EFFICACY OF OZONE THERAPY ON CHRONIC ARM LYMPHEDEMA FOLLOWING RADIOTHERAPY FOR BREAST CANCER

Thesis

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فاعلية العلاج بالاوزون على الورم الليمفاوى المزمن بالذراع عقب العلاج الاشعاعى لسرطان الثدى

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Efficacy of Ozone Therapy on Chronic Arm Lymphedema Following Radiotherapy for Breast Cancer/ Samah Hosney Nagib; Supervisors: Prof. Dr. Wafaa Hussein Borhan, Pro. Dr Mohga Adel Samy, Physical Therapy Department for Surgery, Faculty of Physical Therapy, Cairo University, 2009. (Doctoral Degree)

Abstract

The purpose of this study was to investigate the efficacy of ozone therapy administration in lymphedema after radiotherapy for breast cancer. **Subjects**: Sixty female had upper extremity lymphedema following radiotherapy for treatment of breast cancer .They ranged in age from 40 to 60 years. They were classified randomly into two groups of equal number. Study group: thirty patients were received ozone therapy plus standard physical therapy protocol, and control group: in which, thirty patients were received standard physical therapy protocol only. **Procedure**: all patients were assessed before treatment program by using Doppler ultrasonography. Lymphedema volumes were assessed for patients before and after treatment by using calculated method and volumetric measurement. **The results** revealed a significant improvement ($P<0.05$) in all measured lymphedema of upper limb pre treatment and post 3 months of treatment in both study and control groups. But the differences volumes post treatment between the affected and unaffected limbs in study group were less than that in control group. **Conclusion**: It could be concluded that, administration of ozone therapy plus the standard physical therapy program contribute in controlling lymphedema.

Key words: Lymphedema, Ozone, Radiotherapy, Breast cancer.

CHAPTER I
INTRODUCTION

Lymphedema is the acculumation of protein–rich fluid in soft tissues as a result of interruption of lymphatic flow. It occurs most frquently in extremities, but it can also be found in the head, neck, abdomen, lungs and gential region ***(Kwan,2002).***

Lymphedema is divided into two forms. Primary lymphedema, associated with development abnomalities of the lymphatic system, might be manifested in neonates (congenital), adolescents (praecox), or patients older than 35 years (tarda).The most common form of lymphedema is secondary lymphedema. This usually occurs after oncologic surgery or radiation therapy. The condition occurs as a result of damage by metastatic disease to the lymphatic system, postradiation changes to the underlying skin structures, or surgical removal of one or more lymphatic nodal basins ***(Puleo et al., 2004).***

Six contributing factors have been shown to influence the incidence of lymphedema after treatment for breast cancer: radiation therapy, obesity, age, operative site, incision type, and the history of infection ***(Baron, 2002)***.

Patients with chronic lymphedema for 10 years have a 10% risk of developing lymphangiosarcoma, the most dreaded complication of this disease. Patients with this tumor commonly present with a reddish purple discoloration or nodule that tends to form satellite lesions. It might be confused with Kaposi sarcoma or traumatic ecchymosis. This tumor is highly aggressive, requires radical amputation of the involved

extremity, and has a very poor prognosis. The 5-year survival rate is less than 10%, and average survival following diagnosis is 19 months. This malignant degeneration is most commonly observed in patients with postmastectomy lymphedema (Stewart-Treves syndrome), where incidence is estimated to be 0.5%. ***(Revis, 2005).***

Lymphedema can be treated successfully by a skilled physical therapist with extensive training in all components of Complex Decongestive Therapy (CDT), Which consists of four basic steps: (1) Skin and nail care, that might also include topical and systemic antimycotic druge treatment can be started, (2) Manual Lymphatic drainage, a non- invasive manual technique designed to stimulate the activity of certain lymph vessels, ,(3) Compression therapy, and (4) Decongestive exercises with the patient wearing compression bandages or garments. CDT not only restores the lymphedemateous limb to a normal or near normal sizes but also preserves the success of the treatment ***(Zuther, 2001).***

