

**ENDERMOLOGIE VERSUS NEGATIVE PRESSURE
THERAPY ON POSTMASTECTOMY
LYMPHEDEMA**

By

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CHAPTER I

INTRODUCTION

A mastectomy is the removal of the tissues from one or both breasts. Mastectomies are primarily performed to remove or prevent breast cancer. The operation is most often carried out to remove existing cancerous cells within the breast and thereby reduce the potential for breast cancer to spread (*Newman and Tim, 2017*).

Breast cancer is the most common type of cancer in Egyptian females, 34% of Egyptian females suffer from BC. Women treated for BC are facing a life-time risk of developing lymphedema, its incidence values ranging between 20% and 30% have been considered realistic by several authors (*El-Feqi et al., 2019*).

Breast cancer related lymphedema is the most common chronic impairment following breast cancer surgery. Lymphedema is a chronic disease where lymph accumulation in the limbs was mostly due to obstruction of the proximal lymphatic system due to lymph node dissection for cancer treatment. It is a debilitating disease which can lead to swollen, heavy, painful and infection prone limbs (*Yang et al., 2018*). Problems associated with lymphedema include pain, altered sensation such as discomfort and heaviness, difficulty with physical mobility, psychological distress, recurrent infections, and social isolation (*Dudhagara et al., 2020*).

Endermologie treatment used to facilitate the lymphatic drainage from the affected limb using the mechanized treatment head that allow continuous folding and unfolding of the skin under the continuous action of the rollers allowing for smooth and regulated deep tissue mobilization. As the viscosity of the subcutaneous fat layer decreases, blood flow and

lymphatic drainage increase, facilitating the elimination of excess fluid and metabolites and improving overall cellular function (*Mohamed et al., 2011*).

Negative pressure on the other hand, representing an advancement in conservative lymphatic therapy treatment capability, works by the opposite means to positive pressure whereby a pulling or opening force is applied to the tissues. The technology aims to make local external tissue pressure lower than internal tissue pressure and, therefore, offers a treatment that a manual therapists hands alone cannot deliver (*Frederick et al., 2018*)

Statement of the problem:

The problem will be stated in a questionnaire form:

"Which will be more effective endermologie or negative pressure therapy in reducing limb circumference and volume in postmastectomy lymphedema?".

Purpose of the study:

The main objective of the study is designed to:

To compare between efficacy of endermologie and negative pressure therapy in treatment of postmastectomy lymphedema.

Significance of the study:

The onset of breast cancer-related lymphedema can be gradual or rapid with 15–54% of breast cancer survivors developing lymphedema within 3 years of surgery. One prospective study reported that 75% of the breast cancer-related lymphedema cases were evident in the first year after surgery (*Armer et al., 2019*).

Breast cancer survivors with lymphedema may suffer from multiple lymphedema symptoms, including swelling, heaviness, firmness, tenderness, pain, numbness, aching and stiffness. Consequences of these symptoms include physical deficits involving limb weakness and diminished range of motion limiting an individual's ability to perform activities of daily living and work duties, psychological morbidity, 3 decreased quality of life (QOL) and for the remainder of their life time, increases the risk of infection in the involved extremity (*Kilmartin et al., 2020*).

The endermologie machine was frequently used in the cosmetic field in the treatment of cellulite and body contouring, there are not enough studies carried on about its therapeutic role in the treatment of secondary lymphedema as the machine therapeutic techniques considered to be new. This study will add more support in using the endermologie technique in the future as an accredited physical therapy method for the treatment of lymphedema as there is no absolute cure for lymphedema yet without hazardous side effects and the endermologie machine has no side effects (*Ahmed, 2013*).

Negative pressure therapy can be used to facilitate normal lymphatic system physiology by using variations in interstitial pressures to encourage flow through lymphatic vessels(*Jamalian et al, 2017*).

The goal of this study is to improve the diagnostics and treatment of edema patients. The study attempted to demonstrate the benefit and significance of a lymphatic therapy device in the treatment of patients.

In particular, the aim is to verify the physiological effects of endermologie in swollen tissue.

