Effect of Hyperbaric Oxygen Therapy on thoracic Transcutaneous Oxygen partial pressure measurement of breast cancer patients – methodology and preliminary results

Effet de l'oxygénothérapie hyperbare sur la mesure de la pression partielle d'oxygène transcutanée thoracique chez les patientes atteintes d'un cancer du sein – méthodologie et résultats préliminaires

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Abstract

Hyperbaric Oxygen Therapy (HBOT) has been used for the management of post-radiation injury for decades. It has a central role and is strongly indicated in treating mandibular osteoradionecrosis, post-radiation cystitis and proctitis and preventing osteoradionecrosis after dental extraction. HBOT is suggested in all other radio-induced lesions (bony and soft tissues) as scientific evidence is accumulating but hasn't yet reached sufficient strength. Concerning breast cancer management, surgery may result in complications that affect patients' psychology and health economics and may influence the treatment plan. Among various risk factors, radiotherapy following surgical treatment is an important one. Post-treatment sequelae of radiotherapy have been studied extensively and key role to these effects is the resulting hypoxia, hypovascularity and hypocellularity of irradiated tissues.

A clinical, prospective study in our Department is underway in collaboration with the Surgery Department of a teaching hospital, under the auspices of the Athens Naval Hospital and National and Kapodistrian University of Athens. The study aims to explore the beneficial effects of HBOT on local oxygen supply, in patients referred for treatment because of complications following breast cancer surgical treatment and/or radiotherapy. For that purpose, transcutaneous oximetry (TcPO2) measurements are taken before and after HBOT and are associated with the outcome of post-radiation injury and possible reduction of hospitalization duration (days) and number of surgical operations performed. We will assess the prognostic value of TcPO2 for predicting success of using HBOT for problem wound healing of the thoracic wall following radiotherapy. Methodology of the study will be presented here, together with preliminary results and initial findings.

As in most western countries, bans for women serving in the military and special units have been removed approximately 100%, increasing number of women are treated and supported from military hospitals. Best management, reduced complications and quick return to disease-free status for breast cancer survivors using HBOT may be more relevant in military medicine than previously thought.

Key Words: Breast cancer, Hyperbaric Oxygen Therapy, Transcutaneous Oximetry, Postradiation Injury, Women in Military.

Résumé

L'oxygénothérapie hyperbare (OHB) est utilisée depuis des décennies pour la prise en charge des lésions post-radiques. Elle joue un rôle central et est fortement indiquée dans le traitement de l'ostéoradionécrose mandibulaire, de la cystite et de la proctite post-radiques et dans la prévention de l'ostéoradionécrose après une extraction dentaire. L'OHB est conseillée pour toutes les autres lésions radio-induites (osseuses et des tissus mous) puisque les preuves scientifiques se multiplient mais n'ont pas encore atteint un niveau de preuve suffisant. En ce qui concerne la prise en charge du cancer du sein, la chirurgie peut entraîner des complications qui affectent la psychologie et les aspects économiques de la santé des patientes et peuvent influencer le plan de traitement. Parmi les différents facteurs de risque, la radiothérapie consécutive au traitement chirurgical est un facteur important. Les séquelles post-traitement de la radiothérapie ont été largement étudiées et le principal rôle de ces conséquences est l'hypoxie, l'hypovascularisation et l'hypocellularité qui en résultent pour les tissus irradiés.

Une étude clinique prospective est en cours dans notre département, en collaboration avec le service de chirurgie d'un hôpital universitaire, sous les auspices de l'hôpital naval d'Athènes et de l'université nationale et kapodistrienne d'Athènes. L'étude vise à explorer les effets bénéfiques de l'OHB sur l'apport local d'oxygène, chez des patientes admises au traitement en raison de complications survenues à la suite d'une intervention chirurgicale et/ou d'une radiothérapie pour un cancer du sein. À cette fin, des mesures d'oxymétrie transcutanée (TcPO2) sont effectuées avant et après l'OHB et sont associées à l'issue des lésions post-radiques et à la réduction possible de la durée d'hospitalisation (jours) et du nombre d'opérations chirurgicales réalisées. Nous allons évaluer la valeur pronostique de la TcPO2 pour prédire le succès de l'OHB dans la cicatrisation de la paroi thoracique