Exercise involving the affected arm might be beneficial in controlling lymphedema. Although some clinicians have recommended avoidance of rowing, tennis, golf. Skiing, squash, racquetball or any vigorous, repetitive movements against resistance, there is no published evidence to suggest that these activities promote or worsen lymphedema. Maintenance of ideal body weight should be encouraged. Obesity is a contributing factor for the development of lymphedema. ***(Harris et al., 2001).***

On the other hand, ozone, a naturally occurring configuration of three oxygen atoms best known for its protective role in the earth's ecological harmony, possesses unique properties which are being

defined and applied to biological systems as well as to clinical practice. As a molecule containing a large excess of energy, ozone manifests bactericidal, virucidal and fungicidal actions that might make it a treatment of choice in certain conditions and an adjunctive treatment in others ***(Sunnen, 2005).***

In addition, ozone (O_3) is produced by the reaction of oxygen atoms (O) with molecular oxygen (O_2)- This allotrope (different form) of oxygen possesses unique properties that, while they have yet to be completely defined and understood, have been benefiting clinical practice for years, albeit mostly in Europe. Most of the states in this country have yet to legalize use of the healing powers of this nontoxic molecule ***(Carpendale et al., 1993).***

Patients cured of breast cancer by treatments that include radiotherapy to the armpit might be left with a life-long legacy of arm swelling. This is thought to be due to narrowing of lymphatic vessels that drain tissue fluid out of the arm, rather in the same way that veins drain blood. For many decades, this complication has been assumed to be inevitably progressive and irreversible, but our recent research suggests that the condition might be improved by high-pressure oxygen therapy. One of the ideas we are looking into is that high-pressure oxygen might stimulate the growth of new lymphatic channels as well as lead to a reduction in scar tissues surrounding existing lymphatic channels in the armpit***. (Young and Setlow, 2004).***

Statement of the problem:

Lymphedema is a major complication that can compromise quality of life and need intensive intervention and as the ozone therapy

is a new trend in medical field and also it has achieved best results in variety of diseases and medical problems therefore the problem of the study was designed in a questionary form : Would the administration of ozone therapy plus the standard physical therapy management affect lymphedema after radiotherapy for breast cancer ?

Purpose of the study:

The purpose of the present study was to investigate the effect of ozone therapy in lymphedema after radiotherapy for breast cancer.

Significance of the study:

Lymphedema is a major complication, when the lymphatic impairment becomes so great that the lymph fluid exceeds the lymphatic system's ability to transport it, an abnormal amount of protein-rich fluid collects in the tissues of the affected area. Left untreated, this stagnant, protein-rich fluid causes tissue channels to increase in size and number, reducing the availability of oxygen. This interferes with wound healing and provides a rich culture medium for bacterial growth that can result in infections : cellulitis, lymphangitis, lymphadenitis, and in severe cases, skin ulcers. Ozone therapy has many biological effects and it achieved best results in many branches of the medical field, and it is a new point of research that to administrate it in woman with lymphedema after radiotherapy for breast cancer. The results of current study might help the surgeon, physician and physical therapist to organize a plane of care to overcome the problem of lymphedema followed radiotherapy for breast cancer in short time with economical way of treatment. Furthermore, the results might help in

improving the quality of life for these patients and prevent further other complications.

Delimitations:

This study was delimited to the following aspects:-

Subjects:-

1. Sixty female patients who had upper extremity lymphedema following radiotherapy for breast cancer treatment (post mastectomy).
2. –They were selected from surgical department- National Cancer Institute- Cairo University.
3. Their ages ranged from 40-60 years.

Equipment:-

The main equipment used in this study were delimitated as following:

****Measurement Equipment:***

1. Doppler ultrasonography.
2. Tape measurement.
3. Volumetery.
4. Height and weight scale.

****Therapeutic equipement:-***

1) Ozone generator device.
2) Tools used to administration of ozone
3) Elastic bandage
4) High voltage galavainc device.
5) Mechanical pressure therapy device.