Delimitations:

This study will be delimited in the following aspects:

1. Subjects:

Sixty-eight women will be treated for unilateral breast cancer with secondary upper limb lymphedema post mastectomy will be randomly divided into two groups equal in number each one has 34 patients.

2-Equipment and tools:

2.1-Measurement equipment:

- Limb volume measurement.
- Disability of shoulder joint function through DASH questionnaire.

2.2-Therapeutic equipment:

- Endermologie.
- Negative pressure therapy.

Hypothesis:

It will be hypothesized that:

There is no significant difference between endermologie and negative pressure therapy in reducing circumference and limb volume in post mastectomy lymphedema.

Basic Assumptions:

It will be assumed that:

- All patients will receive the same kinds of medication and the same nursing care.
- All patients are free from any other vascular disease that might affect lymphatic flow.
- All patients will continue in the study.

- All patients are regularly participating in the study.
- All patients will exert their maximum effort.
- All patients will follow the instructions during the treatment.

Definitions of terms:

The following terms will be defined and explained for clear understanding of the terminology used in the present study:

1. Breast cancer related lymphedema (BCRL):

It is a localized fluid retention and tissue swelling which occurs after surgical procedures and/or radiotherapy in a substantial proportion of breast cancer patients. This condition is due to the impaired transport capacity of the lymphatic system of the arm, resulting in the stasis of the lymph in the interstitial space (*Michelotti et al., 2019*).

2. Endermologie:

It is a non-invasive, 100% natural, patented method of mechanical stimulation of cells, aimed at systemic tissue manipulation through application to the skin. Endermologie represents interaction between the dosed vacuum and roller massage, controlled aspiratory force, controlled frequency, controlled velocity and direction of roller movement (*Mezencevová et al., 2017*).

3. Mastectomy:

It is the removal of the tissues from one or both breasts. Mastectomies are primarily performed to remove or prevent breast cancer. The operation is most often carried out to remove existing cancerous cells within the breast and thereby reduce the potential for breast cancer to spread (*Newman and Tim, 2017*).

4. Negative pressure therapy:

Negative pressure representing an advancement in CLT, treatment capability, works by the opposite means to positive pressure whereby a pulling or opening force is applied to the tissues. The technology aims to make local external tissue pressure lower than internal tissue pressure and therefore, offers a treatment that a manual therapist's hands alone cannot deliver (*Malicka et al, 2014*).

CHAPTER II

REVIEW OF RELATED LITERATURES

The review of the related studies and literatures of the main concept of this study will be presented under the following headings:

1-Normal breast anatomy:

1.1:Relevant anatomy:

Breasts are composed of the following structures: Compartmentalized fat bounded by CT septa, mammary glands, connective tissue, blood vessels, nerves and lymph vessels. Mammary glands contain the milk-producing cells. These glands are hormone dependant. They enlarge monthly with the menstrual cycle and during pregnancy. Connective tissue of the breast includes fatty tissue and suspensory ligaments, which support the breast and give it shape while breast arteries and veins allow circulation through the tissues as well as nerves that provide information about touch and pain (*Hamdi et al., 2018*).

Each breast has 15-20 lobes: each lobe has many small lobules where the milk is produced, lactiferous ducts converge and open onto nipple, areola surrounds nipple and conceals sebaceous glands. The breast also contains lymph vessels which drain into lymph nodes. About 75% of the breast lymph goes to the axillary nodes, which are located in the axilla (armpit area), and the rest goes to the parasternal nodes, which are located near the middle of the chest. Because breast cancer has a tendency to spread to local lymph nodes in armpit so they are a crucial component of the breast exam (*Moore et al., 2010*).

1.2: Anatomy of lymphatic drainage of the breast:

The lymphatic system comprises lymph vessels, ducts, and nodes. The lymphatic system or lymph system is similar in many ways to blood circulatory system, in that it involves an extensive network of vessels that traverse almost all our tissues to allow for the movement of fluid called lymph. This fluid drains through these lymphatic vessels in a way that is very similar to the return of blood along the veins back to the heart (*MacGill, 2016*).

