference, t=top of the cone, and b=base of the cone.[3] CDT utilizes manual lymphatic drainage, therapeutic exercises, patient education, and compression (bandages and garments)[2,5] to reach the goal of therapy; decreased physical changes associated with lymphedema that the patient can manage at home with continuation of CDT.[1,3]

An important aspect of CDT that is often overlooked is exercise. The Casley-Smith method has a set of standard exercises to encourage muscles to contract around the lymphatic vessels in a specific pattern, to mimic the way the body normally drains the lymphatic fluid. Exercise has been thought to increase the "uptake" by the initial lymphatics, and increase "pumping" of the vessels. The muscle contraction helps to increase the flow of the lymphatic fluid in the compromised lymphatics.[3] For lower extremity lymphedema, the standard treatment uses the main trunk and lower extremity muscles. The exercises start proximal, with the muscles of the head, trunk, and abdomen, and then progress distal to the muscles of the legs and feet. Of these exercises, there is one focusing on the abdominals and one for the gluteals/posterior trunk.[3] In the standard program, the muscles of the pelvic floor are not addressed.

The abdominal and genital regions of females have multiple conduits for drainage. Each structure of the female genital region utilizes at least two pathways of lymph vessels and nodes for removal of the lymph fluid. The lymph nodes involved in this area are the

superficial and deep inguinal nodes, the external and internal iliac nodes, the sacral lymph nodes, the common iliac nodes, the lumbar preaortic, and lateral aortic nodes.[2,6-10]

The structures of the lower abdominal and pelvic region, including organs and the lymphatic system, are supported by the pelvic diaphragm. The pelvic diaphragm consists of fourteen muscles and fascial covering.[6,8-10] The muscle with the most "functional importance" is the pubococcygeus. "The pubococcygeus gives off innumerable fibers which interdigitate and insert themselves into the intrinsic musculature of the proximal urethra, middle third of the vagina, and the rectum."[11]

A contraction of the pubococcygeus, a Kegel, is based on research by Dr. Arnold Kegel.[11] When one performs a Kegel, she will pull the muscles of the pelvic floor "up and in" or as Dr. Kegel says, "drawing in the perineum."[9-12] Kegels are generally used to strengthen the pelvic floor to increase continence, decrease sexual dysfunction, decrease pain, and to aid in delivery.[9,10] When a therapist is treating patients with urinary incontinence due to a weakened pelvic floor, the standard goal is for the patient to be able to hold a Kegel for ten seconds and to be able to complete three sets of ten repetitions. A contraction of the pelvic floor muscles could impact the lymphatic structures in the pelvic or female genital region.

The focus in the medical community in the past was more on the management of the physical changes associated with lymphedema, not on the impact these changes may have on the individual. "With the exception of a few enlightened doctors, the medical community still tends to downplay or ignore the emotional component of lymphedema."[13] When the person has lymphedema in the lower extremities, these

physical changes can alter the person's mobility, physical appearance, interpersonal relationships, emotional/mental stability, and overall quality of life (QOL). If a person has decreased mobility, deviations in ambulation and/or loss of motion, he/she may loose independence in activities of daily living (ADLs) and the ability to participate in social interactions. The altered physical appearance can decrease a person's self esteem and impact emotional/physical intimacy. Females with lower extremity lymphedema, especially with genital involvement, may have difficulty with the fit of clothing, being intimate with partners, urinary incontinence, pain, and may have an increased risk of gynecological infections.[9,14] A book written for breast cancer patients with lymphedema states, "the emotional discomfort of lymphedema can be as powerful as the physical."[13] The QOL of those with lymphedema should not be overlooked with treatment.

Interest in QOL in the healthcare industry has increased in the recent years. A reliable and valid QOL measurement tool can be especially informative when quantitative measures are limited and/or when trying to compare two or more treatment options. Defining a "meaningful change" with treatment can be different based on who is questioned.[15] A significant reduction in a certain symptom may be meaningful to the patient, while an increase in strength with activities may be meaningful to the practitioner.[15] QOL tools that have the patient rate the importance of the problems/symptoms could help track the efficacy of treatment.

A previous review of the literature published between the years of 1997-2007 found limited research on QOL associated with lymphedema and/or the treatment of lymphedema. At the time of the review, there was not a QOL tool that addressed the

symptoms associated with general lymphedema. The focus of the review was to see if there was a tool able to assess symptoms of pain, urinary incontinence, and sexual dysfunction, all of which can be associated with females diagnosed as having lower extremity lymphedema with or without genital involvement. Unfortunately, the review was not successful in identifying a tool addressing the above three main symptoms of interest.

