

OFFICIAL ORGAN
OF THE



EUROPEAN GROUP OF LYMPHOLOGY
LATIN-MEDITERRANEAN CHAPTER
OF ISL

SOCIETÀ ITALIANA DI LINFANGIOLOGIA
CZECH SOCIETY OF LYMPHOLOGY
ROMANIAN SOCIETY OF LYMPHOLOGY

THE EUROPEAN JOURNAL OF lymphology

and related problems

VOLUME 17 • No. 50 • 2007

INDEXED IN EXCERPTA MEDICA

SUMMARY

EDITORIAL

- Historical record of the GEL

Albert Leduc, Alexandre Pissas

p. 1

CLINICAL SCIENCES

Original articles

- Intermittent pneumatic compression in the treatment of Lymphedema: current state of knowledge

Belgrado J.P., Bourgeois P., Röh N., Moraine J.J.

p. 4

- A new standardized classification tool which measures Lymphedema disability

Michelini S., Failla A., Moneta G., Galluccio A., Risina B.U., Calabrese S., Michelotti L.

p. 11

- Jobst® Elvarex® Soft Seamless: worldwide first flat knit seamless custom-made compression glove

Interview with Ethel Földi

p. 16

- Sonorous waves effect on oedema induced by eccentric contraction in rat skeletal muscle

Gianluca Fulgenzi, Laura Graciotti, Monica Faronato, Fiorenza Orlando, Maurizio Ricci

p. 18

- Management of Lymphoedema: Echo-Colour-Doppler indications for strategies

Marina Cestari, MD

p. 21

- Prevention of Lymphedema following surgery for breast cancer

Boccardo F.M., Michelini S., Eretta C., Pertile D., Da Rin E., Campisi M., Ansaldi F., Icardi G., Campisi Corrado, Bellini C., Campisi Corradino

p. 24

Calendar

SOCIETÀ ITALIANA DI FLEBOLOGIA - 5th MEDITERRANEAN CONGRESS OF PHLEBOLOGY - 28 APRIL / 1 MAY, 2007
PORTO HELY (GREECE)

XXXIII CONGRESS OF EUROPEAN GROUP OF LYMPHOLOGY - MAY 12-13, 2007, PRAGUE (CZECH REPUBLIC)

CONGRESO ARGENTINO DE FLEBOLOGIA - 23 A 25 DE MAYO DEL 2007 - TUCUMÁN (ARGENTINA)

INTERNATIONAL UNION OF PHLEBOLOGY (UIP) - WORLD CONGRESS CHAPTER MEETING - 18 AL 20 DE JUNIO DE 2007
KYOTO (JAPAN)

SOCIETÀ ITALIANA DI FLEBOLINFOLOGIA (SIFL) - V CONGRESSO INTERNAZIONALE DI PHLEBOLOGY - 1-4 LUGLIO 2007
CORFÙ

21st INTERNATIONAL CONGRESS OF LYMPHOLOGY - SEPTEMBER 26-30, 2007, SHANGHAI (CHINA)

UNION INTERNATIONALE DE PHLEBOLOGIE (UIP 50) - 16^o CONGRESSO MONDIALE - AUGUST 31 / SEPTEMBER 2, 2009
GRIMALDI FORUM - PRINCIPATO DI MONACO

p. 29

EDITORIAL

Historique du GEL

Proposé par ALBERT LEDUC et
ALEXANDRE PISSAS

En 1978 lors d'une réunion scientifique organisée à l'Hôpital Universitaire de Grenoble Albert Leduc et Alexandre Pissas après avoir fait connaissance évoquèrent l'éventualité de la création d'une association pour l'étude des lymphatiques dans le cadre d'un groupement de langue française.

La International Society of Lymphology (ISL) existait depuis plusieurs années mais elle tenait ses congrès tous les deux ans dans des régions souvent très éloignées de l'Europe. De plus la langue véhiculaire de l'ISL est strictement limitée à la langue anglaise...

Ces deux arguments ont contribué à prendre la décision de fonder une société européenne dont la langue véhiculaire serait le français avec la possibilité pour les auteurs de communications de s'exprimer dans leur propre langue: anglais, espagnol ou encore italien.

C'est en 1979 qu'une première réunion préparatoire fut organisée, entre quelques collègues et amis, à la Vrije Universiteit Brussel.

Nous avons profité du passage en Europe de Isidoro Caplan pour inviter plusieurs collègues susceptibles d'être intéressées par une telle initiative.

C'est ainsi qu'étaient présents: Bourgeois Pierre, Caplan Isidoro, Hidden Geneviève, Leduc Albert, Lievens Pierre, Pflug Joseph, Pissas Alexandre, Godart Sabine et Theys Serge.

Les statuts d'une société scientifique avaient été préparés par Albert Leduc. Ils furent soumis à discussion et ensuite adoptés à l'unanimité.

Les statuts de la société, tels que nous les connaissons encore aujourd'hui, présentent la particularité de comprendre des membres titulaires ainsi que des membres associés: ces derniers pouvant être titularisés après présentation d'un travail scientifique soumis au jugement des membres titulaires.

Nous avons souhaité, de cette manière créer une société à caractère scientifique susceptible de devenir le creuset de travaux dans le domaine particulier de la Lymphologie.

Le nom de la future société fut suggéré par Alexandre Pissas et c'est ainsi que naquit le «Groupement pour l'Etude des Lymphatiques: GEL».

Sabine Godart demanda de ne pas participer à l'association en qualité de membre fondateur parce qu'elle était déjà membre fondateur de la société internationale de lymphologie (ISL).

Sabine Godart resta toutefois un membre fidèle du GEL et elle participa à toutes nos réunions scientifiques.

Le siège social du GEL fut établi au 103 Laarbeeklaan à 1090 Bruxelles (Faculté de Médecine de la Vrije Universiteit Brussel: service de Motorische Revalidatie).

Historical record of the GEL

Proposed by ALBERT LEDUC and
ALEXANDRE PISSAS

In 1978, at a scientific meeting organized at the University Hospital of Grenoble, Albert Leduc and Alexandre Pissas, after having made each other's acquaintance, evoked the possible creation of a French-speaking association for the study of lymphatics.

The International Society of Lymphology (I.S.L.) had been existing for several years at that time but it organized its congresses every two years in regions often far away from Europe. Moreover, English was its exclusive working language.

These two reasons contributed to our deciding to found a European society. The working language of which should be French but open to the use of other languages such as English, Spanish or Italian if authors wanted to present their papers in their native language.

It was in 1978 that a first preparatory meeting was organized with some colleagues and friends at the Vrije Universiteit Brussel.

We had taken the opportunity of a passing through Europe of Isidoro Caplan to invite several colleagues who might have been interested by this initiative.

Following persons were present: Pierre Bourgeois, Isidoro Caplan, Geneviève Hidden, Albert Leduc, Pierre Lievens, Joseph Pflug, Alexandre Pissas, Sabine Godart and Serge Theys.

The by-laws had been drafted by Albert Leduc. After having been discussed they were adopted unanimously.

The by-laws of the society, which have remained unchanged until today, are particular in so far as they distinguish between full and associate-members, the latter having the possibility to be appointed as full-members after submitting and presenting a scientific work for evaluation by full-members.

By so doing, we wished to create a scientific society which could become the birthplace of studies in the particular field of lymphology.

The name of the society was suggested by Alexandre Pissas and so was born the "Groupement pour l'Etude des lymphatiques: G.E.L."

Sabine Godart requested not to be considered as founding member because she already was founding member of the International Society of Lymphology.

Sabine Godart nevertheless remained a faithful member of the GEL and she took part in all our scientific meetings.

The head office of the GEL was located at 103 Laarbeeklaan, 1090 Brussels (Faculty of Medicine of the Vrije Universiteit Brussel, department of Motor Revalidation).

Albert Leduc fut élu président fondateur du Groupement. Il organisa avec Pierre Lievens la première réunion scientifique du GEL à Bruxelles en 1980. Le GEL fut reconnu par arrêté Royal du 02.12.81.

Les Statuts du Groupement pour l'Etude des Lymphatiques furent publiés dans le Moniteur belge (Journal de l'Etat) le 09.01.82 .

Le GEL était officiellement né.

En 1982, lors de l'assemblée générale qui s'est tenue après le meeting scientifique de Grenoble le nom du GEL fut modifié : tout en conservant les mêmes initiales, l'association devint alors «Groupement Européen de Lymphologie».

Cette modification est parue au Moniteur belge du 21.04.83.

Albert Leduc quitta la présidence du GEL au profit de Geneviève Hidden qui devint ainsi la deuxième présidente du Groupement.

Après une présidence extrêmement appréciée, G. Hidden quitta ses fonctions au profit de Alexandre Pissas.

A. Pissas conservera la présidence pendant plusieurs années. Pierre Bourgeois proposa de créer une revue pour notre société. Il proposa: «The European Journal of Lymphology and related problems» et reçut la responsabilité d'Editeur en Chef.

La première édition de notre revue est parue en mai 1990. P. Bourgeois remplira cette lourde fonction jusqu'à sa désignation à la présidence de notre groupement lors de la réunion de Malmö.

En 1998 Jean Paul Belgrado et Olivier Leduc sont désignés respectivement Trésorier et Secrétaire.

En 2000, l'assemblée générale décide de transférer le siège social du GEL à l'adresse de L'Université Libre de Bruxelles, 50 av. Fr. Roosevelt 1050 Bruxelles service de Kinésithérapie et Réadaptation de A. Leduc.

En 2001, A. Pissas quitte la présidence du Groupement lors de son élection à la présidence de la International Society of Lymphology.

Corradino Campisi succède à A. Pissas, lors du congrès organisé à Porto par le groupe animé par notre vice-président Nuno Grande.

C. Campisi devient ainsi le quatrième président du GEL. Notons également que C. Campisi venait de quitter la présidence de la International Society of Lymphology. Pierre Bourgeois succède à son tour à C. Campisi lors de la réunion organisée à Malmö par Hakan Brorson en 2003.

P. Bourgeois abandonne la fonction d'Editeur en Chef de la revue au profit de Sandro Michelini. Les membres du GEL remercièrent particulièrement Pierre Bourgeois pour le travail accompli.

Le Professeur Joseph Johann Pflug, membre fondateur du GEL nous quitta subitement, à son domicile, en Allemagne le 14.02.05.

En 2005, lors de notre congrès de Rome, la proposition de modifier l'intitulé du GEL en ESL (GEL) (European Society of Lymphology / GEL) est introduite lors de l'assemblée générale.

Albert Leduc was elected as founding president of the GEL. With Pierre Lievens, he organized the first scientific meeting of the GEL in Brussels in 1980.

The GEL achieved legal recognition by Royal decree on 02.12.81.

The by-laws of the Groupement pour l'Etude des Lymphatiques were published in the official Belgian State Journal on 09.01.82.

The GEL was officially born.

In 1982, at the general assembly which was held after the scientific meeting in Grenoble and organized by Alexandre Pissas, the name of the GEL was modified: albeit with unchanged initials, the association became "Groupement Européen de Lymphologie".

This amendment was published in the Belgian State journal dated 21.04.83.

Albert Leduc left the presidency of the GEL and was succeeded by Geneviève Hidden who hence became the second president of the group.

After her highly appreciated presidency, G. Hidden left her function over to Alexandre Pissas.

A. Pissas will remain chairman for several years.

In his turn, he quits the presidency of the Group after having been elected as chairman of the International Society of Lymphology.

The first editing of our Journal was in May 1990. Pierre Bourgeois holds this ponderous office up to his designation to the g.e.l. Presidency in occasion of the Congress of Malmö.

In 1998 both Jean Paul Belgrado and Olivier Leduc were elected respectively treasurer and secretary.

In 2000, the general assembly decides the transfer of the headquarters to the address of the Université Libre de Bruxelles, 50 av. Fr. Roosevelt, 1050 Brussels, Service de Kinésithérapie et Réadaptation.

In 2001 A. Pissas resigned as President of G.E.L. because he was elected President of the International Society of Lymphology.

Corradino Campisi succeeded Alexandre Pissas in 2001, during our congress organized in Porto by the group around our vice-president Nuno Grande.

C. Campisi accordingly became the fourth president of the GEL. It is worthy of note that C. Campisi had just quitted the presidency of the International Society of Lymphology. It was Pierre Bourgeois' turn to take over the succession of C. Campisi during the meeting organized in Malmö by Hakan Brorson in 2003.

Sandro Michelini was elected editor in chief.

The GEL members very much appreciate all the work accomplished by P. Bourgeois to make the journal successful.

On the 14th of February 2005, Professor Joseph Johann Pflug, founder member of GEL, passed away suddenly at his home in Germany.

In 2005, during our congress in Rome, a proposal is introduced to substitute E.S.L./ G.E.L., (initialization of European Society of Lymphology), at the general assembly.

*En 2006, cette modification est votée à Hinterzarten lors de notre meeting organisé par E. Földi
Pierre Bourgeois quitte à son tour la présidence. Sandro Michelin lui succède.
Au cours de la même réunion, Francesco Boccardo est élu Editeur en Chef de la revue.*

This modification is approved by vote during the meeting organized by E. Földi in Hinterzarten in 2006.
Pierre Bourgeois left the presidency of the society and was succeeded by Sandro Michelin.
Francesco Boccardo was elected as editor in chief of the journal.

Liste des congrès GEL / Listing of the GEL meetings

Date	Lieu / Local	Organizer
1980: 1 ^{er} congrès	Bruxelles	A. Leduc / P. Lievens
1981: 2 ^{ème} congrès	Paris	G. Hidden
1982: 3 ^{ème} congrès	Grenoble	A. Franco
1983: 4 ^{ème} congrès	Freiburg	E. / M. Foeldi
1984: 5 ^{ème} congrès	Bruxelles	A. Leduc / P. Lievens
1985: 6 ^{ème} congrès	Oporto	N. Grande
1986: 7 ^{ème} congrès	Nimes-Montpellier	A. Pissas
1987: 8 ^{ème} congrès	Bruxelles	A. Leduc / P. Lievens
1988: 9 ^{ème} congrès	Grenoble	A. Franco
1988: 10 ^{ème} congrès	Oxford	BLS
1989: 11 ^{ème} congrès	Genova	C. Campisi
1990: 12 ^{ème} congrès	Coimbra	N. Canha / R. Branco
1990: 13 ^{ème} congrès	Mont-Godinne	M. Clerin / J.C. Schoevarchts
1991: 14 ^{ème} congrès	Munchen	R. Baumeister
1992: 15 ^{ème} congrès	Oporto	N. Grande
1992: 16 ^{ème} congrès	Praha	O. Eliska
1993: 17 ^{ème} congrès	Milano	U. Fox
1994: 18 ^{ème} congrès	Bruxelles	A. Leduc / P. Lievens
1994: 19 ^{ème} congrès	San Sebastian	E. Samaniego
1995: 20 ^{ème} congrès	Hinterzarten	E. / M. Foeldi
1996: 21 ^{ème} congrès	Roma	S. Michelini / C. Campisi
1996: 22 ^{ème} congrès	Paris	A. Behar
1997: 23 ^{ème} congrès	Montpellier	A. Pissas
1998: 24 ^{ème} congrès	Castellabate	G. Brachiale
1999: 25 ^{ème} congrès	Thessalonica	D. Kiskinis
2000: 26 ^{ème} congrès	Nancy	G. Thibault
2001: 27 ^{ème} congrès	Oporto	N. Grande
2002: 28 ^{ème} congrès	Milano	M. Sigari
2003: 29 ^{ème} congrès	Malmö	H. Brorson
2004: 30 ^{ème} congrès	Bruxelles	O. Leduc / J.C. Wautrecht
2005: 31 ^{ème} congrès	Roma	S. Michelini
2006: 32 ^{ème} congrès	Hinterzarten	E. Foeldi

INTERMITTENT PNEUMATIC COMPRESSION IN THE TREATMENT OF LYMPHEDEMA: CURRENT STATE OF KNOWLEDGE

JP BELGRADO¹, P BOURGEOIS², N RÖH³, JJ MORAINÉ¹

¹ Université Libre de Bruxelles - Belgium

² C.H.U. J. Bordet – Université libre de Bruxelles

³ European Medical Center - Bruxelles

Corresponding Author: JP Belgrado
Université Libre de Bruxelles
CP 168 Av. FD. Roosevelt,50
1050 Bruxelles
Belgium
e-mail belgrado@ulb.ac.be

A. INTRODUCTION

Intermittent pneumatic compression (IPC) is often suggested in the field of physical treatment of primary and secondary lymphedema. The most basic definition of the IPC is that it consists in the application of a force on an edema in order to evacuate its components as much as possible towards the physiological ways of drainage: venous – lymphatics - interstitium.