après une radiothérapie. La méthodologie de l'étude sera présentée ici, ainsi que les résultats préliminaires et les premières conclusions.
Comme dans la plupart des pays occidentaux, les interdictions pour les femmes de servir dans l'armée et les unités spéciales ont été levées à presque 100 %, un nombre croissant de femmes sont traitées et soutenues par les hôpitaux militaires. La meilleure prise en charge, la réduction des complications et le retour rapide à un statut exempt de maladie pour les survivantes du cancer du sein grâce à l'OHB pourraient être plus pertinents dans la médecine militaire qu'on ne le pensait auparavant.
Mots clés : Cancer du sein, oxygénothérapie hyperbare, oxymétrie transcutanée, lésions post-radiques, femmes militaires.

Introduction

Post-surgical complications of breast cancer treatment are not rare. They affect psychology and health economics and may alter the treatment plan. Post-surgical infections can be as high as 10% of cases, while early non-infectious complications like hematoma, wound dehiscence and necrosis can be equally high, resulting in 6% of mastectomies with implantation to necessitate implants removal within 60 days (1). Type and timing of surgery matters and complication rate following breast reconstruction may reach 50%, with 1 of 4 cases necessitating new operation or hospital admission. Risk factors are age, immediate reconstruction, bilateral reconstruction, increased BMI and radiotherapy after surgery (2).

Clinical syndromes induced by radiation therapy have been extensively studied and are progressive and irreversible. Post-radiation injury when manifested, follows the "complex wound" model (3). Reduced cellularity, vascularity, oxygen and resistance to infections are the cause of prolonged and intractable disease after minor injuries complicated by infections on the irradiated normal tissues.

The most frequent disease where high dosage radiation therapy is used is early breast cancer. Post-radiation injury seen in these cases includes upper extremity lymphedema, painful shrinkage of the breast, lung damage, nerve damage and skin damage (4). Radiation therapy after breast conserving surgery in early breast cancer may negatively affect aesthetic outcome and prevalence of post-radiation fibrosis – atrophy at 5 years after radiotherapy reaches 10% (5).

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Hyperbaric Oxygen Therapy (HBOT) has been used for decades in the management of post-radiation injury (6). The list of accepted indications by the European Committee on Hyperbaric Medicine (ECHM) for the use of HBOT includes mandibular osteoradionecrosis and radiation cystitis / proctitis as type I (strongly recommended) indications, other soft tissue radiation injury and surgery / implant in irradiated tissues as Type 2 (recommended), and radiation injury of the larynx and Central Nervous System as type 3 (optional) (7). HBOT acts etiologically reversing radiation pathology and not just treating its manifestations. Central to that is its angiogenetic properties together with wound healing mechanisms enhancement (increased collagen production and fibroblast proliferation) and better infection control. Ischemic ulcers and compromised skin grafts and flaps of various etiology have been indications for this treatment as well. In chronic wounds, especially diabetic extremity ulcers, an important prognostic tool is transcutaneous oximetry. Measuring tissue Oxygen Partial Pressure (pO2) intradermally (TcPO2 = transcutaneous oximetry) near the wound bed and increases of its value under hyperbaric conditions in these cases, has been used successfully to predict patients that will benefit from the therapy (15).

Concerning the use of HBOT for post-radiation injury of the thoracic wall following breast cancer treatment, there are several case reports of its beneficial effects on persisting pain-erythema-oedema after radiotherapy (8) and healing of chronic radiation skin necrosis (9). Also, carefully designed studies have shown improvement in lymph drainage with reduction of lymphedema volume (4, 10) and improvement of warm sensory threshold in patients with radiation-induced brachial plexopathy (11).

There may be a lifelong risk for developing complications after radiation therapy (12) but HBOT has been effective for the prophylaxis from mandibular osteoradionecrosis following tooth removal (13) when used perioperatively. Similar beneficial results have been shown in cases undergoing reduction mammaplasty on irradiated breasts that were treated with HBOT before and after the surgery (14).