The tool that best addresses all three symptoms is the Quality of Life Index (QLI) by Ferrans and Powers.[16] This tool was developed in 1984 to calculate a person's overall QOL by measuring a person's satisfaction with and importance of four different domains: health/functioning (HF), psychological/spiritual (PS), social/economic (SE), and family (FS). The tool has 33 questions on satisfaction and 33 questions on importance of the different aspects of life, for a total of 66 questions. The person answers on a six point scale from "Very Dissatisfied" to "Very Satisfied." Higher scores on the QLI are indicative of a higher QOL, with a final weighted score range from 0-30.[16] Of the 66 questions the tool includes two questions on pain and two questions on the person's sex life. There are no direct questions related to urinary incontinence. Of the tools reviewed, those with incontinence questions were generally focused on incontinence. The QLI addressed two of the symptoms of interest and other general aspects of a person's life. This tool has been used with the general population and adapted for several different diagnoses. The QLI has been shown to be reliable and valid in multiple studies; internal r=0.73-0.99, test-retest r=0.72-0.87, and concurrent validity r=0.61-0.93.[16-21]

Another tool has been developed titled, Assessing Quality of Life of Those with Edema (Appendix E), to assess the QOL of females with lower extremity lymphedema with or without trunk involvement. This questionnaire was a tool developed to obtain general health and condition-specific symptoms for the population of interest. This tool includes questions on past medical history, lymphedema history, genital/abdominal involvement, pain associated with swelling, urinary incontinence, and pain with intercourse.

The purpose of this study was to compare the current Casley-Smith treatment method for lymphedema and a modified form of treatment that incorporates the pelvic floor muscles. The research questions for this study involve two outcome measurements. Will there be a difference in volume reduction, as measured with the truncated cone method, between the standard and modified treatment techniques? Will there be a difference between the standard and modified treatment techniques with QOL quantitative outcomes? The null hypotheses for the study are: 1) the current method of treating lymphedema with the addition of pelvic floor exercises will have no difference in self-reported outcomes for quality of life for females with lower extremity lymphedema, with and without genital involvement, when compared with the use the current method alone. 2) the current method of treating lymphedema with the addition of pelvic floor exercises will have no difference in the quantitative outcomes for volume reduction for females with lower extremity lymphedema, with and without genital involvement, when compared with the use of the current Casley-Smith Method alone.

METHODS AND MEASURES

IRB approval was obtained from Texas Woman's University and Dekalb Medical Center prior to the start of the data collection (Appendix H). The population of interest in this study was females with lower extremity lymphedema with and without genital involvement. Lymphedema was defined by Casley-Smith as the abnormal accumulation of high protein edema in the interstitium.[3] The standard Casley-Smith CDT for lower extremity lymphedema, with and without genital involvement involves compression bandages/garments, skin care, education on causes/prevention, specific exercises performed in a set sequence, and manual lymph drainage (MLD).[3] This study compared this standard treatment with the modified form of treatment, which incorporated Kegels into the standard exercises.

The study used the truncated cone method of volumetric measurements for both groups. The truncated cone method has been found to be reliable and valid as compared to the gold standard of water displacement. For females, the genital edema is often internal or both internal and external. The truncated cone method cannot be used to calculate internal volume. This study used the QLI to assess overall QOL. A second questionnaire, Assessing Quality of Life of Those with Edema, was used to provide more specific QOL information for this specific population (Appendix G).

The study involved female subjects over the age of eighteen years that could read and understand English. All participants were referred to physical therapy for the treatment of lower extremity lymphedema, with or without genital involvement. The participants provided informed consent. Participants would have been excluded if they presented with a

contraindication for lymphedema treatment: untreated DVTs, untreated tumors/cancer, acute infection, acute bronchial asthma, uncontrolled hypertension, and uncontrolled congested heart failure. Pregnant women would have also been excluded. Pregnancy can increase the edema and treatment is not recommended during pregnancy unless the mother was participating in therapy prior to the pregnancy.

The participants were referred to lymphedema treatment by medical doctors in the metropolitan Atlanta area. The participants were scheduled by administrative assistants for an initial evaluation. The principal investigator performed a screen to conclude the participant had been correctly referred for lower extremity lymphedema, and then the participant was informed of the study. After obtaining signed informed consent, the principal investigator completed the evaluation process. Any female that did not wish to participate in the study still received the current treatment for lymphedema without any repercussions. A letter explaining the study was faxed along with the written evaluation to the doctor of any female that consented to participate (Appendix I).