To build up this force, different systems have been proposed: Tubing (Van der Molen)⁽¹⁾, coupled sphygmo-manometer (Theys)⁽²⁾, jet stream, compressive ring (Pflug ring), Mercury bath immersion (Cartier)⁽³⁾, and vacuum pump⁽⁴⁾.

Actually the main devices are pneumatic systems controlled by software included in a microchip that controls the pump, the valves and the sequences.

Generally the pressure receiver, controlling the pressure's feed back, is placed inside of the system in a buffer, and located before the out valves.

When the valve (s) is/are open the air inflates a garment composed by one to twenty-four chambers at the target pressure. When the inflating programming sequence is finished all the chambers deflate and the cycle restarts after a programmed delay.

There are mainly three positions amongst professionals regarding IPC: Those who refuse to use this device, those who integrate it into a multi therapeutic approach⁽⁵⁾ MLD, multilayered bandaging, exercises... and those who make of it their main therapeutic spearhead.

The International Consensus document published by the International Society of Lymphology considers IPC as adjuvant therapy, usually applied to maintain reduction after a complete decongestive therapy⁽⁶⁾.

Furthermore, no consensus has been attained among the users concerning the appropriate protocol of IPC. Some authors advise

the use of IPC for half an hour, others for one or three hours and even some propose it for up to 48 hours⁽⁷⁾.

The same discordance exists about the pressure's value that has to be applied on the swollen limb: the range starts from 30mmHg, 50mmHg, 90mmHg⁽⁸⁾ up to much higher pressures that authors describe as "*so far as the patient tolerates*"...!

Because of the multifaceted aetiology of lymphedema it seems logical that the application of IPC must be adapted to specific cases. However, despite the widely accepted use of IPC, exact physiological mechanisms of action remain to be identified⁽⁹⁾. IPC is known to provide effective prophylaxis against post-surgical deep-vein thrombosis: IPC appears to lead to a significant increase in global fibrinolytic potential⁽¹⁰⁾.

A Cochrane review on IPC for treating venous leg ulcers concluded that there is no strong evidence about the effects of IPC on leg ulcers⁽¹¹⁾.

There exists no specific Cochrane review, however, regarding the use of IPC in the treatment of secondary or primary lymphedema. Considering this lack of information and the existence of so many different points of view, based on our clinical and laboratory experiences, we decided to undertake an overview of the current state of knowledge concerning the use of IPC in the treatment of primary and secondary lymphedema.

B. OBJECTIVES

Overall objective: to review the available evidence concerning the efficiency of IPC in the physical treatment of lymphedema.

Specific queries (fundamental knowledge)

- (1) Is IPC alone more effective than multilayered bandaging and/or MLD, or may it contribute to improving these techniques?

- (2) Does IPC treatment mobilize the proteic part of the lymphedema?
- (3) If not, does IPC used alone increase insidiously the fibrosis of the lymphedema?
- (4) IPC is effective, what is an optimal regimen in terms of inflating and deflating time, target pressure, gradient of pressure, period and duration of compression delivered using IPC devices.
- (5) IPC is effective, what are the contra-indications and side effects? Are there any risks for the patients if some IPC parameters are exceeded such as pressure, treatment duration...?
- (6) From a technical point of view, does the indicated pressure on the device correspond to the real pressure on the patient's skin? If not can we improve this technology?

C. METHOD AND SEARCH STRATEGY

We divided the research of documents into two parts:

A – Fundamental studies;

B – Randomised clinical trials.

We have covered literature in: English- French-German and Italian.

C.1. Fundamental study - (A)

We searched for available literature on IPC in journals and relevant conference proceedings and on the web.

Including criteria were:

- Studies which analyse the technical point of view and physiological effects of IPC, such as hemodynamic effects, capability to allow the extraction of an injected radio-colloid, control of pressure, shifting of the edema, and also its side effects...
- Studies which use methodology and measurement systems that are clearly defined.

C.2. Randomised clinical trials (RCTs) - (B)

We searched for RCTs about IPC exclusively for primary or secondary lymphedema: in journals and relevant conference proceedings - on the web and especially on the AIK info web site ⁽¹²⁾ which is the most complete data base about IPC.

RCTs including criteria were:

- RCTs either comparing IPC with a control group (sham IPC or no IPC), with MLD or with multilayered bandaging.
- RCTs separating primary from secondary lymphedema.
- RCTs including at least 20 patients.
- RCTs measuring the reduction of limb swelling and describing the measuring method and material.
- RCTs describing correctly the parameter of the IPC – such as target pressure, number of chambers, duration of compression...

D. RESULTS FOR THE REVIEW – A

D.1. Evacuation of the liquid phase and reabsorption of stagnant proteins from the interstitium.

- The capacity to lead to an increased venous flow velocity has been confirmed by several studies ⁽¹³⁾ using plethysmography and echo Doppler and Shwan-Ganz catheter ⁽¹⁴⁾.
- Hidden & al. ⁽¹⁵⁾ demonstrated on human anatomical model injected with blue dye that the colorant is propelled through the lymphatics while the limb is placed inside of a working IPC garment.
- Partch & al., Baulieu & al. suggested that IPC facilitated radiocolloid transport in the proximal portion of the limb and also propelled tracer from the injection site toward the lymphatics ^(16, 17, 18).
- Leduc & al. in a similar study comparing a monochamber IPC vs a 5 chambers IPC confirm that IPC push the lymphatic vessels contents towards the lymph nodes, but did not find any evidence of the reabsorption of the injected labelled proteins, ^(19, 20).
- Miranda & al. confirm this last study and conclude the paper suggesting that “*IPC increased transport of lymph fluid (i.e., water) without comparable transport of macromolecules (i.e., protein)*” ⁽²¹⁾.
- Skin mobilization associated to IPC has no more effect on the reabsorption of the injected labelled proteins ⁽²²⁾.

D.2. Effects of the IPC on microcirculation

Authors report that IPC (monochamber) “*induces a significant increase of the oxygen tension compared to a control group*” ⁽²³⁾.

LASER Doppler helps to point out that microcirculation flux under IPC during the inflating phase increases up to 39% compared to the basal flux without IPC ⁽²⁴⁾.

D.3. Use and efficiency of IPC

Authors have proposed to educate patients to use IPC on their own at home when there was no trained physiotherapist available. They conclude that 90% of the patients were satisfied of their results ⁽²⁵⁾. Regarding the efficiency of IPC vs MLD, IPC has a limited clinical role in the treatment of post-mastectomy lymphedema ⁽²⁶⁾ and it seems that there is no significant difference on the reduction of the volume of the edema between MLD and IPC ⁽²⁷⁾.

D.4. Technical point of view

- Multichamber or monochamber IPC garments

Some authors did not find any statistical difference in the reduction of the lymphedema volume when IPC was applied with a mono chamber or multichamber garment, at any level, even when the compression time was not considered ^(28, 19).

Other authors found a difference in the reduction of the volume of the lymphedema comparing a mono chamber garment 0.4 % vs a three chamber garment 7,3% vs a 10 chamber 32% ⁽²⁹⁾.

- IPC device generating a gradient pressure or not

Only one study was found reporting about a permanent edema reduction with uniform pressure IPC but not with differentiated pneumatic massage ⁽³⁰⁾.

- Comparing technology : pneumatic compression, mercury bath, Pflug ring, vacuum compression, IPC by fragmentation

We have not found any study comparing those technologies.

- Control of the pressure

To our knowledge only two studies compared pressure values shown by IPC devices with the real pressures exerted by the inflated garment on the limb. It is indisputable that IPC devices show systematically pressure values that are largely inferior to the reality^(31, 22).

D.5. Side effects of IPC

Using Shwan-Ganz catheters Leduc, Dereppe & al.^(14, 32) demonstrated that IPC applied simultaneously on both legs, patients in a supine position, with a target pressure fixed at 80 mmHg (real pressure on the limbs +/- 160mmHg)⁽³³⁾, the right auricular pressure (RAP), the mean pulmonary arterial pressure (MPAP) and the pulmonary wedge pressure (PWP) reach critical values: RAP: from 3.6 +/- 5 to 7 +/- 7 mm Hg (P 0.001), MPAP: from 25 +/- 14 to 29 +/- 17 mm Hg (p 0.01) and the PWP from 10 +/- 8 to 17 +/- 11 Hg (p 0.01) That was the only study we found on the effect of the IPC on cardiac hemodynamic parameters.

Faila & al. in a review on their experience about IPC in the physical treatment for lymphedema (24), write that sometimes they had to stop the IPC session *“because of increased systo-diastolic parameters”*.

We didn't find any references published by insurances or any other official administration about accidents relative to a misuse of the IPC.

Hassall & al. wrote in a retrospective study using IPC in a paediatric population, *“there was a clinical trend towards reduction or maintenance of the lymphedematous limb size in children using IPC without notable adverse sequelae”*⁽³⁴⁾.

Others warn and refer contraindications and precautions that must be taken into account in order to avoid damage to the soft tissue.⁽³⁵⁾

Eliska & al.⁽³⁶⁾ warn against the possible damage of the lymphatic's endothelium when it is submitted at a pressure up to 60 mmHg.

Specific studies on nephritic or arterial diseases related with IPC are not described in the analysed literature.

Concerning the “pushing” of the edema by IPC towards the interstitium reaching the root of the lower limb, Boris M & al. warn of against the risk for genital edema - *“Of the 75 who did not use pump compression, only 2 had genital edema. Of the 53 patients who used pump compression, 23 patients developed genital edema after pump therapy (p < 0001). The incidence of genital edema was unaffected by age, sex, grade or duration of lymphedema, whether lymphedema was primary or secondary, whether a single or sequential pump was used, the pressure level applied, or duration or hours per day of pump therapy. Compressive pump therapy for lower limb lymphedema produces an unacceptably high incidence of genital edema...”*⁽³⁷⁾.

E. RESULTS FOR THE REVIEW – B

- Only three randomised controlled trials approaching the including criteria were identified^(27, 38, 39). They are small trials (max 30 patients) with women, treated for secondary lymphedema after breast cancer. All of them compare IPC with MLD

E.1.RTCs N.1

Study	Szuba A, Achalu R, Rockson SG	2002
Objectives	To investigate the relative efficacy of IPC when used adjunctively with compression bandaging & MLD	
Population	27 patients (divided in 2 groups) with breast carcinamo-associated lymphedema with an increased volume of the swollen limb ≥ 20%	
Methods	Patients were randomized either to DLT alone or to DLT coupled with daily IPC	
Items observed	Volume reduction by water displacement - Tonometry - Goniometry	
Outcomes	When IPC is used adjunctively with other, established elements of DLT, it provides an enhancement of the therapeutic response. IPC is well tolerated and remarkably free of complications	
Remarks	It is not clear if two groups received exactly the same treatment with and without IPC ... “Patients were randomized to one of two treatment groups. In group I, IPC (30 min. At 30-50 mmHg) was performed daily after MLD & before compression bandaging. Patients in group II received standard, initial, decongestive therapy without the adjunctive IPC”	

E.2.RTCs N.2

Study	Johansson K, Lie E, Ekdahl C, Lindfeldt J.
Objectives	Compared manual lymph drainage (MLD) with sequential pneumatic compression
Population	28 women previously treated for breast cancer
Methods	Each patient was randomly assigned to either one of two treatment regimens (Part II). MLD was performed according to the Vodder technique for 45 min/day and SPC was performed with a pressure of 40-60 mmHg for 2 hours/day. Both treatments were carried out for 2 weeks
Items observed	Arm volume was measured by water displacement
Outcomes	MLD and SPC each significantly decreased arm volume but no significant difference was detected between the two treatment methods

E.3.RTCs N.3

Study	Skall H, Haedersdal C, Winkel A, Gilberg L, Sanderhoff J, Nielsen H, Mogensen H
Objectives	To compare the effects of manual lymph drainage therapy versus sequential pneumatic compression therapy
Population	30 women with lymphedema after breast carcinoma surgery
Methods	The study was done as a randomized, clinically controlled trial. The women were treated for 5 weeks with either (group A) Manual Lymph Drainage (MLD) or (group B) Sequential Pneumatic Compression (SPC). Measures were taken 4 times: at baseline and followed up at 1, 3 and 12 months
Items observed	Edema reduction and self-reported health status (SF-36)
Outcomes	After 1 year there is a trend in favour of MLD, but no statistically significant difference between MLD and SPC
Remarks	This study is not published in the proceeding of the referenced congress. The method of the volume measurement is not described

- We have not found RCTs regarding primary lymphedema.

F. DISCUSSION

F.1. Discussion concerning the review – A

F.1.1. Evacuation of the liquid phase and reabsorption of stagnant proteins from the interstitium

The displacement of a part of the liquid phase of a lymphedema through the venous network using IPC seems established^(13, 14, 21...). IPC increases the fluid reabsorption from interstitium to the venous network and accelerates its flow. Another part of the edema's fluid ascends towards the interstitium towards the subcutaneous space to joint the limb's root⁽³⁷⁾. As soon as the patient gets back into the vertical position, those liquids flow down slowly and "rehydrate" the stagnant proteins of the edema.

Volumetric measures by water displacement – as used generally in studies – are not taken until the root of the limb because of technical difficulties. Thus the classical volumetric measures do not consider the displaced liquid at the root of the limb.

Moreover, we were amazed not to find any detailed description of the applied measuring method and its validity, especially when it

is known that there is a systematic error of 10% on volumetric measures⁽⁴⁰⁾. Only special measuring systems allow to reach a precision of 1%⁽⁴¹⁾.

On the other hand, perimetric measures of the whole limb are able to include the geometric changes at the limb's root. Their precision reaches around 3%.

Also, it might be interesting to precise that some publications praise fabulous volume reductions of edematous limbs by IPC at high pressure in only one session. The announced displaced volume would increase the cardiac output. Fortunately a part of this fluid has only been moved to the limb's root, but this area was not measured (see upper). Some more studies would be helpful to clarify the issue.