Lymph is the fluid carried through the lymph node chains. It bathes the tissue of the breast and then passes through the lymph nodes. Where it is filtered and eventually travels back into the blood stream. There are several areas or chains of lymph nodes that drain the breast. They are located on both sides of chest bone (internal mammary chain), under arms (axillary chain) and above collar bone (supraclavicular chain). The primary route of lymphatic drainage of the breast is through the axillary lymph node groups (*Tank, 2009*).

Lymph nodes are responsible for filtering lymph and providing part of the adaptive immune response to new pathogens, the part of our immunity that has a long memory. Swollen lymph nodes can indicate a response to foreign material such as from a nearby infection, this process is known as reactive lymphadenopathy. Lymph nodes can also become infected themselves, a condition known as lymphadenitis. Lymph nodes are not the only lymphatic tissues in the body, the tonsils, spleen and thymus gland are also lymphatic tissues (*MacGill and MarKus, 2016*).

Fujita et al., 2018 classified axillary lymph nodes into:

- Upper pectoral lymph nodes located between the upper border of the second rib and the lower border of the third rib.
- Central axillary lymph nodes located above upper pectoral lymph nodes.

- Lower pectoral lymph nodes located between the fourth and sixth ribs.

1.3:Types of mastectomy(Newman and Tim, 2017):

There are several types of mastectomy. They include:

1. Total (simple) mastectomy: This involves the surgeon removing the entire breast but leaving the muscles under the breast and the lymph nodes in place.

2. Double mastectomy: This involves the surgeon removing both breasts, usually as a preventive measure if genetic features indicate a high risk of breast cancer.

3. Radical mastectomy: This involves the surgeon removing the entire breast, the underarm lymph nodes, and the chest wall muscles.

4. Modified radical mastectomy: This involves the surgeon removing the entire breast and underarm lymph nodes but leaving the chest wall muscles intact.

5. Skin-sparing mastectomy: This involves the surgeon removing the breast tissue and nipple but leaving the skin intact. A surgeon also reconstructs the breast during the procedure.

6. Nipple-sparing mastectomy: This relatively new procedure involves leaving the skin, nipple, and peripheral breast tissue intact .

If lymphedema is not appropriately addressed by evidence- based interventions, it can lead to progressive arm swelling, infection and eventually tissue and neurologic changes .Lymphedema results in not only significant negative consequences physically, but also

psychologically, and lymphedema can profoundly negatively affect quality of life of survivors (*Hayes et al., 2012*).

2.5:Symptoms:

Studies have shown that self-reported assessment of symptoms (e.g., swelling, heaviness, redness and tenderness) and limb function changes (e.g., reduced range of motion) by breast cancer survivors can be an effective component of assessment for lymphedema. Patient sensations have also been proposed as early indicators of lymphedema and it is recommended that both self-reported sensations and limb measurement be assessed at each follow-up visit. Symptoms of arm swelling and heaviness have been found to be significantly predictive of limb increase in circumferences in early studies (*Armer et al., 2003*).

2.6:Assessment:

There are multiple measurement modalities that have been used to assess and diagnose lymphedema. In the past, water displacement volumetry and, most recently, perometry have been common methods to assess for lymphedema in patients presenting with limb swelling. Both have limitations for routine clinical use, particularly related to clinic space limitations (*Hayes et al., 2012*).

Serial circumferential limb measurements have been used most commonly to assess lymphedema, as this approach is widely available and has no specific space or equipment requirements. Circumferential measurements have been found to be both accurate and reliable when carried out by trained staff (*Armer et al., 2011*).

3-Negative pressure:

3.1: Definition and types:

Negative pressure representing an advancement in CLT treatment capability, works by the opposite means to positive pressure whereby a pulling or opening force is applied to the tissues. The technology aims to make local external tissue pressure lower than internal tissue pressure and, therefore, offers a treatment that a manual therapists hands alone cannot deliver. Kinesiological tape, deep breathing, cupping and medical negative pressure devices, are examples of negative pressure technology or therapies that aim to directly or indirectly impact the lymphatics by utilising negative pressure forces. Kinesiology taping is an example of technology whereby the mechanics of action are not well understood. It is theorized that negative pressure is created indirectly through tissue movement creating skin stretch from adhesive tape pulling on the skin. As superficial tissues are pulled, more space is created between the dermis and fascia, pulling on lymphatic anchor capillaries, which attach the skin and drawing fluid into superficial lymphatic vessels. Further research is required to demonstrate the benefit in lymphoedema management, however, a small sample group study showed promising results (*Malicka et al, 2014*).