We designed this study to explore benefits in local oxygen supply by HBOT in patients that underwent surgical treatment of breast cancer or breast reconstruction and manifest complications after surgery. Also, we included breast cancer patients that received radiation therapy after surgical treatment to investigate HBOT efficiency in reversing local hypoxia and improving post-radiation injury and associated effects.

Main part

The aim of the study was to explore HBOT effect on post-treatment conditions, in breast cancer patients after surgery and/or radiation therapy. For that purpose, we defined the following as *main outcomes*: Surgical Site Infections – Manifestations of post-radiation injury on the irradiated breast at the end of HBOT – Comparative values of transcutaneous oximetry on the operated/irradiated and healthy breast before initiation and during the first HBOT session – Comparative values of transcutaneous oximetry on the operated/irradiated and healthy breast before initiation, at the completion of HBOT and after 2 months. *Secondary outcomes* would be: Manifestations of post-radiation injury on the irradiated breast 2 months after completion of HBOT – Pain on the operated/irradiated breast before, at the end and 2 months after completion of HBOT – Upper extremities circumference measurement before, at the end and 2 months after completion of HBOT.

We included the following as post-radiation injury of the breast: skin lesion, skin thickening, breast oedema, loss of subcutaneous fat, dystrophic calcifications, radiation pneumonitis, pleural effusion, skin ulcer, breast fibrosis/atrophy, rib fractures, pulmonary fibrosis, pericardial effusion. All the above have been described as late effects of radiation therapy on normal tissues.

Study population

Patients eligible for the study are individuals older than 18 years old diagnosed with breast cancer. To enter the study, patients must have tumor surgical excision with complications either before or after radiotherapy, or after breast reconstruction. They must also have the physical and psychological condition needed for HBOT and be able to provide signed informed consent for treatment and subsequent reassessments.

Exclusion criteria

Patients suffering from simultaneous different cancer or have already undergone HBOT after cancer diagnosis will not participate in the study. There are physical and physiological effects of HBOT and so, patients fulfilling any of the exclusion criteria shown on *Table 1* will be excluded from the study.

Table 1. Exclusion Criteria

1	Patient has undergone Hyperbaric Oxygen Treatment already, after cancer diagnosis
2	Claustrophobia precluding staying inside the chamber for 120'
3	Epilepsy, current use of antiepileptics or within last 2 years, convulsions within last 5 years
4	COPD – Emphysema - Bronchiectasis
5	Lung blebs, Uncontrolled Asthma, Acute/Chronic Pulmonary Infection
6	Pneumothorax, history of spontaneous pneumothorax
7	History of middle ear surgery, inability to equalize pressure in the middle ear
8	Implanted or attached medical devices not tested in hyperbaric conditions
9	Preexisting condition that will be affected by HBOT or demands further testing (cardiac, pulmonary etc)
10	Uncontrolled Hyperthyroidism
11	Hemolytic Disorders
12	Recent (< 2 weeks) bleomycin or adriamycin use or concomitant chemotherapy
13	Patient unable to comply with schedule (4 weeks, 5 visits per week)
14	Patient unable to sign informed consent
15	Substances abuse or dependance
16	Treating physicians' perception that HBOT is not safe for the patient

HBOT protocol

Patients will be treated with HBOT for twenty – 20 sessions according to the following protocol: 1 session per day breathing 100% Oxygen at pressure of 2 Atmospheres Absolute (ATA) – total oxygen time 90', 5 sessions per week, 4 weeks in total. HBOT sessions will take place in our multiplace hyperbaric chamber and patients will be breathing oxygen through an airtight oronasal mask. Deviations from the protocol (more or less sessions) for medical or patient's reasons will be recorded.