F.1.2. Reabsorption and transport of stagnant proteins in the interstitial compartment

We have to consider two phenomenons: first, the passage of the macromolecules and fluid from the interstitium into the initial lymphatics (reabsorption phenomenon) and second, the transport^(16, 17, 18, 19, 20, 21, 22), of the lymph fluid through the lymph vessels.

After a detailed analysis of the selected studies and their methodology, it seems that the IPC facilitates only the transport in the lymphatics of the immediately absorbed fraction of injected radio colloid.

The fraction of colloid that penetrated into the lymphatic vessels, entered physiologically, immediately after the injection due to the pressure of the injection and to the tissular pressure; more particularly when the injection remains intradermic.

Consequently, IPC does neither facilitate the reabsorption^(19, 20, 21, 22) of the radio colloid into the initial lymphatics, nor it is efficient to evacuate the proteic part of a lymphedema.

It might be explained by the high pressure (30mmHg up to 160mmHg) of the inflating garment squeezing the lymphatic network... or by the direction of the compression forces on the limb that is perpendicular instead of being tangential to promote reabsorption by stretching of the Leak filaments as in the MLD.

In earlier studies⁽²²⁾ we have tried to pull the Leak filaments provoking the skin's mobilization under IPC by uncompleted electromyostimulation (EMS) and voluntary muscle contractions. Moreover we have controlled the modalities of the injected solution. It appeared that an injection made strictly in the subcutaneous space ICP, even combined with EMS, does help neither transport nor reabsorption of proteins concentrated in the subcutaneous tissue (where the lymphedema is located).

When the injection was made strictly in the dermal space (where the lymph stasis provokes the dermal backflow) the radio colloid penetrated immediately into the lymphvessels under the effect of the tissular pressure and its progression was facilitated by IPC towards the lymphatics.

MLD has yet demonstrated its capacity to favour the reabsorption and transport of macromolecules towards lymph vessels^(42,43).

Of course MLD drains also a small quantity of fluid. But knowing that some proteins can carry up to 20 times their weight by fixing water molecules, it is important to focus the treatment of lymphedema on the reabsorption and transport of the proteins.

F.1.3. Pressure value

First of all it is important to highlight that the pressure indicated by the manometer of IPC devices is never the real pressure compressing the limb. Studies using pressure receivers placed at the interface between the skin and the garment demonstrated that real pressure on the limb is systematically superior and reaches often the double of the target pressure. That is due to the geometry of the limb, the quality of the garments, the law of Laplace and the economic conception of the devices.

This fact has physiological consequences: when the garments are placed on both legs and the patient's supine. When the target pressure is fixed e.g. at 80mmHg, the real pressure reaches more or less 160mmHg. At these pressure values, the whole superficial vascular system and the lymphatics are squeezed, as if a long tourniquet was placed on both legs provoking well known hemodynamic consequences for heart and vessels.

Fortunately this special tourniquet is... intermittent. This point of view is contradicted by Theys in a preliminary study using plethysmography⁽⁴⁴⁾.

Furthermore, even when lower pressures (30mmHg) are programmed on IPC devices, the limb is submitted in reality to pressures reaching 60mmHg.

Compared to MLD the pressure developed by the hand of a trained physiotherapist produces a pressure on the skin not more than 4mmhg⁽³³⁾ and the direction of the strain forces are tangential.

The hand of a trained physiotherapist who drained a limb by MLD produce a pressure on the skin not over than 4mmhg. And this techniques of manual massage has demonstrated its efficiency to reduce lymphedema notably by its capacity of reabsorption of the macromolecules of the interstitium into the lymph vessels^(42, 43).

F.2. Discussion concerning the review – B

It is strange to find only so few RCTs studies with so few enrolled patients for such a common pathology.

Nevertheless they have the merit to exist and to open the way for new studies made on a larger scale.

Multi centric RCTs studies with standardized treatment protocols and measurement protocols would help the clarify the issue

G. CONCLUSIONS

- Generally, samples of the studies are so small, and the measurement errors are so seldom taken into account that statistical analyses are questionable.
- Items observed in the studies are so different that it is nearly impossible to compare them.
- There is no evidence base to use IPC in the treatment of primary or secondary lymphedema
- Nevertheless it seems that the role of IPC is to move the liquid part, but not the proteic part of the lymphedema.
- The use of IPC appears to be less inoffensive than thought. In any case, IPC should not be proposed as the spearhead for lymphedema treatment.
- Trying to substitute MLD by IPC or vice versa is not scientifically based, study their own physiological effects seems more useful.
- More studies are necessary to improve the efficiency and to establish guidelines and protocols for a safe use of IPC.
- IPC devices still have technologic shortcomings that could be resolved by a good dialogue with producers.
- It is not relevant to concentrate on the question if MLD is more efficient than IPC, because of the great difference of their physical parameters and physiological effects, but what matter is to determinate the role of each technique to improve the physical treatment of lymphedema.

H. REFERENCES

- Gruffaz J. *La méthode de Van der Molen dans le traitement des lymphoedèmes des membres inférieurs*. Pr. Méd., 76: 1059-1061.
- Theys S, Legrand C, Vandenbroeck N, Clerin M, Schoevaerdt JC. *La pressothérapie intermittente par fragmentation appliquée en seconde intention: résultats cliniques sur des oedèmes du membre supérieur*. Ann. Kinésithér., t. 17, n. 7-8, pp. 355-357, 1990.
- Cartier JC. *Pressothérapie par bain de mercure dans le traitement des lymphoedèmes et de la pathologie de la circulation de retour des membres*. Ann. Kinésithér., t. 16, n. 4, pp. 175-180, 1989.
- Pitr K, Prucha J, Zabran J, Zahlava. *Vacuum-compression therapy Hemodynamic therapeutic-rehabilitation method in the light of five years of research and experience*. Embitron electromedical equipment, Plzen, Czech Republic.
- Leduc O, Leduc A, Bourgeois P, Belgrado JP. *The physical treatment of upper limb edema*. Cancer 1998 Dec 15; 83 (12 Suppl. American): 2835-9.
- International Society of Lymphology (ISL). *The diagnosis and Treatment of Pheriperal Lymphedema. Consensus document*. Lymphology 36, (2003), 84-91.
- Klein MJ, Alexander MA, Wright JM, Redmond CK, LeGasse AA. *Treatment of adult lower extremity lymphedema with the Wright linear pump: Statistical analysis of a clinical trail*. Arch Phys Med Rehabil 1988 Mar; 69(3 Pt 1): 202-6.
- Theys S, Deltombe T, Jamart J, Schoevaerdt J-C, Buche M. A 30 or 90 mmhg – manual or pneumatic – drainage in primary limb lymphedema: a comparative plethysmographic study. The European Journal of Lymphology, Vol. XII; Nr. 41, Sp. Co 1.2004-3.
- Chen AH, Frangos SG, Kilaru S, Sumpio BE. *Intermittent pneumatic compression devices - physiological mechanisms of actions*. Eur J Vasc Endovasc Surg 2001 May; 21(5): 383-92.
- Giddings JC, Morris RJ, Ralis HM, Jennings GM, Davies DA, Woodcock JP. *Systemic haemostasis after intermittent pneumatic compression - Clues for the investigation of DVT prophylaxis and travellers thrombosis*. Clin Lab Haematol. 2004 Aug; 26(4): 269-73.
- Mani R, Vowden K, Nelson EA. *Intermittent pneumatic compression for treating venous leg ulcers*. The Cochrane Database of Systematic Reviews 2001, Issue 4. Art. No.: CD001899. DOI: 10.1002/14651858.CD001899.
- <http://www.aik-info.de>
- Delis KT, Husmann MJ, Szendro G, Peters NS, Wolfe JH, Mansfield AO. *Haemodynamic effect of intermittent pneumatic compression of the leg after infrainguinal arterial bypass grafting*. Br. J Surg. 2004 Apr; 91(4): 429-34.
- Leduc O, Dereppe H, Hoylaerts M, Renard M, Bernard R. *Hemodynamic effects of pressotherapy - Prograss in lymphology*. Elsevier science publishers B. V. 1990; p. 431-4.
- Hidden G, Guedj R. *Pressothérapie: Validation des manoeuvres d'appel et de résorption sur le cadavre humain*. Ann. Kinésithér., t. 17- n. 7-8, pp. 358-359, 1990.
- Baulieu F, Baulieu JL, Vaillant L, Secchi V, Barsotti J. *Factorial analysis in radionuclide lymphography: assessment of the effects of sequential pneumatic compression*. Lymphology 1989 Dec; 22(4): 178-85.
- Partsch H, Mostbeck A, Leitner G. *Experimentelle Untersuchungen zur Wirkung einer Druckwellenmassage beim Lymphödem*. Phlebol. u. Proktol. 9: 124-128 (1980).
- Partsh H, Mastbeck G, Leitner G. *Experimental investigations on the effect of a pressure wave massage apparatus (Lympha Press®) in Lymphedema*. Phlebologie und Proktologie, Vol. 2/80, May 1980.
- Leduc A, Bastin R, Bourgeois P. *Lymphatic reabsorption of proteins and pressotherapies*. Progress in Lymphology. XI. 1988.
- Leduc A, Geysels Y. *Approche expérimentale de l'influence de la pressothérapie sur la résorption lymphatique*. Lympho-Infor, n. 2, 1986.
- Miranda F Jr, Perez MC, Castiglioni ML, Juliano Y, Amorim JE, Nakano LC, de Barros N Jr, Lustre WG, Burihan E. - *Effect of sequential intermittent pneumatic compression on both leg lymphedema volume and on lymph transport as semi-quantitatively evaluated by lymphoscintigraphy*. Lymphology, 2001 Sep; 34(3): 135-41.
- Belgrado J-P, Bourgeois P, Brack C, Leduc O, Leduc A. *Electromyostimulation combined with intermittent pneumatic compression*. European Journal of Lymphology and related Problems, 2005; Vol. 15, n. 45:17-21.
- Stahler J, Zabel M. *Transkutane pO₂-Messung vor und nach intermittierender apparativer Kompressionstherapie*. Sonderheft Kompressionstherapie vasomed Sept. 96 8. Jahrg. 293-5.
- Failla A, Moneta G, Santoro A, Tenan L, Domonici N, Michelini S. *Impiego della pressoterapia sequenziale nel trattamento delle linfostasi primarie e secondarie degli arti: nostra esperienza*. Linfologia oggi, p 16-19, n. 3/2002.
- Pecking AP, Cluzan RV. *Results of a self sequential pressotherapy as a substitute for classical - decongestive therapy in a group of patients with a refractory upper limb lymphedema*. XIX International Congress of Lymphology, 01-06 Sept. 2003, Freiburg/Germany.
- Dini D, Del Mastro L, Gozza A, Lionetto R, Garrone O, Forno G, Vidili G, Bertelli G, Venturini M. *The role of pneumatic compression in the treatment of postmastectomy lymphedema. A randomized phase III study*. Ann Oncol. 1998 Feb; 9(2): 187-90.
- Johansson K, Lie E, Ekdahl C, Lindfeldt J. *A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema*. Lymphology 1998 Jun; 31(2): 56-64.
- Risto T, Pohjola MD, Kalle Pekannmäki MD, Ph.D., Pertfi J. Kolari, M.Sc. *Intermittent pneumatic compression of lymphedema: valuation of two clinical methods*. E.J.L.R.P., Vol. 5, Nr 19, 1995; 87-90.
- Bergan JJ, Sparks S, Angle N. *A comparison of compression pumps in the treatment of lymphedema*. Vasc. Surg., Vol. 32, 455-462, 1998.

30. Zanolla R, Monzeglio C, Balzarini A, Martino G. *Evaluation of the results of three different methods of postmastectomy lymphedema treatment.* J Surg Oncol 1984 Jul; 26(3): 210-3.
31. Leduc O, Belgrado J-P, Moens R, Leduc A. *Intermittent sequential pneumatic compression (I.S.P.C.) from the device to the patient.* Progress in Lymphology, XVI, p 227-220, September 1997.
32. Dereppe H, Hoylaerts M, Renard M, Leduc O, Bernard R, Leduc A. *Hemodynamic impact of pressothérapie.* J Mal Vasc. 1990; 15(3): 267-9.
33. Segers P, Belgrado JP, Leduc A, Leduc O, Verdonck. *Excessive pressure in multichambered cuffs used for sequential compression therapy.* Phys Ther. 2002 Oct; 82(10): 1000-8.
34. Hassall A, Graveline C, Hilliard P. *A retrospective study of the effects of Lymphapress pump on lymphedema in a pediatric population.* Lymphology 2001 Dec; 34(4): 156-65.
35. Herpertz U. *Apparative intermittierende Kompression Ein Plädoyer für den gezielten Einsatz von Kompressionsgeräten.* Lymph Forsch 7(1) 2003; 30-1.
36. Eliska O, Eliskova M. *Are peripheral lymphatic damaged by high pressure manual massage?* Lymphology 1995; 2: 21-30.
37. Boris M, Weindorf S, Lasinski BB. *The risk of genital edema after external pump compression for lower limb lymphedema.* - Lymphology 1998 Mar; 31(1): 15-20.
38. Skall H, Haedersdal C, Winkel A, Gilberg L, Sanderhoff J, Nielsen H, Mogensen H. *Manual lymphdrainage compared with sequential pneumatic compression, evaluated by volumetrical and scintigraphical techniques and by health survey SF-36 - XIX International Congress of Lymphology 01-06 Sept. 2003 Freiburg/Germany.*
39. Szuba A, Achalu R, Rockson SG. *Decongestive lymphatic therapy for patients with breast carcinoma-associated lymphedema. A randomized, prospective study of a role for adjunctive pneumatic.*
40. Lefevre Ph., Lewillie L, Rooze M, Sporcq J. *Methodological approach of the measurement of the hand volume with an ordinary device.* Cahier d'Anthropologie et de Biométrie Humaine XIV, n. 3-4, p. 427-438, 1996.
41. Lefevre Ph., Leduc B, Carlens D, Mannaert G, Rooze M. *Ajustment of a volumetric device. Application to the hand volume.* Biom. Hum & Anthropol. 2000; 18, 1-2 p. 101-107.
42. Leduc O, Bourgeois P, Leduc A. *Manual lymphatic drainage: scintigraphic demonstration of its efficacy on colloidal protein reabsorption.* Progress in Lymphology XI. P. Ed. Excerpta Medica 1988.
43. Ferrandez JC, Vinot JM, Serin D. *Evaluation comparative lymphoscintigraphique du drainage lymphatique manuel et de la pressothérapie sur l'œdème du membre supérieur secondaire au traitement d'une tumeur mammaire.* Ann. De Kinésithérapie t17, n. 7-8, pp. 360-362, Masson Paris, 1990.
44. Theys S, Fourneau M, Schoevaerdt JC, Clerin M. *Objectivation pléthysmographique de la pressothérapie par fragmentation dans les œdèmes des membres inférieurs. Étude préliminaire.*

A NEW STANDARDIZED CLASSIFICATION TOOL WHICH MEASURES LYMPHEDEMA DISABILITY

MICHELINI S.* , FAILLA A.* , MONETA G.* , GALLUCCIO A.* , RISINA B.U.** , CALABRESE S.** , MICHELOTTI L.**

* San Giovanni Battista Hospital - Acismom - Rome - Italy

** Rehabilitative Centre Vaclav Vojta - Rome - Italy

ABSTRACT

The more commonly used classification tools that indicate the parameters of the disability of an individual contain scores that aren't pertinent to the description of the disabling vascular pathologies, among which primary and secondary lymphedema. For these reasons the authors, in compliance with the recommendations of the World Health Organization, have adopted the International Classification of Functioning (I.C.F.) in their daily practice in the definition of the single clinical cases of lymphedema of the upper and lower limb.