Cupping is the primitive form of local negative pressure devices, being used in Chinese alternative medicine since the second century AD and continuing to be used in contemporary Chinese medicine (*Iblher and Stark, 2007*).

In small case studies in clients with lymphoedema, when compared with manual lymphatic drainage, LymphaTouch was shown to improve treatment outcomes, decrease treatment time and improve patient satisfaction (*Vuorinen et al, 2013; Osborne, 2015; Whitaker, 2015*).

3.2: Mechanism of action of negative pressure therapy:

The literature on negative pressure in wound healing has informed our understanding of the two main mechanisms of action of negative pressure: macrodeformation (or macrostrain) and microdeformation (or microstrain). Macrostrain can be described as the visible movement of the tissues as seen when a negative pressure therapy(NPT) device is placed onto the tissues, whereas microstrain includes cellular and vessel tissue changes that we cannot see with the naked eye (*Glass et al, 2014*).

3.3: Negative pressure and lymphedema:

Negative pressure, in the context of lymphoedema, is theorised to result in changes in transmural pressure across lymphatic vessel walls to allow for dilation or slight distention of the vessel and surrounding tissues. The contractile profile of the lymphatics have been shown to be quite sensitive to changes in mechanical loads with modulation of intraluminal pressure resulting in dynamic shifts in lymphatic pump frequency and stroke volume (*Nipper and Dixon, 2011*).

Under normal physiologic conditions the ‘suction pressure’ in collecting lymphatic vessels, manifesting as a transient drop in pressure downstream of the inlet valve following contraction, allows fluid to be drawn in through initial lymphatic's (*Jamalian et al, 2017*).

Negative pressure could, therefore, be being used to facilitate normal lymphatic system physiology by using variations in interstitial pressures to encourage flow through lymphatic vessels.

4- Endermologie:

4.1: Definition:

Endermologie is a machine-assisted massage system that allows positive pressure rolling, in conjunction with applied negative pressure to the skin and subcutaneous tissues (*Moseley et al., 2007*).

4.2: Mechanism of action:

One new therapy is LPG technique® (Endermologie®) which was originally developed in France and is currently available in the private sector. This system delivers mechanical massage to the limb via two motorized, cylindrical skin rollers which pick up and massage the skin inside its treatment head. Pilot studies of this equipment have shown that it improves superficial lymphatic drainage (*Bartolo and Allegra, 2001*) and lymphatic transport capacity (*Leduc et al., 1995*), decreases fibrotic induration (*Campisi et al., 2001*) and functional discomfort (*Guillot, 2001*).

It involves the use of a motorized device with two adjustable rollers and controlled suction which creates a symmetrical skin-fold allowing for smooth and regulated deep tissue mobilization. It was originally developed to soften scars but now it is widely used as an alternative method for altering fat distribution in the subcutaneous plane (*Moseley et al., 2007*).

As the viscosity of the subcutaneous fat layer decreases, blood flow and lymphatic drainage increase, facilitating the elimination of excess fluid and metabolites and improving overall cellular function (*Moseley et al., 2007*).

4.3: Effect on lymphedema:

Decrease of the excess limb volume from 5% to 10% after Endermologie therapy and reduction of the fibrotic tissue components, softening of the skin and superficial tissue through improving the lymphatic drainage of the affected limb in patients with secondary lymphedema of arm and leg treated by combining physical therapy through applying Endermologie technique along with microsurgical operations (*Camplsi et al., 2002*).

Endermologie therapy accompanied by elastic compressive treatment two sessions a week for four weeks induced significant reduction in the circumference of the affected limb as well as significant improvement of microcirculation of the cutaneous oxygenation and of the interstitial metabolism in the patients underwent surgery for malleolar and calf lipolymphedema (*Bacci et al., 2002*).