The circumference measurements for the truncated cone method of calculating volume were obtained of the lower extremitites of each participant. The calculated volume was documented for each participant. The participant was provided with the two QOL tools, the Quality of Life Index and the Assessing Quality of Life of Those with Edema questionnaire. The participants were asked to complete both tools prior to the beginning of treatment. The principal investigator assigned the participants into either the control group (group A) or the experimental group (group B) using an every other person design.

On the first day of actual treatment all of the participants turned in the QOL tools and were provided with a general overview of lymphedema (Appendix J). The principal investigator went over the education handout and answered any questions the participant had regarding lymphedema and the treatment. Group A was then instructed in the Casley-Smith exercises for lower extremity lymphedema (Appendix K) and Group B was instructed in the modified Casley-Smith exercises for lower extremity lymphedema (Appendix L). The forms had the same name so as not to give any additional information to the participant as to what group she was assigned to for the study. Group B had additional instruction on how to properly perform a Kegel (Appendix M). Group B participants were to hold Kegels for five seconds and repeat ten times every time the Kegels were listed on the handout for the exercises, a total of six sets. The participants in both groups were to perform all of the exercises in order once daily at home.

Each participant received the standard of care for lymphedema per the Casley-Smith guidelines. The involved area(s) were covered with gradient compression bandaging at the end of each visit and were un-bandaged and cleaned with soap and water at the beginning of the next treatment. Each participant received manual lymphatic drainage (MLD). This varied slightly with each participant, as MLD was personalized to account for scars and other physiological differences among the participants. The participants were educated in self-MLD to perform at home, based on the pathways used by the principal investigator.

The therapy continued until the participant's volume reduction reached the maxium potential. This was a clinical decision on the part of the principal investigator, based on reduction leveling off, improvement in skin conditions, and the shape of the participant's

lower extremities. When the participant reached maxium potential with therapy, she was provided with a prescription from her medical doctor to order appropriate compression garments to maintain the volume reduction.

On the last visit the final volume measurements were obtained and the participant completed both QOL tools again. The participant was educated on how to continue with her home program to maintain the volume reduction and skin improvements. Those participants in the control group were educated on how to perform a Kegel and were provided with the modified exercise handout.

The time commitment varied per participant, based on the involvement of the lymphedema with the participant. The amount of edema and fibrotic or scar tissue impacted the time commitment needed for each visit. The participants could expect each session to last anywhere from one to two hours. The ideal situation would have been for each participant to come to therapy five days a week (Monday through Friday). Participants had economic concerns and/or transportation difficulties, and often were not be able to attend five days a week. Each participant was expected to attend a minimum of three days a week to a maximum of five days a week.

Data Analysis

Data collected by the principal investigator for the study was analyzed using Excel and SPSS. The QLI subscales and overall score were computed per instructions by Ferrans and Powers in Excel. The scoring did involve weighting the "satisfaction" responses of the participants with the answers from the "importance" section.[16] Descriptive statistics were computed for the overall QLI score, the QLI subscales, and the symptoms of interest.

Tests of homogeneity of regression were computed with SPSS to assess the linear relationship between the dependent variables (post QOL and post volume) and the covariates (pre QOL and pre volume). Then analysis of covariance (ANCOVA) was computed with SPSS on the two dependent variables with the above mentioned covariates. Alphas for both of the ANCOVAs tests were set at α=0.05.

RESULTS

Ten women completed the study, five in the control and five in the experimental group. Twelve women consented to the study, one had to withdraw for medical reasons and one was removed for non-compliance with attendance. The descriptive results for the study are presented in Table 6. The average age of the participants was 59.9 years with a range of 39-79 for the entire group, for the control group 64.2 years (range 47-79) and the experimental group 55.6 years (range 39-74). The average number of treatments for all participants was 19.6 with a range of 7-38. Nine of the females were African American, one in the control group was Caucasian. All five females in the experimental group and two in the control group had bilateral lower extremity involvement, one in the control group had unilateral lower extremity involvement, one in the control group had bilateral lower extremity and trunk involvement, and one in the control group had bilateral lower extremity, trunk, and confirmed external genital involvement by visual/palpation evaluation.