KEY WORDS: lymphedema disability, classification.

INTRODUCTION

The standard disability scales that are usually used in clinical practice (Barthel, FIM, SMWT, etc.) are too generic and don't have the specifics that can give an adequate clinical picture of lymphedema. The International Classification of Functioning scale (I.C.F.), that recently has been adopted in clinical practice (even though still not utilized on a large scale basis) is proving itself to be a valid and efficient clinical tool which analyses the needs of a disabled person in a more global context. It transforms the limited "medical model" (based on the simple listing of the physical impairments) to a more sophisticated multidimensional approach – "bio-psycho-social model" – that not only evaluates the bodily biological damage (codes preceded by the letter *s*) and of the bodily functions (codes preceded by the letter *b*), but also the psychological and behavioural repercussions the patient manifests, as well as his interaction with the environment (codes preceded by the letter *d*), the environmental factors which facilitate or limit the level of integration of the disabled person (codes preceded by the letter *e*); The I.C.F. analyses the degree of assistance necessary which has to be provided by caregivers that are part of the rehabilitation team (family, friends, health/social care professionals, etc.). What we obtain from this scale is a clear and articulated picture of each single disorder, before beginning any kind of treatment.

METHOD

To define the single clinical case it is necessary to describe the following codes:

- ICD9 (International Classification of Diseases) with the definition of the disorder that is the main objective of the rehabilitation project and those which indicate in the same subject, the coexistence of correlated disorders of relevant clinical importance (es.: diabetes mellitus, arterial hypertension).

- I.C.F. contain the subgroups (domains) that describe the following conditions:

- interest in the abnormal bodily structure (*s*)
- interest in specific bodily functions (*b*)
- integration of the disabled patient with the environment and his reduced ability in certain aspects of daily living as well as his capability to relate with others (*d*)
- patient dependence on other people (family, friends, health/social care professionals, others) or prosthesis or special garments, environmental factors in the activities of daily living (*e*).

With these presuppositions the AA., of 18 months, describe the cases of lymphedema according to the following schemes.

Lymphedema of the upper limb

Codes International Classification of diseases ICD9:

- 459.89 (vascular structural damage);
- 457.0 (lymphedema post-mastectomy) (Fig. 1);
- 174.9 (breast cancer);
- 715.91 (arthritis of the shoulder) (Fig. 2);
- 728.9 muscular hypotrophy/atrophy. Specification of the muscle groups which are directly involved (deltoid, biceps, triceps, pronators, supinators, flexor and extender muscles of the fingers (Fig. 3);
- 353.2 (cervical neuropathy).



Fig. 1 - Upper limb lymphedema. Fig. 2 - Arthritis of the shoulder.

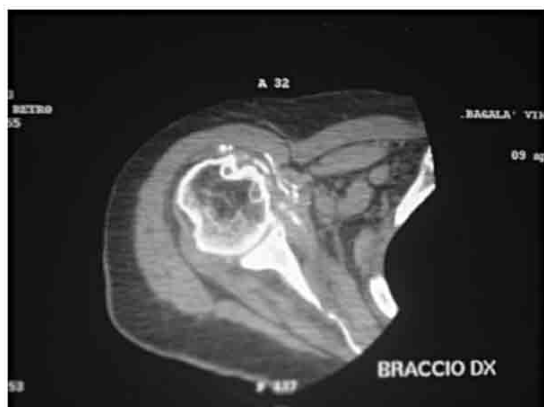


Fig. 3 - Ipotrophy of left deltoid muscle in secondary lymphedema of the upper limb.

Codes International Classification of Functioning:

- s 730: upper limbs-arms – hands;
- s 8: skin and connective tissue;
- s 720: shoulder region;
- s 760: chest;
- b 710: articular mobility;
- b 730: muscle strength;
- b 735: muscle tone function;
- b 122: global psychological function;
- b 134: dominant state/sleep;
- e 310: nuclear family;
- e 320: friends;
- e 355: professional health-care workers;
- d 430: to lift and to transport;
- d 440: fine motor ability, to grip/hold;
- d 640: household chores;
- d 415: daily routine (ADL/IADL);
- d 445: use of arms and hands;
- d 470: ability to use means of transport as a passenger;
- d 475: ability to use means of transport as the driver;
- d 620: ability to errands (ex.: go shopping);
- d 510: wash oneself;
- d 540: dress oneself;
- d 740: relate to family members;
- d 770: engage in intimate relationships.

Lymphedema of the lower limb.

Codes International Classification of Diseases ICD9:

- 459.89 vascular structural damage;
- 457.1 (other primary and secondary lymphedema) (Fig. 4);
previous cancer code body organ in question;
- 715.97 (arthritis of the ankle) (Fig. 5);
- 728.9 (muscular atrophy: quadriceps, gemelli, tibial etc.)
(Fig. 6);
- 353.1 (lumbo sacral radiculopathy).



Fig. 4 - Secondary lymphedema of right lower limb because of bladder tumor.

Fig. 5 - Arthritis of the ankle.

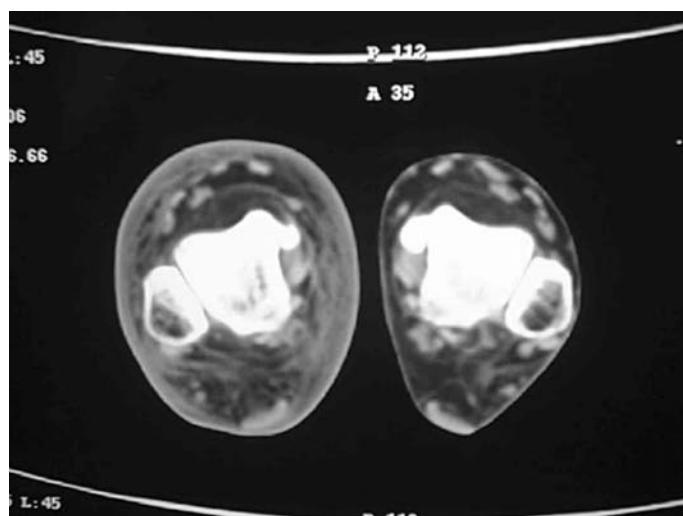


Fig. 6 - Ipotrophy of gemellus muscles in secondary lymphedema of the right lower limb.

Codes International Classification of Functioning:

- ┆ s 750: lower limbs –legs, feet;
- ┆ s 8: skin and connective tissue;
- ┆ s 410: cardiovascular system;
- ┆ s 275: pain level;
- ┆ s 740: pelvis;
- ┆ s 760: chest.

- ┆ b 710: articular mobility;
- ┆ b 730: muscle strength;
- ┆ b 735: muscle tone function;
- ┆ b 122: global psychological function;
- ┆ b 134: dormant state/sleep;

- ┆ e 310: nuclear family;
- ┆ e 320: friends;
- ┆ e 355: professional health-care workers;

- ┆ d 455: movement;
- ┆ d 450: ability to walk;
- ┆ d 415: to maintain a bodily position;
- ┆ d 510: wash oneself;
- ┆ d 540: dress oneself;
- ┆ d 640: household chores;
- ┆ d 415: daily routine (ADL/IADL);
- ┆ d 475: ability to use means of transport as the driver;
- ┆ d 620: ability to errands (ex.: go shopping);
- ┆ d 740: relate to family members;
- ┆ d 770: engage in intimate relationships.

Next to the single items of the domains of the I.C.F. must also indicate the intensity in which bodily functions are affected or the particular aspects that influence personal activities, ability to relate and other social functions of the individual (preceded by the symbol + if positive, no symbol if negative: es. +2, 1, etc.). The numeric indicators are defined “*qualifiers*” and vary, numerically, in function to the results of the treatment underwent.

The physical repercussions of a lymphedema (sense of weight, muscular hypotrophy, muscular weakness, reduction of the articular functional capabilities, pain, skin problems), not enough to delineate the single clinical picture, is combined with a description of the psychological repercussions (the simple existence of the lymphedema constantly reminds the patient of his illness which has determined this condition), the relationship with the macro-environment and the dependence on others (caregivers). The present study has been conducted on 269 patient affected by lymphedema (176 of the upper limb, 93 of the lower limb), age range 0 to 82 years old, 189 females and 80 males. The clinical phase of the participants of the study were the most evolved (III, IV and V).

All the patients were submitted to clinical examination (comprehensive of the measurements of the circumferences of the limbs, at various levels and in comparison), and instrumental examinations; lymphoscintigraphic exam, high-resolution

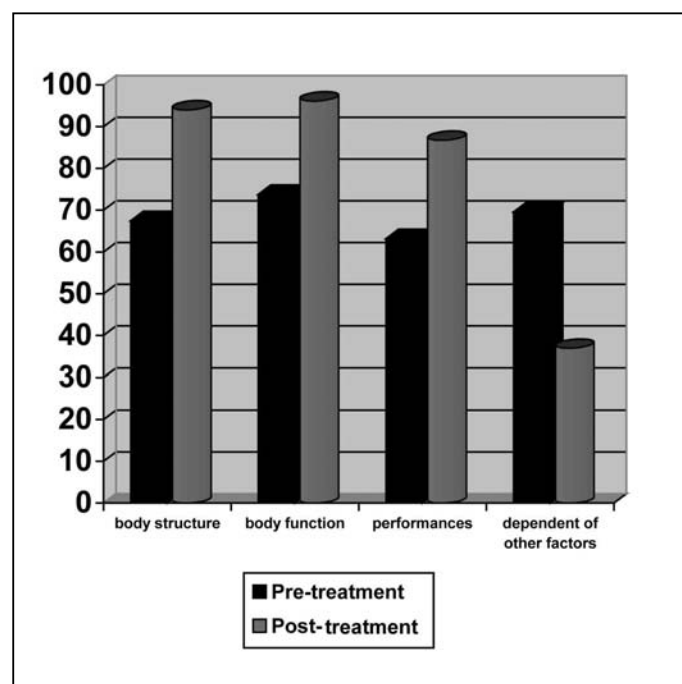
ultrasound in some cases computerized tomography. All the patients underwent a complete protocolized clinical treatment which was personalized for each subject that consisted of the following:

- manual lymphatic drainage;
- sequential pressotherapy;
- multi layer-elastic bandage;
- isotonic gymnastics aimed to stimulate the muscular pumps of the limbs in question and for the reduction in the shrinkage of the individualize muscular tumor masses identified as hypostenic;
- mobilization and pumpage of the articular structures of the affected limb;
- ultrasounds in the areas where an increase of the consistence tissutale was found (fibrosis).

All the patients were studied and assisted by a psychologist (member of the rehabilitation TEAM) with a complete analysis of the premorbid personality. All the patients, at the end of the rehabilitation cycle, were prescribed the definitive elastic garment (standard or custom made) in collaboration with the orthopedic technician.

RESULTS

After the treatment cycle the data highlights that there was a reduction of the value of the qualifiers correlated to the need of assistance of a caregiver, on behalf of participants of the study, in addition an improvement of personal performance and relationship ability and in some cases the elimination of ailments induced by the rehabilitation intervention (ex. muscular atrophy) (Chart).



Results post-treatment.

Example of before and after treatment of patient with secondary lymphedema of the upper right limb



S Body structure	In	Out	D Limitations in daily living activities	In	Out
120 – spine cord and peripheral nerves	2,2,1	1,2,1	430 – to lift	2,2	1,1
410 – cardiovascular system	2,2,0	1,2,0	440 – fine motor ability (hand)	2,1	0,1
710 – head and neck region	2,2,1	1,2,1	470 – use of means of transport	2,1	1,1
720 – shoulder region	2,2,1	1,2,1	475 – to drive	2,1	1,1
730 – upper extremity (arm, elbow, forearm and hand)	3,3,1	1,3,1	510 – to wash	2,2	1,1
760 – Trunk	1,3,1	1,3,1	620 – ability to do errands (go shopping)	3,2	1,1
810 – skin condition	2,5,3	1,5,3	630 – prepare meals	3,2	1,1
430 – respiratory system	2,2,0	1,2,0	740 – engage in formal relationships	2,2	1,1
			750 – engage in informal relationships	2,2	1,1
			770 – intimate relationships		
			850 – paid work		
B Body function	In	Out	E Environmental factors	In	Out
8 – functions of the skin and the connective tissue	2	1	110 – food and drugs	+3	+3
280 – pain	2	1	115 – products and technology for personal use in daily living	+4	+3
410 – heart			225 – climate	2	1
420 – blood pressure	2	1	310 – nuclear family	+2	+1
440 – breathing	3	2	320 – friends		
530 – weight control	1	1	325 – acquaintances, colleagues, neighbours and other members of society	+2	+1
640 – sexual functions			355 – health care workers	+3	0
710 – articulation motility	2	1	360 – other care workers		
730 – muscle strength	2	1	575 – services and social policy		
735 – muscle tone					

Disorder treated : Secondary Lymphedema of the upper right limb 457.0 – 459.89

Other associated diseases : Breast cancer 174.9, pronator muscular Hypertrophy 728.9, Arthritis of the right shoulder 716.91,

Arterial Hypertension 401.9, Chronic pulmonary insufficiency 491.8, Cervical Neuropathy 353.2

Example of before and after the rehabilitation project of a patient with lymphedema of the lower limb



S Body structure	In	Out	D Limitations in daily living activities	In	Out
120 – spine cord and peripheral nerves	2,2,3	1,2,3	450 – to walk	2,2	1,1
410 – cardiovascular system	2,2,0	1,2,0	465 – Mobility with the use of support equipment/prosthesis		
740 – Hip region (pelvis)			70 – use of means of transport	2,1	1,1
750 – lower extremity	4,3,3	2,3,3	475 – to drive		
	(Legs and Feet)		620 – ability to do errands (go shopping)	3,2	1,1
810 – skin condition	4,5,3	2,5,3	630 – prepare meals	3,2	1,1
430 – respiratory system	2,2,0	1,2,0	740 – engage in formal relationships	2,2	1,1
			750 – engage in informal relationships	2,2	1,1
			770 – intimate relationships		
			850 – paid work		
B Body functions	In	Out	E Environmental factors	In	Out
8 – functions of the skin and the connective tissue	2	1	110 – food and drugs	+3	+3
280 – pain	2	1	115 – products and technology for personal use in daily living	+4	+3
410 – heart			225 – climate	2	1
420 – blood pressure	2	1	310 – nuclear family	+2	+1
440 – breathing	3	2	320 – friends		
530 – weight control	1	1	325 – acquaintances, colleagues, neighbours, and other members of society	+3	+2
640 – sexual functions			355 – health care workers	+3	0
710 – articulation mobility	2	1	360 – other care workers	+4	0
730 – muscle strength	2	1	575 – services and social policy		
735 – muscle tone					

Disorder treated : primary late onset lymphedema of the lower limb 457.1 – 459.89

Other concomitant diseases: Breast Cancer 183, subacute lymphangitis 457.2, hypertensive cardiopathy 401.9, osteoarthritis lumbosacral

723.4, Arthritis of the ankle 716.97, Chronic pulmonary insufficiency 491.8, Hypertrophy mm. subscapularis 728.9

CONCLUSION

The study highlights the importance of the availment of a classification tool that better defines the levels of disability of a patient with lymphedema, which considers the complex clinical picture that implies an intensive rehabilitation cycle in an acute phase, continuous monitoring and the necessity of maintenance re-training cycles.