Results collection and analysis

After referral by the treating surgeon either for post-surgical complications (ischemia, infection etc) or for radiation-induced effects on normal tissues, patients were assessed by the Hyperbaric physician initially completing a medical history and demographics questionnaire. A clinical examination, recording of significant results, data and coexisting pathology especially when affecting healing capacity took place, and eligibility to enter the study confirmed. After explaining the treatment protocol, the patient was given an information leaflet and asked to provide an informed consent. Diagnoses, medical reports and test results were scrutinized for any of the exclusion criteria. After that, the exact date of treatment start was arranged. That day, TcPO2 values were measured at the "suffering" site before and during the first HBOT session with simultaneous measurement of the "healthy" breast symmetrically. Patient's chart included assessment of radiation morbidity using the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer (RTOG/EORTC) criteria (16), the Subjective, Objective, Medical management and Analytical evaluation of Late Effects on Normal Tissues (SOMA-LENT) criteria (17) and the Common Terminology Criteria for Adverse Events (CTCAE) (18) when post-radiation injury was the main etiology involved. For post-surgical events the ASEPSIS wound scoring method and the Southampton scoring system were used (19) and values were recorded before and after treatment. Other assessments included: Pain (using VAS), upper extremities circumference measurement (arm and forearm). Timing of assessment and parameters assessed are shown on *Table 2*.

The study was approved by the Athens Naval Hospital Scientific Committee acting as the Ethics Committee and by the National Kapodistrean University of Athens Bioethics Committee. Besides the signed informed consent given by the patients before entering the study, they were assured of their right to withdraw from it, at any time and without the obligation to give a specific reason, without this decision affecting their overall treatment plan.

Preliminary results

Between January 2020 and May 2024, 22 patients have entered the study. 3 patients were assessed but excluded due to medical reasons and 1 patient although eligible did not provide signed consent after explanation of the treatment process.

Patients are 100% female, representing 23 breasts (one patient was treated after mammoplasty and lift of both breasts-one breast was previously irradiated). Age range: 38 to 65 y.o., average 53,1 y.o.. Of the 22 patients, 18 had been previously irradiated. One patient entered the study but was taken to OR for surgery after 3 sessions and did not return, so end of treatment assessment was not made. Of the rest of the 21 patients, we have TcPO2 values before and after the treatment for all and measurements 2 months after the end of HBOT for 13 of them. 3 were lost to follow-up and 5 of them are pending for the 2 months interval to complete.

Range of HBOT sessions was 10 to 21. Average was 16 sessions and median 20 sessions, pointing to rather good compliance. Deviations from the prescribed protocol of 20 sessions were transportation issues, and patients visiting from outside Athens. One patient ceased treatment after pregnancy diagnosis. On one occasion, scheduled sessions were cancelled due to a diving incident necessitating emergency treatment. No patient experienced HBOT side-effects leading to alteration of treatment schedule. Treatment was uneventful for all patients and proceeded without problems. Almost all patients reported improvement in subjective symptoms at the "suffering" breast e.g. less numbness, elimination of pain, better mobility of upper extremity etc.

Table 2. Parameters assessed across the study

Before HBOT	End of HBOT	2 months after HBOT
Demographics, medical history, smoking, other disease affecting healing, history and management of breast cancer, RT medical report		
Clinical (healing, oedema, infection etc)	Clinical (healing, oedema, infection etc)	Clinical (healing, oedema, infection etc)
Tissue Radiation Injury (RTOG, SOMA_LENT, CTCAE grading) – when applicable	Tissue Radiation Injury (RTOG, SOMA_LENT, CTCAE grading) – when applicable	Tissue Radiation Injury (RTOG, SOMA_LENT, CTCAE grading) – when applicable
Subjective (Pain)	Subjective (Pain)	Subjective (Pain)
UE circumference measurement	UE circumference measurement	UE circumference measurement
TcPO2 measurement – lesion ("suffering") & symmetrical healthy	TcPO2 measurement – lesion ("suffering") & symmetrical healthy	TcPO2 measurement – lesion ("suffering") & symmetrical healthy
Other	Other	Other

COPD = Chronic Obstructive Pulmonary Disease
HBOT = Hyperbaric Oxygen Therapy
RT = Radiation Therapy
RTOG = Radiation Therapy Oncology Group/
SOMA-LENT = Subjective, Objective, Medical management and Analytical evaluation of Late Effects on Normal Tissues
CTCAE = Common Terminology Criteria for Adverse Events
UE = Upper Extremity
TcPO2 = Transcutaneous measurement of Oxygen partial pressure