6) Shoulder wheel.

Limitations:-

This study was limited by the following factors−:

1. Psychological status of patients at the time of measurement which might affect the results.
2. Individual differences in the patients and their effects on the degree of treatment achievement, and the rate of recovery.

Basic assumptions:-

It was assumed that:

1. All physical exercises and functional activities were at the same degree and dose.
2. The calibrations of all instruments used in this study were accurate.
3. All patients were under the same kinds of medications.
4. Patients were free from any other dysfunctions which might affect the results as vascular disorders except lymphedema.

Hypothesis−:

It was hypothesized that using ozone therapy plus standard physical therapy protocol in lymphedema after radiotherapy for breast cancer treatment might not reduce or control lymphedema when compared with the standard physical therapy protocol only.

Definition of Terms:

The following terms were defined and explained for clear understanding of terminology used in this study:

1- Arm Lymphedema: lymphedema is a symptom of lymphatic transport malfunction that occurs when the lymphatic load exceeds the transport capacity of the lymphatic circulatory system. It presents clinically with swelling of the soft tissue because of accumulation of protein- rich fluid ***(Cameron and Monoroe, 2007).***

2-Body mass index (BMI) or Quetelet's index*:** is a convenient index of relative weight through a ratio using an equation to indicate and characterize body fatness (BMI = weight (Kg) / height $(m)^2$). So according to (BMI), accept table weight is defined as (BMI) between 20 and 24.9. Overweight is defined as (BMI) between 25 and 29.9. Obesity is defined as (BMI) between 30 and 39.3 and gross obesity is defined as (BMI) above 40 ***(Ogden et al., 2002).

3-Chemotherapy is the systemic treatment of breast cancer by anti- malignant drugs. The drugs are toxic and have many side effects but these are reversible ***(Hoskin et al., 1992).***

4-Filariasis: disease caused by the presence of parasitic worms that occlude the lymphatic channels ***(Foldi, 2003).***

5- Lymphangitis: Inflammation of one or more lymphatic vessels ***(Andersen and Hojris., 2000)***

6- ***Modified radical mastectomy***, the breast and axillary contents are removed through a horizontal incision, and the pectoralis muscles are preserved. The cosmetic result is improved by the more normal appearance of the upper chest wall ***(Bland and Krontiras, 2004)***.

7-Radical mastectomy, this procedure involves entire removal of the breast, pectoral muscles, and axillary contents. This operation is not indicated today except perhaps for the removal of very large, fixed tumors ***(Ravdin and Osborne, 1995).***

8- Radiotherapy ،after breast cancer – conserving surgery typically consists of tangential irradiation of the whole breast designed to minimize lung and heart exposure using super- voltage equipment and isocentric technique in which the deep edges of fields are co-planer. ***(Harris et al., 1996).***

9-Simple mastectomy, involves removal of the breast only, no muscle tissue or nodes are removed. It might done for extensive fibrocystic disease (benign). It is frequently followed by radiotherapy to the axillary nodes when performed for malignancy ***(Cash, 1997).***

10-Subcutaneous firosclerosis: Hardening below the skin caused by abnormal formation of fibrous tissue ***(Kubik, 2003).***

11- Ozone: Ozone is normally present as a gas made of three atoms of oxygen with a cyclic structure. The medical generator of ozone produces it from pure oxygen passing through a high voltage gradient (5–13 mV) according to the reaction:

$$3O_2 + 68;\ 400\ cal \rightarrow 2O_3$$

Ozone is 1.6-fold denser and 10-fold more soluble in water than oxygen. Although ozone is not a radical molecule, it is the third most potent oxidant after fluorine and persulfate. Ozone is an unstable gas that cannot be stored and should be used at once. ***(Bocci, 2006).***

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