The best results were obtained when taken into account the various aspects of the disability using a **global approach** (Rehabilitation Project) that analysis and corrects the different types of deficit the patient has: physical, functional, psychological, relational and social.

For a preventive measure and after assuming the responsibility of taking care of a patient affected by lymphedema the I.C.F proved to be a valid and articulated disability Classification Tool because of its multidimensional nature which considers the patients needs in a global manner which strongly supports the ideology of the patient centered care model.

We strongly recommend the employment of this classification tool as a standard scale to be used in everyday clinical practice in a multidisciplinary setting. Not only is it a highly valid and reliable classification tool it also offers the necessary data for the health and welfare authorities to better define appropriate **care** parameters.

REFERENCES

1. Weiss J.M., Spray B.J.: *The effect of complete decongestive therapy on the quality of life of patients with peripheral lymphedema*. Lymphology, 2002; 35(2): 46-58.
2. Pereira De Godoi J.M., Braile D.M., Fatima De Godoi M., Longo O.: *Quality of life and peripheral lymphedema*. Lymphology, 2002; 35(2): 72-75.
3. Casley Smith J.R.: *Alteration of untreated lymphedema and its grades over time*. Lymphology, 1995; 28: 174.
4. Tobin M.B., Lacey H.J., Meyer L.: *The psychological morbidity of lymphedema*. Cancer 72 (1993), 3248.
5. Michelini S., Failla A., Moneta G., Barbato N.: *Proposal of evaluation of disability in patients suffering from lymphedema*. European Journal of Lymphology and related problems, Vol. 6, Sp Co I, 20, 1996; Abstract.
6. Lannois R., Alliot F.: *A specific quality of life scale in upper limb lymphedema: the ULL-27 questionnaire*. European Journal of Lymphology and related problems. Vol IX (33), 24, 2001; abstract.
7. Corda D., Monticone M., Moschi A., Failla A.: *Rehabilitation procedure for patient with lymphedema. Our proposal: from project to rehabilitative program*. European Journal of Lymphology and related problems; Abstract.
8. Haigh R., Tennant A., Sorensen F.B., Grimby G., Marincek C., Philips S., Ring H., Tesio L., Thonnard J.L.: *The use of outcome measures in physical medicine and rehabilitation within Europe*. Journal Rehabil Med, 2001; 33: 273-278.
9. Tesio L., Granger C.V., Perrucca, L., Franchignoni F.P., Battaglia M.A., Russel C.: *The F.I.M. instrument in the United States and Italy*. Am. J. Phys. Med. Rehabil. Vol. 81, n. 3, 168-176.
10. Michelini S., Failla A.: *Linfedemi. Inquadramento diagnostico clinico e strumentale*. Minerva Cardioangiologica, 1997; 45 Suppl. I al 6°: 11-15.
11. Michelini S., Failla A., Moneta G., Macaluso B.: *Disability and lymphedema: which functional scale to determine the necessity of assistance?* The European Journal of Lymphology, Vol. 10, N. 37-38, 2002-2003: 5-7.
12. ICF Disability and Health. World Health Organization, Geneva 2005.

Technological Quantum Leap in Lymph Therapy

JOBST® ELVAREX® SOFT SEAMLESS: WORLDWIDE FIRST FLAT KNIT SEAMLESS CUSTOM-MADE COMPRESSION GLOVE

27 bones, 36 joints and 39 muscles – so reads the technical specification of a high-performance tool – the human hand. It can pet tenderly, grip tight, feel the finest surfaces and perform precision tasks. The precondition for this universal range of operations is that the sense of touch and freedom of movement of the hand are not restricted. For people with lymphoedema of the hand this is a virtually impossible demand. Up to now, that is. With its patented Jobst® Elvarex® Soft Seamless going on the market in the second quarter 2007, innovative traditional manufacturer JOBST has made a technological quantum leap: the first flat knit seamless custom-made compression glove. Relation AG spoke about the novel technique and its medical effectiveness with renowned lymphologist Prof. Dr. Ethel Földi, Director of the Földi Clinic in Hinterzarten and Juergen Greve, Head of Development at BSN-JOBST GmbH.

Professor Földi, you are one of the most internationally renowned lymphologists and have been researching that field for decades. Why does compression therapy still represent the gold standard in lymphoedema therapy?

Professor Földi: From long years of experience today we know that we can use compression therapy very successfully in a way which is custom-made to the individual, targeted and largely free from side-effects. The therapeutic effectiveness of compression therapy is mainly based on the following factors:

- Enlarged veins are diluted; regurgitate blood flow is reduced;
- Tissue pressure is increased, producing an anti-oedema effect.

Lymphoedema corresponds to a chronic inflammatory process. It can be positively influenced by compression therapy.

Despite the proven success of compression therapy, lymphoedema remains a chronic condition with all the associated negative physical and mental consequences for the patient. From a medical point of view, what demands do you place on the design of compression garments?

Professor Földi: In addition to medical effectiveness compliance aspects are decisive. For that reason in addition to relief of symptoms and wearing comfort – particularly with visibly worn compression garments – as with a glove, aesthetic aspects take on particular importance. Breast cancer patients in particular often feel stigmatised by the clinical “look” of the compression glove.



Prof. Dr. Ethel Földi

Why is provision of flat-knit compression the number one choice in the treatment of lymphoedema?

Professor Földi: Only through custom-made flat-knit design can the sometimes complex contours of the affected extremities conditioned by lymphoedema be precisely matched without areas of constriction. In addition only a flat-knit design can ensure adequate distribution of compression.

Mr Greve, Jobst® Elvarex® flat-knit seamed compression products have been the appliance of choice for decades. Numerous product improvements have been introduced in recent years. What options remain open to you to make what is good even better?

Juergen Greve: As the term “flat-knit seamed product” already indicates, the classical Jobst® Elvarex® is initially a

two-dimensional double-surface fabric which only assumes three-dimensional – i.e. anatomical – form by being sewn together. As the seams interfere – particularly in the area of the fingers – and reduce wearing comfort, we told ourselves that if the seams cannot be manufactured in a significantly flatter and visually more attractive form, then they will have to disappear altogether! The logical conclusion was to develop a flat-knit compression glove with no seams.

That sounds just as simple as it is self-evident. But what is actually involved in this innovation?

Juergen Greve: The real challenge in this new technology consists in working in the compression yarn in a controlled and uninterrupted way during the entire knitting process. In a technical and product development phase lasting several months we developed a solution which we have meanwhile protected with a patent which has now been awarded. Besides this purely technical innovation we have also made the knitted fabric softer with a more pleasant feel by using novel, skin-friendly and breathable materials. The overall result combines all the advantages of flat knit technology with a fit and optimum wearing comfort never before achieved.

What does that mean? What underlies the advantages of seamless flat-knit fabric?

Juergen Greve: The advantages are in the truest sense of the word “on hand”.

- Non-existent seams cannot be bulky. That has a positive effect on oedema control, wearing comfort and durability.
- No seams at the finger extremities and at the wrist prevents undesirable expansion, curling and constriction.
- The continuously worked in compression yarn facilitates controlled compression over the entire glove, including at particularly critical places.
- The special knitting technique leads to optimum gradation of the fingers and thus to an improved fit in the spaces between the fingers.
- The softer knitted fabric – in conjunction with the innovative knitting technique – increases freedom of movement of the fingers and of the whole hand.
- The anatomical shaping and special yarns improve ease of putting on and removing.

The enabling technology sounds very promising, but what about the medical efficacy?

Professor Földi: An initial wear trial confirms the positive properties of the new product cited earlier. Trial patients suffering from cyclical idiopathic oedema reacted very well to wearing the new compression glove – both with regard to objective therapeutic effect and to subjective assessment. Particularly emphasised was the improved motor activity, in particular fine motor activities such as computer operation and typing and the long duration of complaint-free wear and



Juergen Greve

the hard-wearing properties of the new Jobst® Elvarex® Soft Seamless.

What other user studies have been or are being carried out?

Professor Földi: In December 2006 a clinical multiple person study commenced in the Földi Clinic in which trial patients alternately wear conventional compression gloves and the new Jobst® Elvarex® Soft Seamless glove. Experience gained over a period of months are being documented during this user study both in respect of therapeutic effectiveness and subjective wearing comfort.

Juergen Greve: In addition to the Földi Clinic other specialist lymphology clinics are involved in our user study. With these studies we also want to demonstrate the functionality and wearing comfort of Jobst® Elvarex® Soft Seamless on the basis of a greater number of patients.

Products manufactured using seamless flat knitting technology would also be conceivable and desirable in other wearing applications. How do you see future developments?

Juergen Greve: Amongst other things we are working intensively on a seamless toe cap. Also theoretically feasible are seamless flat-knit arm sleeves and hosiery. Specialist doctors and therapists must decide on the therapeutic benefit of such developments.

Future Jobst® developments in the field of lymphological compression treatment are always marked by two considerations - medical therapeutic functionality on the one hand and increased patient compliance by means of continuous improvement of wearing comfort and aesthetics on the other.

SONOUROS WAVES EFFECT ON OEDEMA INDUCED BY ECCENTRIC CONTRACTION IN RAT SKELETAL MUSCLE

GIANLUCA FULGENZI*, LAURA GRACIOTTI*, MONICA FARONATO*,
FIORENZA ORLANDO**, MAURIZIO RICCI***

* Dep. of Molecular Pathology and Innovative Therapies, University of Ancona

** Physical Medicine Unit, United Hospitals of Ancona

*** I.N.R.C.A. Dipartimento Ricerche Gerontologiche e Geriatriche "N. Masera"

Authors Address: Dott. Maurizio Ricci
Direttore U.O. Medicina Riabilitativa
Azienda Ospedaliera Umberto I, Ancona
Via Conca, Torrette di Ancona, 60100
Tel 0715963178
m.ricci@ao-umbertoprime.marche.it

SUMMARY

The authors verified the effectiveness of an electro-medical instrument named Flowave with an animal model of inflammation and edema induced by eccentric exercise. In conclusion the study demonstrated with Muscles wet and histological section Flowave stimulates progression lymphatic liquids.

KEY WORDS: sonorous resonance; lymphoedema; sound waves.

INTRODUCTION

Lymph edema is a condition in which liquids and proteins remain in the interstitial tissue and it may be caused by inflammatory stimuli triggered by muscle and ligament pathologies. Inflammation leads to edema principally by the accumulation of plasma protein in extracellular spaces. Lymphatic in skeletal muscles shows no spontaneous lymphatic contraction and their function relies on muscle contraction and its pumping effect (Schmid-Schonbein, 1990). Therefore limited mobility reduces lymphatic reabsorbing of essudate and prolongs inflammation and pain. In our Rehabilitative Center the use of the sonorous waves for the treatment of the edema is a common practice (Bistolfi, 1989). The clinical casuistry, which includes more than the 50 cases published, daily demonstrates the effectiveness of this physical therapy in activating lymphatic drainage and therefore reducing the edema from the pathological limbs (Ricci, 2006). In the cases of venous lymph edema the clinical evidence demonstrates that sonorous waves are able to influence the

mobility of interstitial proteins, that result more easily drained by lymphatic (Ricci, 2005).

To gain a more detailed understanding of the sonorous wave effect in edema drainage (Ho, 1996) we applied sonorous waves delivered by the Flowave instrument to an animal model of inflammation and edema induced by eccentric exercise.

METHODS

Experiments were performed on the soleus muscles of 8 adult male Sprague Dawley rats (250 g average body weight). All procedures were conducted in accordance with the Italian legislation for animal care.

Model of eccentric exercise

Eccentric exercise was performed as previously described (Heap 2006). Briefly Soleus muscle was indirectly stimulated during its lengthening phase when the animals were pedaling on a custom made cycle.

Under Fluothane anesthesia (2% Fluothane in 95% O₂ and 5% CO₂) and aseptic conditions, a small incision was made to isolate the Achilles' tendon. The tendons of gastrocnemius and plantaris muscles were cut to increase the load on the soleus during the lengthening contractions and the wound was closed. Stainless steel Teflon insulated electrodes were implanted in the vicinity of the right popliteal nerve in a position which ensured stimulation of the triceps surae and secured by sutures of the adjacent muscles. The

wires were led under the skin to the back of the animal to be connected to a stimulator and the wounds on the thigh and on the back of the animal were closed.

The animal, still under Fluothane anesthesia, was then placed on a wooden block ventral side down and secured in this position by a tape.

Its right paw was firmly fixed to a padded pedal of a wheel which was electrically rotated with cycle duration of 600 ms (100 revolution min^{-1}).

A S8800 stimulator (Grass Medical Instruments, USA) was used to stimulate the soleus during the lengthening phase for 260 ms at 30 Hz, pulse width 0.3 ms at a voltage sufficient to produce visible contractions (usually 5–12 V).

The stimulation during the lengthening of the muscle was driven by a computer connected to the pedal. The stimulation was carried out for 10 min and the anesthesia was then discontinued.

The animals recovered within 10–15 min and were housed individually for 24 h as preliminary histological controls revealed the presences of muscle edema at that time.

Final experiments were performed under sodium pentobarbitone anesthesia (50 mg/kg body weight i.p.).

The animals were divided randomly in two groups. In one the exercised legs was subjected to 5 min treatment with FLOWAVE tip, with a standardized program which consisted of compensated two-phases waves, of amplitude between –12 and +12 Volts, with the machine turned on (Eccentric Exercised Flowave Treated **EEFT**) while the second group had the machine turned off as control group (Eccentric exercised only **EE**).

One hour after the end of the treatment the animals were sacrificed and the soleus muscle was taken off from the exercised and contralateral legs for histology and weight examination.

Muscle weight

One third of the muscle was taken and immediately weighted in a precision balance (wet weight), then it was lyophilized for 24 h (Freeze Dryer Modulyo, Edwards) and then weighted again to determinate the dry weight. The ratio between wet/dry weights was calculated and averaged for each experimental group.

Light microscopy

Transverse sections from the mid-belly of the soleus about 5 mm thick were mounted on cork using OTC medium and frozen quickly in isopentane precooled in liquid nitrogen. Cryostat sections 8 μm thick were stained for haematoxylin and eosin to assess and quantify muscle damage edema.

For future electron microscopy analysis, a piece of the muscle was fixed in 3% glutaraldehyde and 1% paraformaldehyde phosphate buffer (300 mOsm, pH 7.4) for 8 h. Later small pieces were postfixed in OsO_4 for 1 h and embedded in epoxy resin.

Image processing

Haematoxylin-eosin stained sections were visualized by Zeiss optical microscope. Pictures from 2 different sections for each muscle (10X magnification) were captured by a digital camera and elaborated by a custom written computer program that extracted randomly 5 boxes of 400 μm^2 . Each box was then used to calculate

the area occupied by cells and the area occupied by edema. Values obtained from the two sections were separately pooled and used to calculate the mean value for each specimen.

Statistical analysis

All results are expressed as means $\pm$ SD analyzed by unpaired Student's t test. A value of $P < 0.05$ was accepted as representing a significant difference.