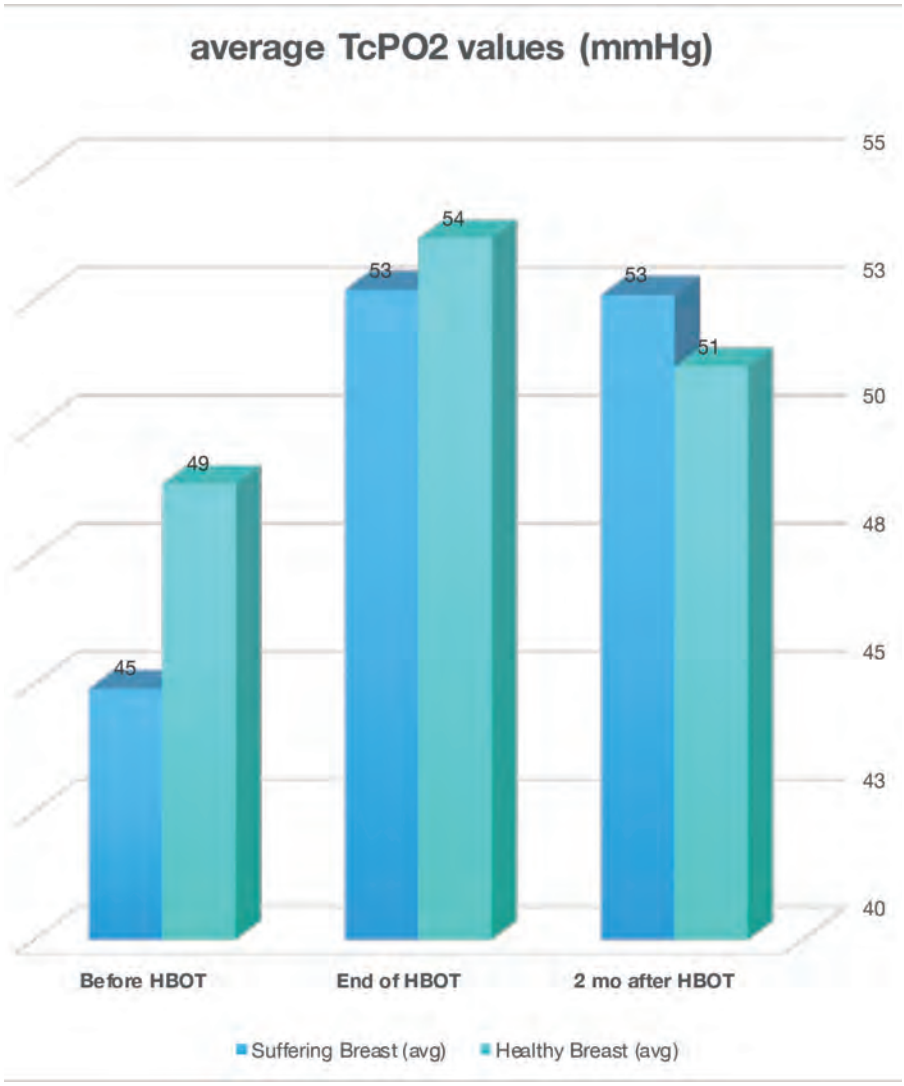

Figure 1. Average TcPO2 values before, after and at 2 months after HBOT

Some of these reports will be analyzed later when results and possible changes in scores of the criteria used in the study are processed. In 2 cases, preexisting fluid collection and oedema shown on breast ultrasound were resolved according to follow-up U/S study. Interestingly, a patient reported clear increase in endurance, among other improvements, judging by fatigue amelioration and time to walk a known distance daily during sessions. No case had diagnosed lymphedema before starting HBOT and initial (before analysis) reading of upper extremities' circumference values before and after treatment doesn't show marked differences.