Table 6. Descriptive Statistics of the 10 Female Participants

	All Participants	Control Group	Experimental Group
Average Age	59.90	64.20	55.60
Age Range	39-79	47-79	39-74
Average Number of Treatments (Range)	19.60 (7-38)	20.20 (8-38)	19.00 (7-26)
Married	6	3	3
Previous CDT	2	2	0
Presence of Pain	9	4	5
Pain Rating Average (Range)	4.5 (0-9)	4.4 (0-9)	4.6 (2-7)
Presence of Incontinence	3	3	0
Sexually Active	4	1	3
Pain with Intercourse	1	0	1
Average Length of Edema (Years)	12.78	8.20	17.35

The most common co-morbidity of the participants was hypertension at 80%, followed by previous history of surgery at 60%, and diabetes at 40%. Other conditions reported by the participants were gynecological concerns at 20%, and depression,

cerebral vascular accident, deep vein thrombosis, seizures, cardiac concerns, and cancer all at 10% or only in 1 participant.

The scores for the overall QLI score and the individual subscale scores for health/functioning (HF), psychological/spiritual (PS), social/economic (SE), and family (FS) were calculated per participant. The averages of the overall QLI scores for each group pre and post treatment are in Figure 7. The average overall QLI scores for the control group was 19.1 with a range of 13.2-28.1 pre treatment and 22.1 with a range of 16.4-28.0 post treatment. The overall QLI average scores for the experimental group was 20.4 with a range of 14.3-22.6 pre treatment and 24.8 with a range of 17.5-29.5 post treatment.

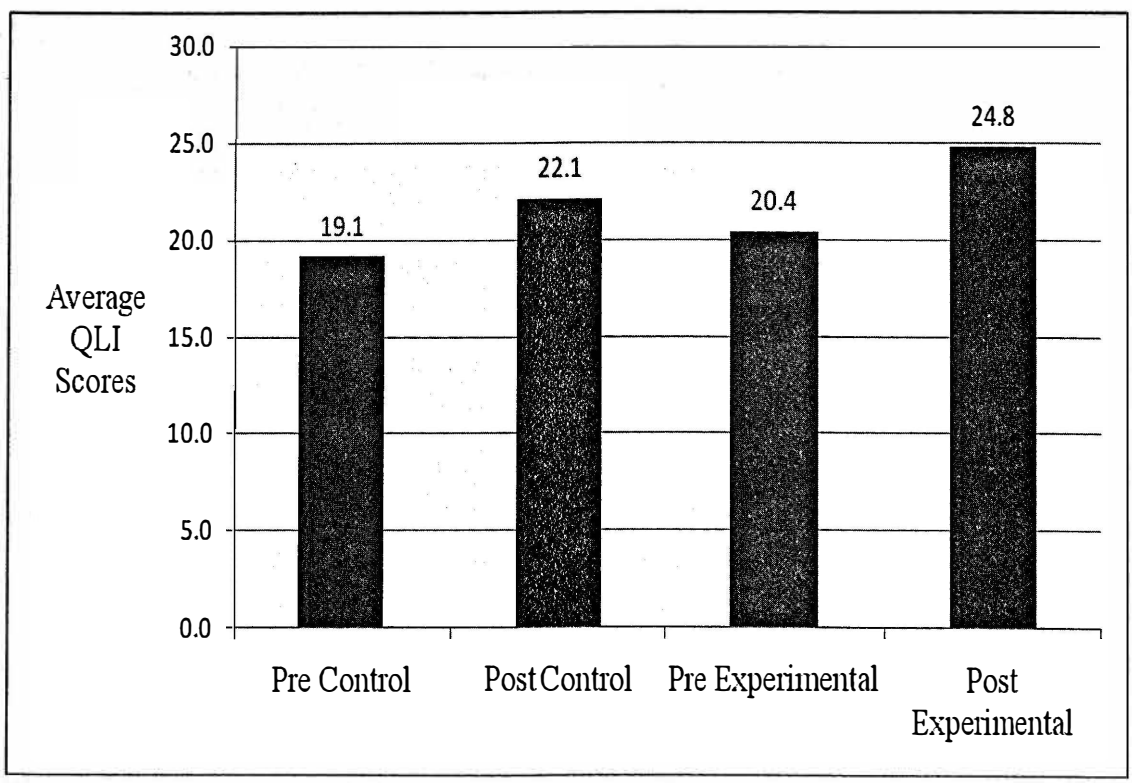

Figure 7. Average overall QLI scores pre and post treatment for control and experimental groups