RESULTS AND DISCUSSION

Muscle weight

The comparison of wet and dry weight allowed us to directly measure the amount of edema present in the muscle immediately after its excision from the animal.

The results are shown in table 1. The small differences obtained between EE and contralateral not exercised group, and between EE and EEFT although slight (due to dimension of the samples), indicate a less amount in water and therefore edema in EEFT respect EE. The limiting factor in this assay is the size of the piece of muscle considered. As the muscle has to be divided in 3 parts for histological examination, the portion reserved for this assay was limited, in future whole muscle will be analyzed to get significant data.

Histology

We analyzed the exercised muscle in cross section stained with standard haematoxylin-eosin (Fig 1).

Sections from contralateral muscle did not show any sign of damage and very limited edema.

The exercised muscle, either treated or not with Flowave, showed multiple foci of fiber necrosis, massive inflammatory infiltrate and diffuse edema.

Quantification of the edema by the described morphological method showed a significant increase of the extracellular space over the space occupied by the muscle fibers, in EE muscles compared to the EEFT consistent with a reduced edema after Flowave treatment (Table 2).

It is clear that the eccentric exercise protocol applied to the animal induced focal lesion of muscle fiber, and that those lesion induced an inflammatory response, resulting in cell necrosis, leucocytes infiltration and edema.

Treatment with Flowave reduced the amount of edema.

CONCLUSION

These data together suggest that an effect on oedema re-absorption was obtained with Flowave treatment, probably due to a specific effect on interstitial proteins but also to a stimulation of lymphatic and bloody vessels from the sonorous waves reinforcing the effectiveness on the liquid drainage.

In conclusion we obtained a direct measure of oedema in an animal model that can be used to estimate the efficacy of various treatments, and will allow the dissection of mechanism at the base of physical therapies.

Table 1 - Muscles wet/dry weight ratio.

	EE	CL	EE+FWT	CL
mean	79.45	78.04	78.76	78.67
St err	0.36	0.47	0.53	0.28

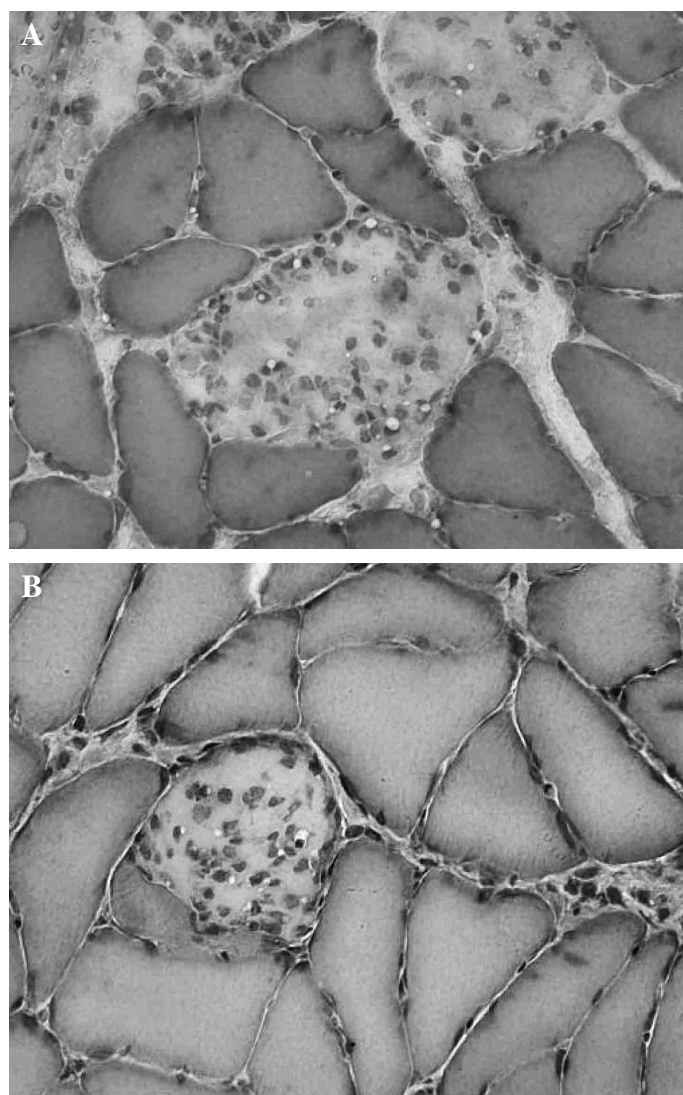


Fig. 1 - Section showing muscle damage and oedema in Eccentric Exercised (A) and Eccentric Exercised Flowwave Treated (B) soleus muscles.

Table 2 - Extracellular area (% over total).

	EE	EE+FWT
mean	43*	31
St err	4	3

(*) $p < 0.05$.

REFERENCES

1. Bistolfi F. (1989): *Radiazioni Non Ionizzanti, Ordine, Disordine e Biostrutture*. Ed. Minerva Medica, Torino.
2. Del Giudice E., Doglia S., Milani M. and Vitiello G. (1988): *Structures, correlations end electromagnetic interactions in living matter: Theory and applications*. In: "Biological Coherence and Response to External Stimuli" (H. Frohlich, ed.) Springer-Verlag, Berlin-Heidelberg: 49-64.
3. Ho M.W. (1996): *Bioenergetics and the coherence of the organism*. In: "Hoomopathie-Bioresonanztherapie" (P.C. Endler and J. Schulte, eds.) Verlag Maudrich, Wien: 17-34.
4. Lubert Stryer: *Biochimica*. Ed. Zanichelli.
5. M. Ricci: *The sound wave limphatic drainage*. Eur J Lymphol 2005; 15(44): 33.
6. M. Ricci, S. Paladini (2006): *Demonstration of Flowwave's effectiveness through lymphoscintigraphy*. Eur J Lymphol 2006; Vol. 16, N. 49: 14-18.
7. S.J. Heap, G. Fulgenzi, O. Hudlicka (SH e GF shared first authorship): *Microcirculation in rat soleus exercise. The effect of nifedipine*. Eur J Appl Physiol. 2006 Aug; 97(6): 687-94. Epub 2006 Jun 13.
8. Schmid-Schonbein G. (1990): *Microlymphatics and lymph Flow*. Physiological Reviews, Vol. 70(4), 987-1027.

MANAGEMENT OF LYMPHOEDEMA: ECHO-COLOUR-DOPPLER INDICATIONS FOR STRATEGIES

MARINA CESTARI, MD

Operative Unit of Territorial Rehabilitation - Angiology Outpatients' Surgery

A.S.L. 4 - Terni - Italy

cestari.marina@libero.it

SUMMARY

The diagnosis of lymph-oedema is essentially clinical, however, we must not ignore the accuracy of the high resolution scan when it is performed by experienced operators using high technology instruments.

We evaluated the utility of this methodology using Echo-Colour-Doppler Sonoline Antares apparatus, in lymph-oedematous upper and lower limbs diagnostics because it provides us with information on structural characteristics of the examined tissue, and in the ambit of personalized therapeutic strategies.

KEY WORDS: lymphedema management. Echocolour Doppler indications.

INTRODUCTION

The first evaluation of patients with lymph-oedema, performed in a team ambit, leads to the compilation of a specific clinical report and personalized rehabilitation project.

Among the instrumental exams requested in the specific clinical report, the Echo-Colour-Doppler is always present: a non-invasive diagnostic approach, repeatable and relatively cheap, it has proved to be indispensable both in differential diagnostics with other oedematous pathologies, both in the ambit of rehabilitative projects and in the choice of selected therapeutic strategies thanks to the precise information on the structural characteristics of the examined tissue.

This method is also used for therapeutic monitoring as verification of the validity of treatment effectuated and for follow-up.

MATERIALS AND METHODS

In the ambit of instrumental diagnostics of upper and lower limb lymph-oedema, we use a Sonoline Antares Echo-Colour-Doppler instrument with high frequency (13.5 Mhz) electronic linear probe (4.5 cm), proceeding along the examined limb with longitudinal and transversal scansions; a large quantity of gel avoids pressure on the skin and a subsequent collapse of the superficial lymphatic vessels.

The instrument available is provided with the "Siescape panoramic reconstruction" function, a system option which allows the acquisition of bi-dimensional ultrasound images with an extended visualization field (photo 1). In order to obtain good images, the scansion must be performed slowly using a large quantity of gel to favour the movement of the probe on the skin.

Before and after the therapeutic treatment and in follow-up we use as markers:

- the same circumferential measurements (lateral, medial, anterior and posterior regions of the examined limb),

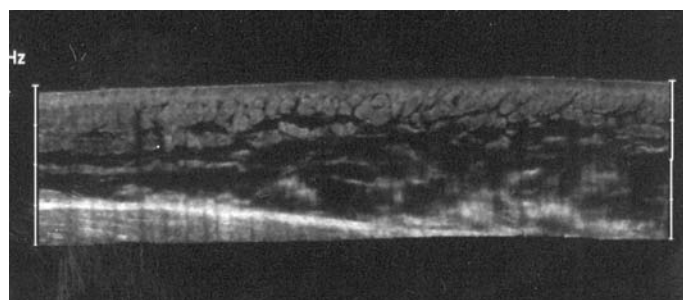


Photo 1

- the superficial vessels in the examined limb which prove to be a useful spy of eventual probe hyper-pressure, which would cause the collapse of vessel walls (photo 2). It is interesting to note how it is possible to observe both the calibre and the flow speed of the superficial and deep veins in the lymph-oedematous limb, proof of the venous-lymphatic twinning useful in the case of lymphatic system insufficiency; after the combined treatment, a reduction of both the parameters is evident sign of the validity of the therapeutic strategy carried out.

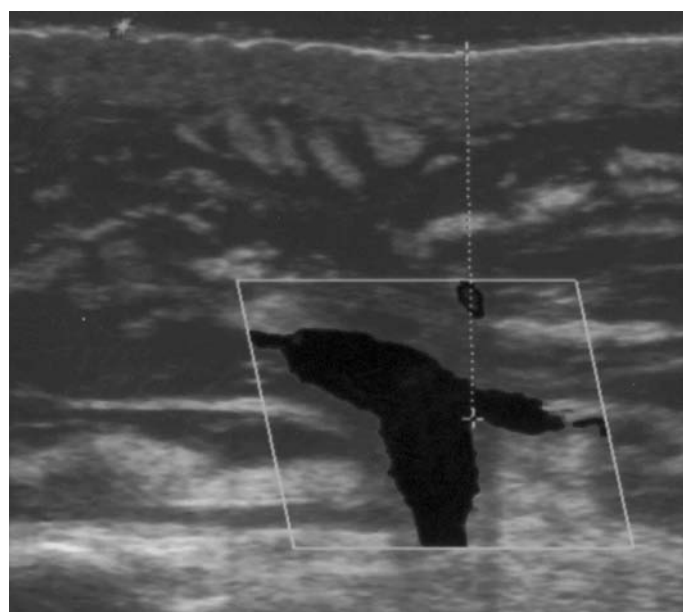


Photo 2

Obviously other points can be taken into consideration, if considered interesting on palpation, aimed with a view to therapy selection (photo 3).

RESULTS

Echo-Colour-Doppler diagnostics provide important indications on structural characteristics of examined tissue:

- derma layer: it is possible to identify an increased thickness with a reduced echogenicity due to the presence of interstitial oedema, or an increased echogenicity due to tissue fibrosis (photo 4)
- subcutaneous tissue: it is possible to highlight ectasia of lymphatic collectors, located at the epifascial level and in proximity of the superficial venous vessels, and the pre-collectors which can be found as anechogenic network in the adipose tissue.

Tissue compression with probe empties the lymphatic vessels which slowly fill up after its removal, differently to the lymphatic lakes, anechogenic network without evident walls, which do not respond to compression. In more advanced studies, a progressive increase of the echogenic tissue, due to the presence of fibrosis, can be noted (photo 5).

The increased thickness, easily measurable before and after rehabilitative treatment, highlights the quantity of oedematous tissue and the efficacy of the therapy applied; furthermore it is a useful parameter to monitor the evolution of lymph-oedema:

- adipose tissue: it is possible to find a prevalence of this tissue due to hypertrophic and hyper-echogenic adipose lobes, with denser aspect of subcutaneous tissue (photo 6);
- lymph-nodes: with Echo-Colour-Doppler it is possible to identify the morphological characteristics and vascularization; in the case of inflammation for example, the hyperplasic reactive lymph-node presents an increased dimension with cortical hypertrophia and conservation of hilum.

In oncological patients, with secondary post-surgical lymph-oedema, eventual vascularized neoformations and/or regional lymph-nodes which present a reduction of the longitudinal diameter, with spherical form, and altered hilum structure, induce us not to take on the patient and to contact the patient's oncologist for a further specialist evaluation.

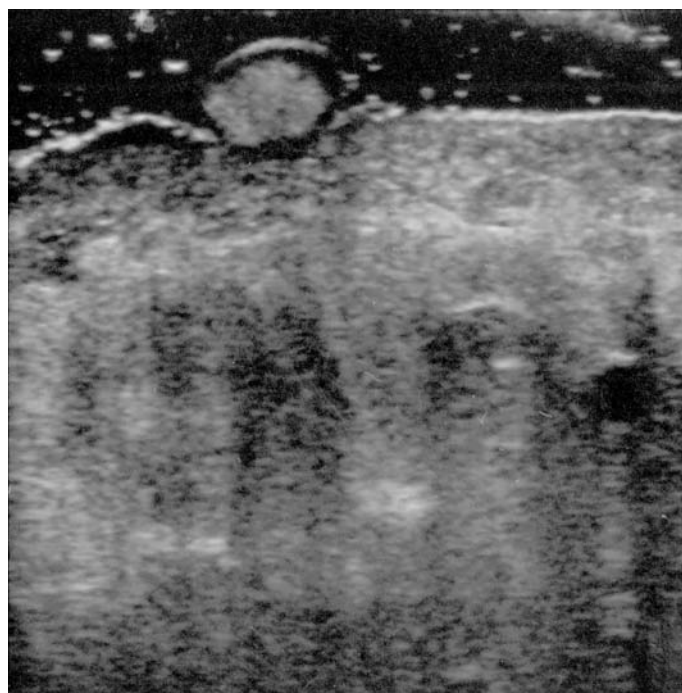


Photo 4

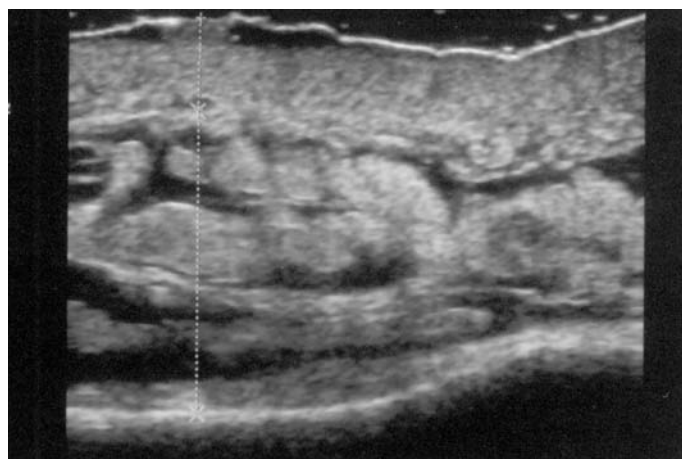


Photo 5

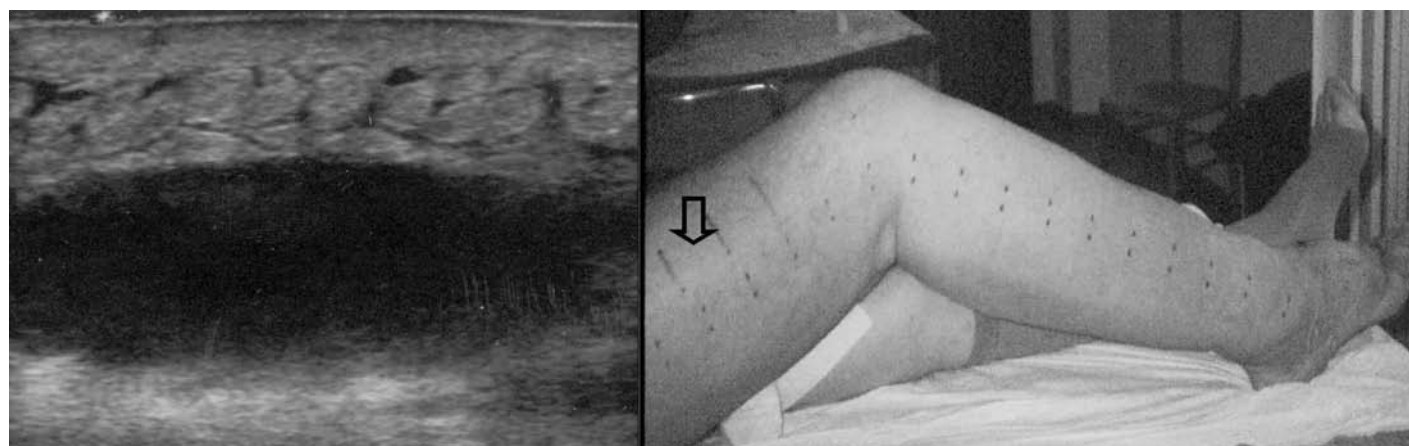


Photo 3



Photo 6

DISCUSSION

We have tried to compare the clinical impressions, based on tissue consistency on palpation, with the echo-graphic imaging highlighting three different clinical-instrumental situations, with relative prognostic implications which allow us to decide precise rehabilitation programs and therefore optimize therapeutic treatment.