CHAPTER III

SUBJECTS, MATERIALS AND METHODS

In this part of the study, the materials and methods will be presented under the following headings: subjects, equipment, procedures of the study and the statistical procedures.

1-Subjects (sample size):

Sample size calculation is performed using G*POWER statistical software (version 3.0.1.0, Math. -Nat. Fakultät, Universitat Dusseldorf, Germany) based on data of VSS from the previous study (*Intsar et al., 2021*) who reported a significant effect of endermologie compared with control in treating post mastectomy lymphedema. The required sample size for this study was 34 subjects per group. Calculations were made using $\alpha=0.05$, power 90% and effect size = 0.8 and allocation ratio $N_2/N_1 = 1$.

Sixty- eight women treated for unilateral breast cancer with secondary upper limb lymphedema post mastectomy will participate in this study. Their ages will be ranged from 40 to 60 years, they will be free from any other diseases that will affect or influence the results and the participants will be selected from National Cancer Institute and randomly distributed into two equal groups in number.

1.1: Design of the study:

In this study the patients will be randomly assigned into two groups equal in number (34 patients for each group).

1.1(a): Group A:

This group includes 34 patients who will receive 30 min Endermologie 3 times per week in addition to their physical therapy program (active range of motion and elevation); hygiene and skin care for 6 weeks.

1.1(b): Group B:

This group includes 34 patients who will receive 30min negative pressure therapy 3 times per week in addition to their physical therapy program (active range of motion and elevation); hygiene and skin care for 6 weeks.

1.2: Criteria for the patient selection:

1.2(a): Inclusion Criteria:

- The subject selection will be according to the following criteria: -
- Only females will participate in the study.
 - Patients' age will be ranged between 40-60 years.
 - All patients suffer from post mastectomy lymphedema.
 - All patients suffer from grade II lymphedema without skin changes one year post mastectomy.
 - All patients enrolled to the study will have their informed consent.

1.2(b): Exclusion Criteria:

The potential participants will be excluded if they meet one of the following criteria:

- primary lymphedema.
- Diabetes mellitus.

- Pregnancy.
- Recurrent cancer.
- Current or recent cellulitis.
- Current metastases.
- Venous thrombosis.
- Photosensitivity.
- Phlebitis in development stage.
- Infection.
- Receiving anti-coagulant treatment.

2-Equipment:

The study equipment's will be divided into measurement and therapeutic equipment and tools:

2.1: Measurement equipment

2.1(a):Limb volume measurement:

This will be performed by measuring the circumference of each segment of the limb between two consecutive circumferences as a truncated zone.

The volume of the segment was calculated as:

$$V=h (C1^2+C1C2+C2^2)/12\pi,$$

where V is the volume of the segment, C1 and C2 are the circumferences at the ends of the segment, and h is the distance between them (*Taylor et al., 2006*).

Measurement of limb volume measurement will be conducted pretreatment and after treatment course (6 weeks).

1.2(b): Measuring Disability of the arm, shoulder and hand by:

DASH questionnaire (Disability of the arm, shoulder, and hand).

2.2-Therapeutic equipment:

2.2(a):Endermologie:

Endermologie is a machine-assisted massage system that allows positive pressure rolling, in conjunction with applied negative pressure to the skin and subcutaneous tissues (*Moseley et al., 2007*) .

Endermologie is also known as vacuum massage, depressomassage or vacuotherapy. It is a non-invasive mechanical massage technique performed with a mechanical device that lifts the skin by means of suction and mobilizes the skin. Vacuum massage originates from cupping therapy, a traditional Chinese medicine therapy dating back at least 2000 years (*Moortgat et al., 2016*).

Endermologie machine (perfection by joycare, made in Italy) used to decrease postmastectomy lymphedema for group (A) (*Fatma et al., 2011*).