The results were then analyzed using the five labels created by Yamada, 0-5 very poor QOL, 6-11 poor QOL, 12-17 regular QOL, 18-23 good QOL, and 24-30 very good QOL.[22] Figure 8 shows the distribution of all scores pre and post treatment for both the control and the experimental groups. Both groups had the highest percentage in the "good" category (36.0% control, 68.0% experimental). The control group had the next highest percentage in the "regular" category (32.0%) followed by "very good" (24%). The second highest category for the experimental group was "very good" (16%) followed closely by "regular" (12%). Neither group had any in the "very poor" category. The control group had a more evenly distributed representation of the top three categories, while the experimental group was predominately located in only one category for pre treatment scores. For the post treatment scores, neither group had any scores in the two categories of "very poor" and "poor." The control group had the most scores in the "good" category (52%), followed by the "very good" (32%). The experimental group had the highest percentage in the "very good" (64%), followed by the "good" (24%).

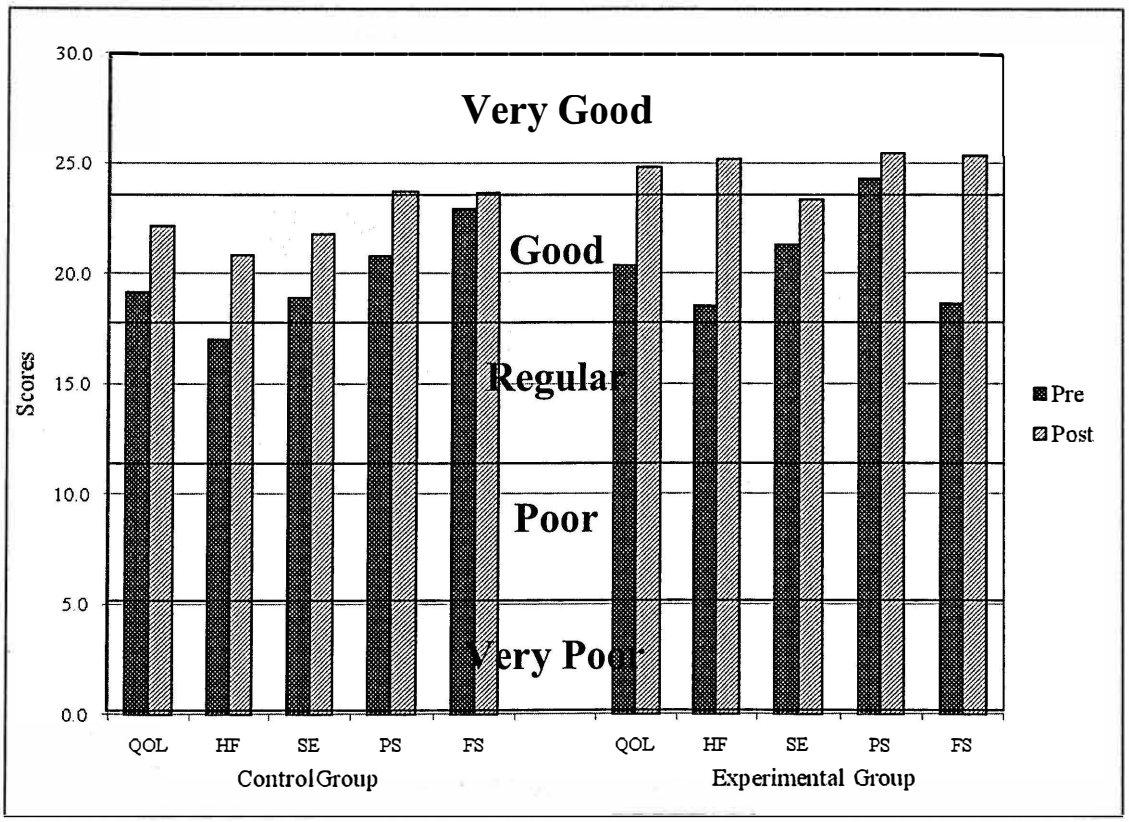

Figure 8. Pre and post treatment distribution of scores for the QLI using Yamada's categories

The volume of the entire lower extremities of each participant was calaculated pre and post treatment. For those with bilateral lower extremity involvement, the average volume of the two extremities were used in the pre and post calculations. This was done to provide one volume value for all subjects pre and post treatment, due to one participant in the control group with only unilateral involvement. Figure 9 shows the average volume pre and post for each participant and an average for each group.