1) Lymph-oedema with optimal response to therapeutic treatment:

- on palpation the oedema appears to be of soft consistency with pitting, while with echo-graphic examination we observe hypoanecogenic tissue due to interstitial fluid, with lymphatic collector and pre-collector ectasia.

In this case both rehabilitative treatment (combined therapy) and pharmacological treatment with natural cumarine is carried out.

Furthermore the patient learns, if able to do so, combined self-care (self-drainage and self-bandaging with associated motorial therapy) in the ambit of self-care.

2) Lymph-oedema with poor response to therapeutic treatment:

- on palpation the oedema appears to be of hard consistency without pitting, while the echo-graphic examination highlights extended hyperechogenic tissue upon the fascia, due to fibrosis. In this clinical-instrumental situation we carry out rehabilitative treatment, with particular utilization of special manoeuvres for fibrosis, and bandaging with suitable under-bandaging ("Schneider pack") prescribed and prepared by the physiotherapist in charge of the patient.

- on palpation oedema appears to be of medium-hard consistency without pitting, prevalently, on echo-graphic examination, with hypertrophic and hyperechogenic adipose tissue, which would indicate an adequate liposuction in highly specialized centres; in any case, elastic compression with personalized tutor is indispensable.

- 3) Lymph-oedema whose response to treatment is based on clinical-instrumental characteristics with oedema of medium consistency and mixed echo-graphic characteristics. In these cases we refer to echo-graphic characteristics for therapeutic strategies. Although conditioned by technical limits, being above all operator dependent, Echo-Colour-Doppler diagnostics provides important data which lead to an improvement in lymph-oedema management, helping the lymphologist and physiotherapist in the choice of precise strategies and therefore the setting up of personalized therapeutic programs, with subsequent therapeutic optimization.

BIBLIOGRAPHY

1. Balzarini S., Milella M., Civelli E., Sigari C., De Conno F.: "Ultrasonography of arm edema after axillary dissection for breast cancer: a preliminary study". *Lymphology*, Vol. 34, No. 4, December 2001.
2. Cavezzi A.: "Il ruolo dell'eco-color-doppler nel linfedema degli arti". *Linfologia*, n. 1, 1998.
3. Cavezzi A., Michelini S.: "Il flebolinfedema". Ed. Auxilia, 1997.
4. Földi M., Földi E., Kubik S.: "Textbook of lymphology". Urban/Fischer, 2003.
5. Michelini S., Failla A., Moneta G., Paradiso M.: "High resolution echography in the diagnosis, monitoring and in the prognostic value in lymphedema". *The European Journal of Lymphology and Related Problems*, Vol. 11, No. 39, 2003.
6. Michelini S.: "Classification of lymphedema by ultrasonography: is there a real one? What do we classify?". *The European Journal of Lymphology and Related Problems*, Vol. 12, No. 41, Sp. Co. I. 2004.
7. Leduc P.O., Fumière E., Brognard L., Wilputte F., Stenhouse A., Leduc A., Delcour C.: "Imagery of the lymphatic system by means of echography and magnetic resonance". *The European Journal of Lymphology and Related Problems*, Vol. 15, No. 43, 2005.
8. Valiant L., Auriol F., Calliens A., Pruvost F., Berson M., Lorette M.: "High resolution echography in the diagnosis of lymphoedema". XVIIIth Meeting of the European Group of Lymphology. Bruxelles, 6-7 May 1994.
9. Cestari M.: "Management of lymph-oedema: Echo-Colour-Doppler indications for strategies". XXXI Congress GEL, Rome 2005.

PREVENTION OF LYMPHEDEMA FOLLOWING SURGERY FOR BREAST CANCER

FRANCESCO M. BOCCARDO¹, MD, PHD; SANDRO MICHELINI³, MD; COSTANTINO ERETTA¹, MD; DAVIDE PERTILE¹, MD; ELISA DA RIN¹, MD; MIRKO CAMPISI¹, MD; FILIPPO ANSALDI², MD; GIANCARLO ICARDI², MD; CORRADO CAMPISI¹, MS; CARLO BELLINI¹, MD; CORRADINO CAMPISI¹, MD

¹ Department of Surgery – Unit of Lymphatic Surgery and Microsurgery

² Department of Health Sciences

³ Vascular and Neurological Rehabilitation Center, S. Giovanni Battista Hospital, Rome
S. Martino Hospital – University of Genoa, Italy

Send proofs to: Francesco M. Boccardo, MD, PhD
Via Fiasella 16/4
16121 Genoa, Italy
Phone: +39 010 3537281
Fax: +39 010 532778
E-mail: francesco.boccardo@unige.it

ABSTRACT

Objective. To assess the efficacy of a specific diagnostic and therapeutic protocol in the prevention of lymphedema after breast cancer treatment.

Summary Background Data. Lymphedema is a common complication of axillary dissection, affecting approximately 25% of patients. As lack of awareness of the problem and the progressive evolutive nature of lymphedema remain major limiting factors in management, emphasis should be placed on prevention. This study investigated the effect of a protocol of prophylactic measurements including prospective monitoring and early intervention.

Methods. Fifty-five women, who had breast-conserving surgery or modified radical mastectomy for breast cancer with axillary dissection, were randomly assigned to either the preventive protocol (PG) or control group (CG) and assessments were made preoperatively, at 1,3,6,12 and 24 months postoperatively. Arm volume (VOL) was used as measurement for the detection of arm lymphedema. Clinically significant lymphedema was confirmed by an increase of at least 10% of excess volume from the preoperative difference between the two arms. The preventive protocol for the PG women included preoperative upper limb lymphoscintigraphy (LS), principles for lymphedema risk minimisation and early management of this condition when it was identified.

Results. Assessments at 2 years postoperatively were completed for 89% of the 55 women who were randomly assigned to either PG or CG. Of the 49 women with unilateral breast cancer surgery who were measured at 24 mo., 10 (21%) were identified with secondary lymphedema using the VOL; the PG women had an incidence of 8% and the CG women had an incidence of 33%.

Conclusions. These prophylactic strategies appear to reduce the development of secondary lymphedema and alter its progression in comparison to the CG women.

INTRODUCTION

Secondary arm lymphedema is a common and disabling complication of breast cancer treatment. A degree of arm swelling in the early postoperative period may only be a transient reaction to the surgical and radiotherapy treatments and tend to settle spontaneously within a matter of weeks.¹⁻³ Lymphedema may arise at any time, months or years after breast cancer surgery (till over 20 years after the initial treatment).⁴⁻⁶ About 75 per cent of cases, however, occur in the first year after surgery.⁷⁻¹⁰ Quoted prevalence rates for secondary arm lymphedema vary from 5 to 60% in different studies,¹¹⁻¹² perhaps as a consequence of differences between the number of cases examined, different levels of awareness of the problem, measurements methods, lack of a universal definition of criteria used for the diagnosis of lymphedema, duration of follow-up, surgical procedures. The major risk factors for later development of arm lymphedema comprise “rough” surgical technique, the extent of axillary dissection, axillary radiotherapy, and complications in wound healing including those caused by bacterial infection.¹³ Using atraumatic surgical technique, tissues are minimally injured and resprouting of lymphatics is facilitated¹⁴ allowing for new lymphatic-lymphatic or lympho-venous connections. Such lymphangiogenesis and lymphovascuogenesis improves the lymphatic transport capacity.¹⁵

The potential later development of lymph stasis in the upper extremity is probably unavoidable after axillary nodal dissection including sentinel node(s) removal. It is only a matter of time (sometimes years) before the first episode of dermatolymphangioadenitis (DLA) occurs, and lymphedema becomes clinically manifest.¹³

The question remains open, however, which patient will develop overt lymphedema and in whom lymphedema will remain “latent”. This prospective randomised controlled study was designed to objectively determine the effects of a specific protocol of

prophylactic measurements on the development of secondary lymphedema and to assess the role of early lymphoscintigraphy in evaluating the extent of lymph stasis and in predicting the likelihood of later development of arm lymphedema.

PATIENTS AND METHODS

Patients scheduled to undergo breast-conserving surgery or modified radical mastectomy for breast cancer were randomly allocated to either the preventive protocol group (PG) or control group (CG) after informed consent was obtained. Fifty-five of the 73 women scheduled for breast cancer surgery during the study period met the inclusion criteria preoperatively. Four patients were excluded postoperatively when the planned axillary dissection was not performed. The remaining 18 women were excluded due to: refusal to perform lymphoscintigraphy preoperatively, and difficulty to accurately follow the protocol guidelines. The mean age of the women in this study was 54.07 years (SD = 10.54) and 48 % underwent breast-conserving surgery. As concerns radiotherapy, there was no significant difference between the two groups in the sites that were irradiated with the breast being the most common site, then the chest wall, supraclavicular fossa and internal mammary chain in decreasing frequency.

Each woman was assessed preoperatively and then postoperatively at 1 (1 mo.) month, three (3 mo.), six (6 mo.), twelve (12 mo.) and twenty-four (24 mo.) months.

The volume (VOL) of each woman's arms were assessed using water displacement and measured to the nearest 5 ml. The

difference between the VOL measurements of both arms (operated arm OA – unoperated arm UOA) was determined. Both arms were measured at each review period and compared to preoperative data. The use of the difference between the two arms ensures that changes measured in the operated arm (that may have indicated early lymphedema) are not due to variability in arm volume over time. The criteria used to identify early secondary lymphedema included a difference of over 10% of excess volume from preoperative VOL measurements (OA – UOA VOL).¹⁶⁻¹⁷

The preventive protocol for the PG women (25) included preoperative upper limb lymphoscintigraphy (LS),¹⁸⁻¹⁹ principles for lymphedema risk minimisation²⁰ and early management of this condition when it was identified.²¹

LS reveals different lymphatic patterns, including no useful lymph drainage with marked tracer dispersion (dermal back flow) throughout the arm (severe lymphatic impairment – LI), partially intact lymphatic collectors but with tracer dispersion in the forearm (mild to moderate LI), intact trunks without dermal back flow (no LI).

In women (18) with negative LS (NEG LS) the preventive protocol included the use of blue dye (Blue Patent V) injected at the volar surface of the arm at the time of breast cancer surgery in order to point out and try to preserve lymphatic vessels coming from the arm stained in blue. Patients (7) with positive LS (POS LS) underwent a microsurgical operation of lymphatic-venous multiple anastomoses²² at the volar surface of the proximal third of the arm performed at the same time of axillary nodal dissection (Fig. 1).

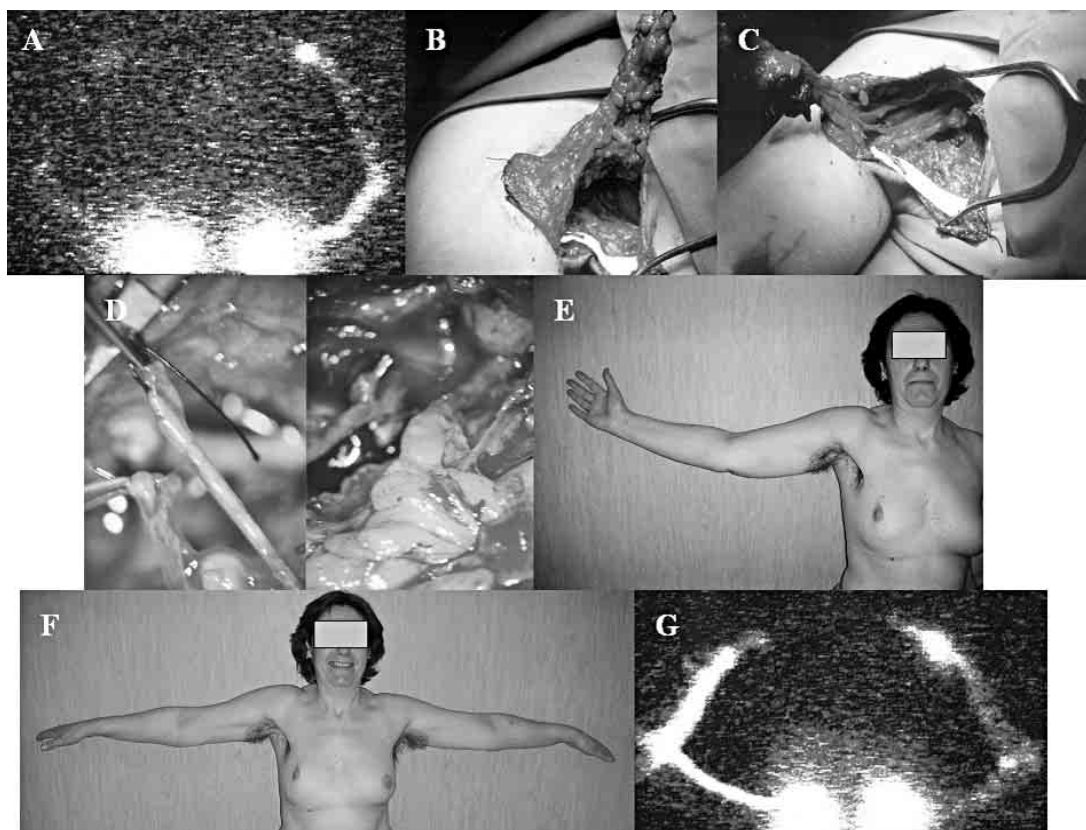


Fig. 1 - Patient affected from right breast cancer and addressed to lumpectomy and axillary lymph-nodal dissection. Lymphoscintigraphy performed before breast surgery showed a lymphatic impairment at the right upper limb (A). It was, thus, decided to perform lymphatic-venous anastomoses at the upper third of the arm at the same time of axillary dissection. The blue dye was injected at the volar surface of the arm so allowing to identify lymphatic collectors draining the arm. A collateral of the axillary vein is prepared for anastomoses. Telescopic lymphatic-venous anastomoses are performed at the operating microscope (25x) (B, C, D). Short and long term clinical assessment of the result (E, F). Lymphoscintigraphy after 9 months after microsurgery points out the good lymphatic drainage of the right upper limb (G).