2.2(b):Negative pressure therapy:

A device designed for manual lymphatic therapists. Developed in Finland in 2005 and reaching the market in 2009, the portable unit of 1.2 kg is designed for use both in the clinic setting, as well as in the home. The unit includes the vacuum unit for creating the negative pressure and patented mouth pieces which create a tissue seal. The level of negative pressure can be accurately quantified at the tissue interface from 20-250

mmHg by sliding the touch screen scale with the treatment head measuring negative pressure 300 times per second (*Iivarinen et al, 2013*).

3-Procedures of the study:

3.1-Measurement procedures:

3.1(a):Limb volume measurement:

With the patient in a comfortable sitting position, a standard 1-cm retractable fiberglass tape was used for measuring the circumference. The limb was placed on a bedside table in the horizontal position and was fixed with an adhesive measurement strip from the axilla to the wrist to ensure consistency of the measurement at 10- cm intervals. Measurements were initiated at the ulnar styloid process and subsequently at 10, 20, 30, and 40 cm proximally.

3.1(b) Assessment of Disability of the arm, shoulder and hand::

The disabilities of the arm, shoulder and hand questionnaire (DASH)

- The disabilities of the arm, shoulder and hand (DASH) questionnaire is a self-administered region-specific outcome instrument developed as a measure of self-rated upper-extremity disability and symptoms.
- The DASH consists mainly of a 30-item disability/symptom scale, scored 0 (no disability) to 100.
- The main purpose of this study is to assess the longitudinal construct validity of the DASH among patients undergoing surgery.
- The second purpose is to quantify self-rated treatment effectiveness after surgery.

- This questionnaire asks about patient symptoms as well as the patient ability to perform certain activities. Patient answer every question, based on his condition in the last week, by circling the appropriate number.
- If patient won't have the opportunity to perform an activity in the week, please make him best estimate on which response would be the most accurate. It doesn't matter which hand or arm you use to perform the activity; patient answer based on his ability regardless of how he performs the task.

3.2-Therapeutic procedures:

3.2.(a):Procedures of Endermologie:

Endermologie therapy will be three sessions per week for six weeks (total 18 sessions).

The study group will receive 18 sessions by Endermologie system (perfection by joycare, made in Italy) used to decrease postmastectomy lymphedema for group (A), three sessions per week for six weeks.

Each session was 30 minutes at the posterior thorax, upper arm, forearm and the hand (*Fatma et al., 2011*).

3.2.(b):Procedure of negative pressure therapy:

- Pressure: 20–250 mmHg.
- Total treatment period: 6weeks
- A number of sessions: 3sessions/ week.
- Time of application : 30 min

3.2.(c):Physical therapy program for both groups:

-Therapeutic exercises:

All patients will be advised to perform daily limb exercises active range of motion and elevation), hygiene and skin care (*Kozanoglu et al., 2009*).

- Active range of motion for upper limb:

Active ROM (AROM) is movement of segment within the unrestricted ROM that is produced by active contraction of the muscles crossing that joint. AROM for shoulder joint, elbow joint, wrist joint and hand. _

-Hygiene and skin care:

All patients will be advised to:

- Avoid sun beds, steem room, and saunas .
- Avoid taking very hot baths or showers.
- Avoid wearing tight-fitting clothes.
- Avoid wearing tight-fitting jewellery.
- Look for changes or breaks in the skin.
- Keep skin supple by moisturizing it every day.
- Keep nails short.
- Raise the affected limb above the level of the heart whenever possible
(*Nossair et al., 2018*)

4-Statistical procedures:

Descriptive statistics:

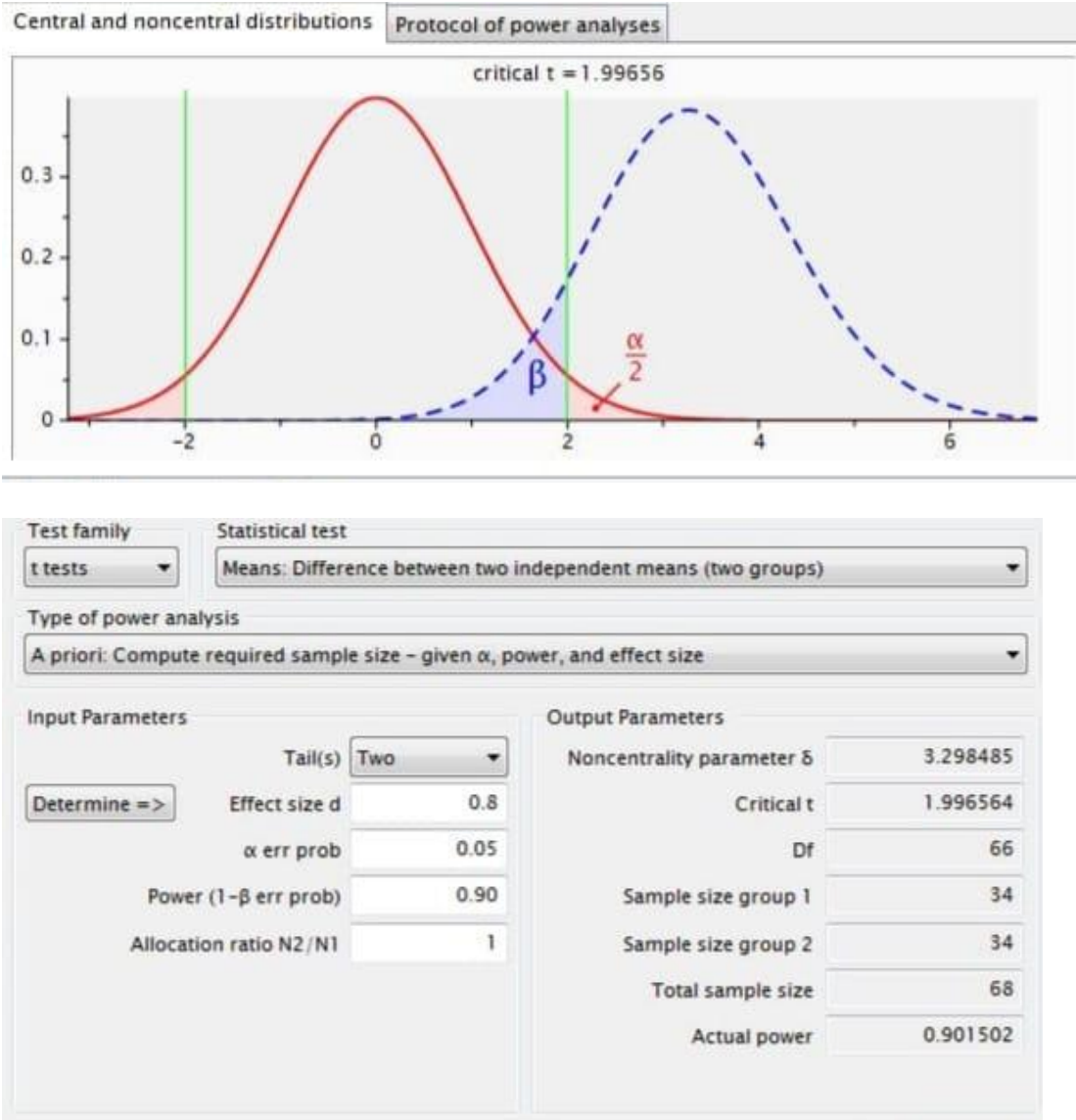
In this study, the descriptive statistics (the mean and the standard deviation) will be calculated for all subjects in all groups of the study to determine the homogeneity of the groups.

Analytical statistics:

Comparison will be made by student's t-test to compare the variables between all groups of the study. Paired t-test was used to compare before and after treatment in the same group. A value of $p \leq 0.05$ will be considered statistically significant (**Maronna et al., 2006**).

Sample size:

Sample size calculation is performed using G*POWER statistical software (version 3.0.1.0; Math.-Nat. Fakultät, Universität Dusseldorf, Germany) based on data of VSS from the previous study (**Intsar et al., 2021**) who reported a significant effect of endermologie compared with control in treating post mastectomy lymphodema. The required sample size for this study was 34 subjects per group. Calculations were made using $\alpha=0.05$, power 90% and effect size = 0.8 and allocation ratio $N2/N1 = 1$.



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