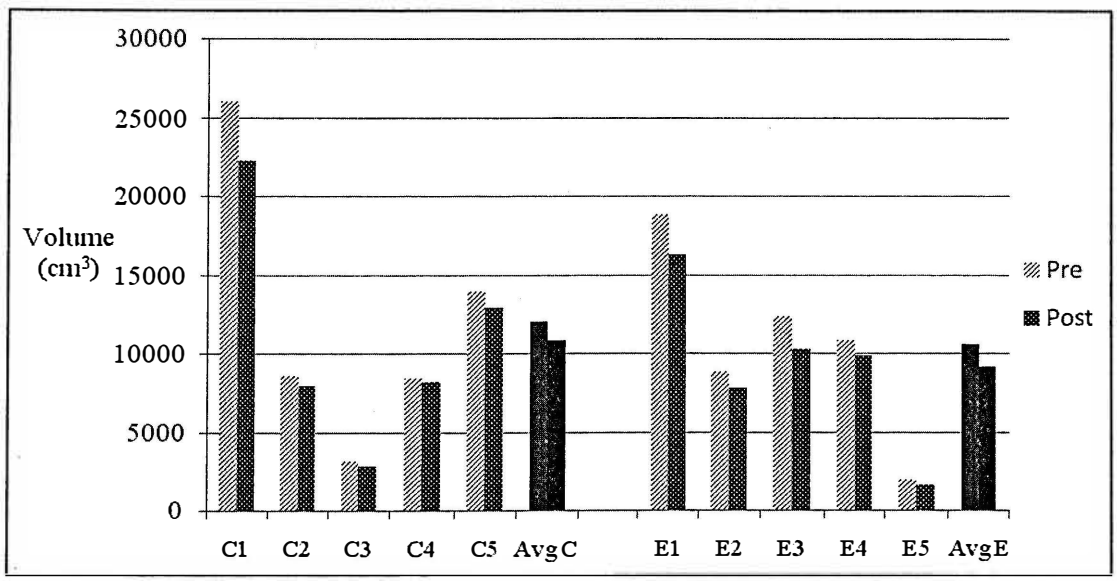

Figure 9. Average pre and post treatment volumes
(C=Control Group, E=Experimental Group)

To compare the effect of the treatment on the volume and QLI scores for the participants an ANCOVA test was conducted to measure the difference between the control and experimental groups while controlling for the influence of the two groups' pre treatment volume and QLI scores. Before conducting the ANCOVA analysis, the independence of the pre treatment QLI scores and volume measurements from the control and experimental groups was confirmed via tests of homogeneity of regression, $\alpha=0.05$. The results from the homogeneity of regression tests are in Table 7. Both of the p-values were greater than the alphas, so there was not a significant relationship between the independent factor and the covariate, and ANCOVAs could be applied.

Table 7. Homogeneity of Regression Test Results

Source	Sum of Squares	df	Mean Square	F	p	Partial Eta Squared	Observed Power
Group * VOLpre	335529.71	1	335529.71	3.06	0.13	0.34	0.31
Group * QLIpre	0.65	1	0.65	0.15	0.71	0.02	0.06

ANCOVAs were conducted for both dependent variables (post QLI and post volume), using the independent variable of group (control and experimental), and the covariates (pre QLI and pre volume). Alphas for both ANCOVAs were set at α=0.05. The original and adjusted means for the QLI scores and volume measurements are listed in Table 8. The results of the ANCOVAs for both volume and the QLI are in Table 9. The final p-value for volume was 0.006 and for QLI was 0.035. Both of these p-values were less than the alphas. Therefore, the null hypothesis of no difference between group in QOL outcomes and the hypothesis of no group differences in volumetric measurements can both be rejected.

Table 8. Original and Adjusted Means for QLI and Volume

	Original QLI Mean	Adjusted QLI Mean	Original Volume Mean	Adjusted Volume Mean
Control Post	22.13	22.92	12613.82	11382.33
Experimental Post	20.4	19.61	9206.41	10437.9

Table 9. Results of ANCOVAs for Volume and QLI

Source	Type III Sum of Squares	df	Mean Square	F	p	Partial Eta Squared	Observed Power[b]
Group Vol Post	2100556	1	2100556	14.786	0.006	0.679	0.907
Group QLI Post	25.762	1	25.762	6.79	0.035	0.492	0.611

a. R Squared Vol = .966 (Adjusted = .995); R Squared QLI .793 (Adjusted = .734)

b. Computed using alpha = .05

DISCUSSION

Ten participants completed this study, and all showed improvement in at least one subscale of the QLI tool and all had a reduction in volume at the end of treatment. The assignment to each group was based on an every-other group design. This was to prevent investigator bias with the groups. The age of the participants, the marital status, pain associated with edema, pain ranges, and co-morbidities were all fairly evenly distributed between the two groups. No significant outliers for these categories were noted.