The NEG LS group was followed-up clinically (VOL) and by lymphoscintigraphy (at 6 mo. post-op).

When post-op LS pointed out disruption or blockage of arm lymphatic drainage before the onset of limb swelling, women underwent early use of elastic sleeves, supplemented by manual lymphatic drainage, prophylactic external compression, and remedial exercises.²³

In case of appearance or worsening of lymphedema notwithstanding the physical methods, the patients underwent early microsurgical operation.²⁴

STATISTICAL ANALYSIS

The comparison between variables age, BMI, lymphonodes removed, metastatic lymphnodes (MLN), surgical procedure, axillary dissection level, site of radiotherapy, wound infection, operated arm (OA) volume at baseline in PG and CG was performed using t-test as data were normally distributed (one-sample Kolmogorov-Smirnov p-value NS for every variables). As variable "MLN" was not normally distributed both in PG (one-sample Kolmogorov-Smirnov p-value=0.004) and CG (p-value=0.003), Mann Whitney-test was used. Nominal baseline variables were compared using Chi square or Fischer's Exact Test. The comparison between percentage increase in comparison with baseline volume after 1, 3, 6, 12 and 24 months from operation in PG and CG was performed using the Mann Whitney test (between groups) and Wilcoxon test (between timing), as data are not

symmetrically distributed and normal distribution could not be assumed as demonstrated using one-sample Kolmogorov-Smirnov test (see Results section). The percentage increase was represented by box plots showing the median, inter-quartile range, outliers and extreme cases of variables. Number of patients with increase >10% at different timing in PG and CG were compared using 2-sided Fischer's Exact Test.

RESULTS

Assessments at 2 years postoperatively were completed for 89% (49) of the 55 women who were randomly assigned to either PG (25) or CG (24).

The demographic and surgical data and OA baseline volume are reported in Table 1. No significant difference was observed as regards age, BMI, lymphonodes removed, MLN, surgical procedure, axillary dissection level, site of radiotherapy, wound infection, operated arm (OA) volume.

The baseline volumes in PG and CG were overlapping both in terms of central trend index (mean and median) and absolute dispersion (standard deviation and range). The percentage increase in comparison with baseline volume after 1, 3, 6, 12 and 24 months in PG and CG is reported in Table 2. The data distribution is not normal for PG at 3 months (one-sample Kolmogorov-Smirnov test p-value=0.001) and 6 months (p-value=0.001) and for CG at 3 months (p-value<0.001), 6 (p-value=0.003), 12 (p-value=0.008) and 24 (p-value=0.011) months.

Table 1 - The study population.

		PG	CG	p-value
Subjects (n.)		25	24	
Age Mean±Standard Deviation (years)		53.4±7.2	54.6±7.9	NS
BMI Mean±Standard Deviation (Kg/m ²)		27.3±5.4	29.9±6.8	NS
Lymphonodes Removed Mean±Standard Deviation (n.)		15.2±3.8	15.1±3.8	NS
MLN Mean±Standard Deviation (n.)		1.5±1.8	1.4±1.7	NS
Surgical Procedure (n.)	<i>CLE & AD</i>	12	13	NS
	<i>MRM & AD</i>	13	11	
Axillary dissection level	<i>I</i>	4	5	NS
	<i>II</i>	17	13	
	<i>III</i>	4	5	
Radiotherapy (n.)	<i>Breast</i>	15	14	NS
	<i>Chest wall</i>	4	3	
	<i>Internal mammary chain</i>	3	2	
	<i>Supraclavicular fossa</i>	3	3	
Wound infection (n.)		3	3	NS
OA Baseline Volume (cc)	<i>Mean±Standard Deviation</i>	2144±618	2163±623	NS
	<i>95% Confidence Interval</i>	1889-2400	1901-2427	
	<i>Median</i>	2140	2143	
	<i>Min-Max</i>	1235-3100	1235-3100	

MLN = metastatic lymphnodes;

OA = operated arm.

Table 2 - Percentage increase in comparison with baseline volume.

	Time after operation (months)				
	1	3	6	12	24
PG women					
Mean±Standard Deviation	3.8±1.7	0.9±1.6	2.4±4	1.1±0.6	1.3±0.7
95% Confidence Interval	3.1-4.5	0.3-1.6	0.7-4	0.9-1.4	1-1.6
Median	3.5	0.5	1.2	1.2	1.1
N. (%)>10	0	0	2 (8)	0	0
Wilcoxon p-value (in comparison with the previous timing)		<0.001	<0.001	0.036	0.022
CG women					
Mean±Standard Deviation	3.7±1.7	2.8±6.3	6.2±8.6	7.8±9.8	8.3±10.1
95% Confidence Interval	3-4.4	0,2-5.5	2.6-9.9	3.7-11.9	4-12.5
Median	3.4	0.5	1.4	1.7	1.9
N. (%)>10	0	2 (8.3)	6 (25)	8 (33.3)	8 (33.3)
Wilcoxon p-value (in comparison with the previous timing)		0.028	<0.001	NS	<0.001

PG and CG showed similar percentage increase at 1 month (Mann Whitney test p-value=0.873) and 3 month (p-value=0.734). The increase of volume was higher in the Control group in comparison with PG group at 12 month (p-value=0.038) and 24 month (p-value=0.012), while at 6 month the difference was not statistically significant (p-value=0.17). The number of patients with a volume increase>10% is showed in Table 2 and the proportion was higher in the CG at 12 month (Fischer's Exact Test p-value=0.004) and 24 month (p-value=0.004) – Fig.2.

Of the 49 women with unilateral breast cancer surgery who were measured at 24 mo., 10 (21%) were identified with secondary lymphedema using the VOL (OA-UOA).

In PG, two women showed over 10% increase in volume at the 6th month, but the volume decreased after 12 and 24 months. The other 23 women did not showed an increase of over 10% in volume (2/25: 8%). In CG, 6 (25%) patients revealed an over 10% volume at 6 month that was confirmed at 12 and 24 months. Other 2 women showed the increase at 12 and 24 months (8/24: 33%).

DISCUSSION

The incidence of clinically evident secondary lymphedema at 2 years after unilateral breast cancer surgery was 21% (10 out of 49 patients). All women were at risk of developing secondary lymphedema due to the surgical excision of the axillary lymph nodes. The clinical changes in the operated arm were confirmed by an increase of at least 200 ml from the pre-operative volumetric measurements. At 2 years, 33% of the CG women had been identified with secondary lymphedema compared to only 8 % of the PG women.

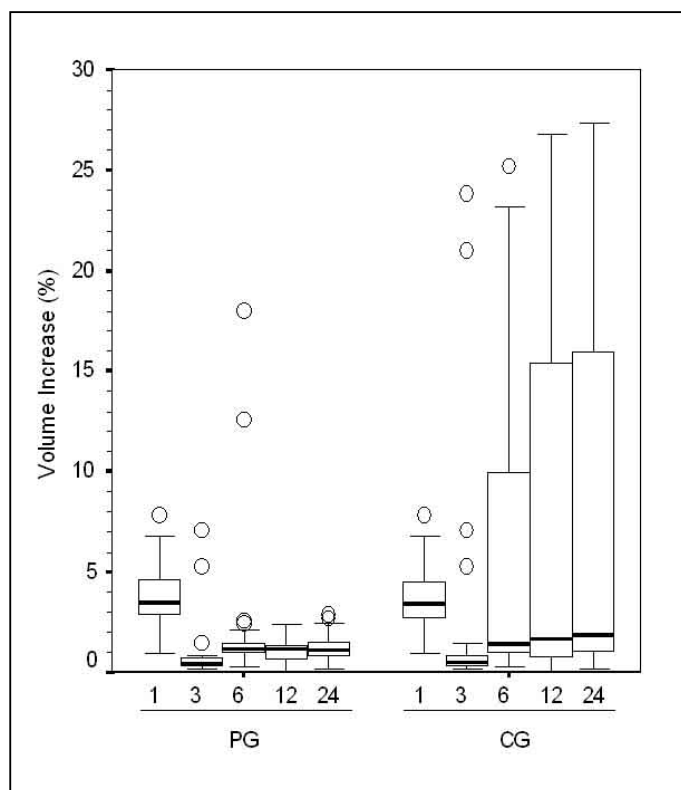


Fig. 2 - The percentage increase is represented by box plots showing the median, inter-quartile range, outliers and extreme cases of variables. Number of patients with increase >10% at different timing in PG and CG are compared using 2-sided Fischer's Exact Test.

Most of the CG women detected with an increase of over 10% from their pre-operative volumetry had persistent changes in arm volume from 6 to 12 months postoperatively. For two of the PG women, secondary lymphedema was first detected at 24 months but there tended to be a steady progression in the difference between the OA and UOA. In comparison, the pattern of change in volume measurements was inconsistent for the surviving women in the PG or CG, and in the majority of cases, did not exceed the clinical criteria. There are a few CG women who have increases in their volume but at the time of their 2 years review did not have clinically significant lymphedema.

Using the volumetric criteria and clinical signs, this study has demonstrated that the incidence of early secondary lymphedema at 24 months is similar to that detected previously in women who were assessed at later stages postoperatively when the only postoperative difference between the arms was considered. In the majority of women, changes consistent with lymphoedema were detected from 6 mo. postoperatively suggesting the early onset of significant secondary lymphedema may be detected with clinical assessment and objective measurement within the first year postoperatively. The early detection may result in more effective management and the resolution of acute lymphedema before it develops into a more chronic condition, identifying as a high priority the early detection of possible benefits of early intervention for secondary lymphoedema.²¹

Secondary arm lymphedema has been identified in 21% of the women who were assessed at 2 years after unilateral breast cancer surgery using a comparison to the preoperative measurements for each woman. The criteria, an increase of >200 ml from the preoperative volumetric conditions, was determined to be a sensitive measurement to detect early clinically significant secondary lymphedema.

The qualitative results of this study suggest that the strategies incorporated into the preventive protocol for the prevention and early intervention of secondary lymphedema do influence the occurrence and severity of secondary lymphedema in the TG women compared to those in the CG. At 24 months after breast cancer surgery, the CG women have almost three times the incidence of secondary lymphedema compared to the TG and in two-thirds of the CG women it was detected from 6 months postoperatively. The extension of this study to monitor the progress of the surviving women for another 3 years postoperatively will continue to provide further information on these early effects on the incidence and progression of secondary lymphedema after breast cancer surgery due to the use of this diagnostic and therapeutic preventive protocol.

REFERENCES

1. Pain SJ, Purushotham AD. *Lymphoedema following surgery for breast cancer*. British Journal of Surgery 2000; 87: 1128-1141.
2. Clodius L. *More on axillary lymphadenectomy*. Lymphology 2003; 36; 1-6.
3. Roses DF, Brooks AD, Harris MN, Shapiro RL, Mitnick J. *Complications of level I and II axillary dissection in the treatment of carcinoma of the breast*. Annals of Surgery 1999; 230(2): 194-201.
4. Pressman P. *Surgical treatment and lymphedema*. Cancer 1998; 83: 2782-2787.
5. Kissin MW, Querci della Rivere G, Easton D, Westbury G. *Risk of lymphoedema following the treatment of breast cancer*. Br J Surg 1986; 73: 580-4.
6. Schunemann H, Willich N. *Lymphoedema of the arm after primary treatment of breast cancer*. Anticancer Res 1998; 18: 2235-6.
7. Hardy JR. *Lymphedema – Prevention rather than Cure*. Annals of Oncology 1991; 2: 532-533.
8. Burstein HJ, Winer EP. *Primary Care for Survivors of Breast Cancer*. N Engl J Med 2000; 343: 1086-1094.
9. Hoe AL, Iven D, Boyle GT, Taylor I. *Incidence of arm swelling following axillary clearance for breast cancer*. Br J Surg 1992; 79: 261-262.
10. Duff M, Hill AD, McGreal G, Walsh S, McDermott EW, O'Higgins NJ. *Prospective evaluation of the morbidity of axillary clearance for breast cancer*. Br J Surg 2001 Jan; 88(1): 114-7.
11. Mortimer PS, Bates DO, Brassington HD, Stanton AWB, Strachan DP, Levick JR. *The prevalence of arm oedema following treatment for breast cancer*. Q J Med 1996; 89: 377-80.
12. Lin PP, Allison DC, Wainstock J. *Impact of axillary lymph node dissection on the therapy of breast cancer patients*. J Clin Oncol 1993; 11: 1536-1544.
13. Olszewski WL. *Axillary dissection for breast cancer*. Lymphology. 2002 Mar;35(1):41-2.
14. Clodius L. *Minimizing Secondary Arm Lymphedema from Axillary Dissection*. Lymphology. 2001 Sept; 34(3):106-10.
15. Földi M. *On the pathophysiology of arm lymphedema after treatment for breast cancer*. Lymphology. 1995 Sep; 28(3): 151-8.
16. Box RC, Reul-hirche HM, Bullock-Saxton JE. *The intra- and inter-tester reliability of three measurement methods for the early detection of lymphoedema after axillary dissection*. Eur J Lymph 1999; 27: 74-79.
17. Starritt EC, Joseph D, McKinnon JG, Lo SK, de Wilt JHW, Thompson JF. *Lymphedema after complete axillary node dissection for melanoma: assessment using a new objective definition*. Annals of Surgery 2004; 240(5): 866-874.
18. Mariani G, Campisi C, Taddei G, Boccardo F. *The current role of lymphoscintigraphy in the diagnostic evaluation of patients with peripheral lymphedema*. Lymphology 1998; 31 (Suppl): 316-9.
19. Bourgeois P, Leduc O, Leduc A. *Imaging techniques in the management and prevention of posttherapeutic upper limb edemas*. Cancer 1998 Dec 15; 83 (12 Suppl American): 2805-13.
20. Clodius L. *Minimizing secondary arm lymphedema from axillary dissection*. Lymphology 2001; 34(3): 106-110.
21. Consensus document of the International Society of Lymphology. *The diagnosis and treatment of peripheral lymphedema*. Lymphology. 2003 Jun;36(2):84-91.
22. Campisi C, Boccardo F. *Microsurgical techniques for lymphedema treatment: derivative lymphatic-venous microsurgery*. World J Surg. 2004 Jun; 28(6): 609-13.
23. Földi M. *The therapy of lymphedema*. Eur J Lymph 1994; 14: 43-49.
24. Campisi C, Boccardo F. *Lymphedema and microsurgery*. Microsurgery. 2002;22(2):74-80.