As for TcPO2 measurement, values on the "suffering" area **before HBOT** were: range 20-80 mmHg, average 44,9 mmHg, median 44 mmHg. On the healthy breast: range 22-79 mmHg, average 48,9 mmHg, median 50 mmHg. **At the end of HBOT** peri-hypoxic TcPO2 values became: range 29-108 mmHg, average 52,7 mmHg (**17% increase**), median 51 mmHg and on the healthy breast: range 28-74 mmHg, average 53,7 mmHg (9,8% increase), median 51 mmHg. Interestingly, the increased oxygen supply at the irradiated/operated breast as shown by TcPO2 was preserved 2 months later: range 34-96 mmHg, average 52,6 mmHg, median 48 mmHg. No further change of the contra-lateral breast TcPO2 values was noted. Graphics from these values are shown on *Figure 1*. Complete results

and thorough statistical analysis will be processed and presented in the future. Patients' recruitment will be concluded in the following few months.

Conclusion

Preliminary results show that HBOT is beneficial when used in breast cancer patients after radiation therapy.

This study targets an area of late effects of radiation on normal tissues that influences morbidity and quality of life for an increasing percentage of the population worldwide. Usefulness of HBOT in reversing radiation damage, although strongly indicated by extended research in other body areas (mandible, bladder) has not been systemically approached and studied in thoracic wall lesions (as a consequence of breast cancer treatment). So, with our results we expect to inform the results of HBOT use for post-radiation thoracic wall injuries. It is important to produce quantitative HBOT benefits for post-radiation injuries following breast cancer treatment and the use of TcPO2 offers this capability. The fact that we have adjusted our equipment for use inside the chamber under hyperbaric conditions gives us the opportunity to produce a database of measurements we can study and maybe relate to the final outcome or even explore its prognostic value, if any.

Relevant to the above, we seek to produce quantitative evidence of HBOT benefits when used before (dealing with irradiated breasts) or after breast reconstruction following breast cancer treatment, similar to the practice used when removing teeth from irradiated jaws.

We plan to extend the study by following-up and comparing long-term effects on aesthetic outcome - complication rate - need for additive operations for our patients.

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After graduating the Military Medical Academy and Medical School of Aristotle University (Thessaloniki) in 1996 he was sworn an officer of the Hellenic Navy. He has graduated from the Naval Medicine school, Aerospace Medicine school and Diving & Hyperbaric Medicine seminar. He was trained and received his SCUBA diving certificate from the Underwater Demolition Unit of the Hellenic Navy and had his first stimuli that attracted him to Hyperbaric Medicine. After becoming a specialist (1999-2005 internship) he served as Consultant to the Department of Hyperbaric & Diving Medicine and since June 2013 he is the Director of the Department. Following institutionalization of Hyperbaric Medicine as Fellowship in Greece (2016) he is Hyperbaric Expert certified by the Hellenic Ministry of Health. He has been teaching in the annual Diving & Hyperbaric Medicine seminar for 25 years and is the Seminar Director since 2010. During his fellowship in Scotland-UK (2003-2005 Prof Phillip James), he was granted the degree of MPH (Master of Public Health) by the UNIVERSITY OF DUNDEE. His dissertation was concerning Hyperbaric Oxygen Therapy (HBOT) and Radiation Therapy either in combination for treatment of cancer or for the treatment of post-radiation injury (Title: Hyperbaric Oxygen – a Review of its Usefulness in Relation to Radiotherapy). From 1999 until 2015 he was a member of the NATO Submarine Escape & Rescue Working Group as National Representative for the Medical Panel. He is involved in the management of the full spectrum of conditions treated by HBOT. In brief, areas of main interest: Decompression Illness (DCI) – Management of diving incidents – Sport Injuries – Diabetic Foot complications (chronic ulcers, infections, ischaemia etc) – Post-Radiation Injury (post-radiation cystitis / proctitis / enteritis / radiation dermatitis, osteoradionecrosis etc) – Chronic Osteomyelitis, Delayed/Nonunion of fractures, Pseudarthrosis, Aseptic Osteonecrosis (avascular necrosis of the bones) – Healing disorders (trauma, chronic ulcers)