All of the symptoms of interest were not evenly distributed between the control and experimental groups. The three participants reporting urinary incontinence were all in the control group. Another symptom of interest was pain with intercourse, only four of the participants were even sexually active and only one in the experimental group had a history of pain with intercourse. At the end of therapy, this individual did report she was without any pain related to her edema or intercourse. The only symptom of interest that was equally distributed in the groups was pain related to the edema. Pain was present in nine of the

participants, one in the control group did not have any pain associated with the edema. All the participants with pre treatment pain associated with edema had a decrease in the pain levels post treatment. (Ranges pre treatment 0-9, post treatment 0-3 on a VAS pain scale). A future study with a larger sample size might investigate the impact these symptoms have on overall QOL and treatment outcomes.

All of the participants showed an improvement in the QLI scores and a reduction in volume after treatment was completed. When the covariates, pre QLI scores and pre volume measurements, were statistically controlled, the ANCOVA analysis showed significant differences between treatment techniques on QLI scores and volume reduction post treatment. The addition of the contraction of the pubococcygeus muscles during the exercise portion of the treatment may have assisted in removal of the edema via the lymph vessels and nodes in the pelvic region. Additional studies with larger sample sizes need to be completed to further investigate this relationship. The addition of the contractions of the pubococcygeus in the male population and the involvement of other truncal muscle groups for upper extremity involvement would both be of interest. There may be a need for other alterations to the standard CDT method from the 1950s.

Limitations of the Study

The main limitation to the study is sample size. Lymphedema is a chronic condition that requires significant time commitments from both the therapist and the participant to properly treat. Each session requires a minimum of one hour, so it limits the number of patients a therapist can have on census in the clinic at one time. The number of visits necessary to reach a reduction of volume, improvement in skin condition, and to obtain

appropriate garments limits the start of a new patient in treatment. This current study was unable to acquire more participants mainly due to the time commitment with treatment. This study was originally planned to last one year and initially sought twenty participants. The study actually lasted thirteen months and was only able to complete treatment with ten participants.

Another limitation was the questionnaires that were self-reports. This could have led to bias by the participant or inaccuracies, intentionally or unintentionally. This limitation would be difficult to avoid in future studies, for there is no other way to gain this information from the participant.

The home program portion of this study was based on commitment of the participants. Other than oral reporting from the participants, there is no way to truly monitor the compliance with the home exercise and self MLD portions. It would require more time commitment for treatment to include these portions in each treatment session. This would limit the number of participants in a study or increase the total time necessary for the study.

The compression bandages can slide down if the participant is too active and/or there is a significant reduction in volume in a short time. When participants do not come 5 days a week, the chance of bandages sliding is increased. This will decrease the effectiveness of the bandages. Requiring all participants to attend treatment five days a week will decrease this limitation. This requirement may also increase financial burdens (travel, time off from work, and insurance co-pays) on the participant, which could adversely impact QOL.

CONCLUSION

The medical profession is showing an increased interest in a person's quality of life, how it is impacted by conditions/diseases, and how the QOL is altered with treatment. This study has shown that CDT can reduce the volume of the involved areas and improve the quality of life of someone with lymphedema. This study has also shown that addressing the pubococcygeus muscles in those female patients with lower extremity lymphedema, with and without genital involvement, is beneficial in volume reduction and QOL improvements. There needs to be additional research in the future with a larger population on overall QOL with those with lymphedema and on altered methods of CDT.

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CHAPTER VI

SUMMARY

STATEMENT OF THE PROBLEM

Millions of people around the world suffer from the incurable condition of lymphedema. The research supporting treatment options, advances/alternatives in treatment, outcomes and/or quality of life as it relates to this condition is under-represented in the medical community.

REVIEW OF METHODOLOGY

A review of literature was completed to assess what was available on lymphedema, especially as it related to females with lower extremity lymphedema. The review focused on the anatomy of the lymphatic system, the pathology and physiology of lymphedema, signs and symptoms of lymphedema, treatment options for lymphedema, documentation of lymphedema, and quality of life in general and as it relates to lymphedema. Three different studies were developed from the results of the literature review.

SUMMARY OF FINDINGS

The literature review confirmed the need for research on documentation among therapists treating patients with lymphedema to improve communication on progress by the patients, treatment outcomes, and to justify insurance claims associated with treatment. A quality of life (QOL) tool addressing this population was not identified

during the literature review. There were also limited studies on the QOL of those affected by lymphedema. Lastly, the review found that the proven method of treatment, complete decongestive therapy (CDT), has not altered significantly over the last twenty years.

After completion of the review, research questions, hypotheses, and studies were developed. The first study measured the reliability of using the truncated cone method of documenting the volume of a lower extremity with lymphedema. The second study was designed to establish baseline QOL measurements for females with lower extremity lymphedema, with and without genital involvement, using the Quality of Life Index. The final study compared the volumetric and QOL outcomes of the current Casley-Smith CDT Method and an altered form of CDT developed by the principal investigator.

The volumetric study found an excellent relationship between the truncated cone measurement method and the gold standard of water displacement. The study also found excellent intertester reliability of the therapists completing the truncated cone measurements.

The second study provided baseline data on QLI scores for females with lower extremity lymphedema, with and without genital involvement. The study also found the mean QLI score of the general population was significantly higher than females with lower extremity lymphedema, with and without genital involvement. The study was not able to show a relationship between the three symptoms of interest (pain with intercourse, urinary incontinence, and pain) and QLI scores.

In the final study all of the participants showed an improved QLI scores and reduced volume after treatment. The analysis of the data showed significant relationships

between treatment techniques and QLI scores and volume reduction post treatment. The altered form of CDT was shown to be more effective in volume reduction and QOL improvements as compared to the standard CDT treatment.

DISCUSSION OF FINDINGS

Communication is vital in the medical community. Communication about particular conditions with other health professionals; on improvements to standard treatement techniques; about treatment outcomes with patients, insurance companies, and other medical providers; and on research involving alternative or advances in current treatments. Lymphedema is lacking in advancements with therapy treatments and in all areas of communication currently. The three studies recently completed will help bridge the gaps in the field of lymphedema.

The volumetric study found the truncated cone method is a reliable way to calculate volume. This can help with showing patients, doctors, and insurance companies the amount of edema present in an individual and justify the need for proper treatment. The progress of the actual treatment can also be demonstrated with this method. Conversely, if previous measurements are available, then a change can be detected if a patient is non-compliant with a home program or after additional insults. Volumetrics can also be used to evaluate effectiveness of altered treatment techniques. This can provide a standard form of communication involving the extent of the volume as it relates to lower extremity lymphedema.

Interest in QOL is increasing in the medical community. The use of QOL tools has increased the ability to assess treatments for conditions on a more personal level.

Communication about these results is easier when a standardized tool for the particular population is utilized. Until recently there were no baseline QOL measurements for those with lymphedema. The second study, while limited in size, did show lymphedema can impact a person's QOL. This is important for the health community to realize, so more than just the physiological symptoms can be addressed with treatment. This study has provided the health community with baseline QOL score for females with lower extremity lymphedema.

The initial literature review found that surgeons, pharmaceutical companies, and product companies have been attempting to enhance the treatment of lymphedema. The approach to treatment by therapists has changed little over the last 50 years. CDT while accepted as the treatment of choice cannot be said to be the best treatment if it is not challenged. The final study did show the addition of the contraction of the pubococcygeus muscles during the exercise portion of the CDT treatment had a greater impact on the reduction of edema and improvement of the QLI scores on the QLI as compared to standard CDT with females with lower extremity lymphedema. The study should increase the concept that there may be ways we can improve the current CDT to provide better results for the patients with lymphedema.

IMPLICATIONS FOR THE FUTURE

There are so many individuals affected with this condition; yet, there is limited research and communication available on lymphedema. These studies have provided platforms for future research and improved methods of communication about the research. There needs to be more studies on QOL and how it relates to lymphedema.

Baseline QOL scores need to be gathered on other areas of involvement, on males and females, and pre/post treatment options. The current CDT method needs to be critically examined to see if there are ways to enhance the treatment. The use of pelvic floor muscles needs to addressed with a larger population. Other muscle groups may need to be considered in future research. All aspects of the health community should strive to continually improve treatment options and increase communication about the success or failure of these options.

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