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ULTRASOUND THERAPY OF CHRONIC ARM LYMPHEDEMA AFTER SURGICAL TREATMENT OF BREAST CANCER

A. Balzarini, C. Pirovano, G. Diazzi, R. Olivieri,F. Ferla, G. Galperti, S. Sensi, G. Martino

Department of Physical Therapy and Rehabilitation, National Cancer Institute, Milan, Italy

ABSTRACT

The treatment of chronic arm lymphedema following axillary dissection for breast cancer is still a therapeutic challenge. To examine other treatment options, we undertook a pilot study on the efficacy of ultrasound therapy (UST) in management of these patients. Fifty patients with post-surgical arm lymphedema and without regional irradiation underwent ultrasound treatment (2 cycles at 4 month intervals) and the results were compared up to 1 year with 100 other patients treated by standardized mechanical pressure therapy (MPT) using a pneumatic pump. In this report we evaluate 96 patients who have been followed after 1 year, 31 of whom belong to UST group and 65 to the MPT group. UST did not show a statistically significant difference in whole arm reduction of lymphedema although there was initially a greater reduction in size after the first 4 months of treatment. The addition of an elastic sleeve did not improve lymphedema in either group. Advantages of UST were an overall shorter length of treatment, a tendency to greater softening of the arm, patient satisfaction by avoidance of an uncomfortable and constrictive device and better relief of osteomyofascial pain, greater scapulohumeral motion, and less intercostobrachial pain-dysesthesia.

Edema of the arm is a recognized complication of axillary dissection in patients treated for breast cancer. Less extensive operations, improved high energy complementary radiotherapy and rehabilitative programs designed to improve both early and long-term arm-shoulder function have resulted in a lower incidence of arm lymphedema, which is now estimated to affect 10% of these patients (1).

Mechanical pressure therapy, either manual or "constrictive" or in combination have thus far been the most popular methods to control gross edema. Unless pressure therapy is instituted within 6 months after the onset of edema, the chance of edema resolution is poor (2). Moreover, the tendency to progressive fibrosis after mechanical therapy, the effort and intensity of manual massage, and the low tolerance for pneumatic compression are commonly observed during treatment (3) and have spurred a search for a better treatment option.

Our research work, supported in part by the Italian National Council for Scientific Research (C.N.R.) (4-7), has included about 1600 patients with chronic arm edema following axillary dissection (~150 patients each year in our department). This preliminary study on the efficacy of ultrasound (US) for the treatment of iatrogenic chronic arm lymphedema was developed in this clinical setting.

US is an "old" practice in physiatry for treatment for osteomyofascial pain (8,9) but thus far has not been used for treatment of diffuse, peripheral edema. The basis to test US in treatment of chronic lymphedema derives from its "soft action" (in contradistinction to

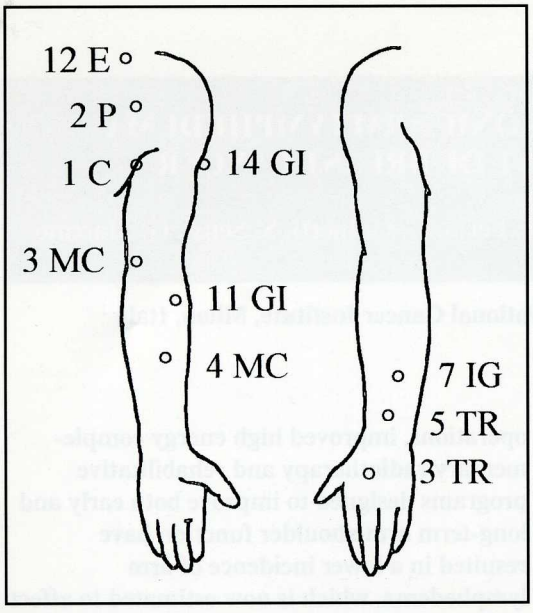

Fig. 1. Position of the ultrasound transducers on acupoints located along the meridians of the arm in agreement with the principles of Chinese Traditional Medicine. E: "Estomac"; P: "Poumon"; C: "Coeur"; MC: "Maitre du Coeur"; GI: "Gros Intestin"; IG: "Intestin Grele"; TR: "Tros Rechauffeurs".

mechanical pressure therapy or MPT), and that it primarily operates by micromassage exerted through wave propagation at a cellular level with slight heat (a Joule effect) that modifies cell metabolism and the microcirculation (10), which, in turn, may promote lymph flow and possibly reduce firmness and fibrosis so commonly observed after MPT. Because chronic lymphedema patients often display osteomyofascial pain, this symptom potentially may also be alleviated by UST. Nowadays, we use US equipment fitted with 10 fixed sequenced transducers, which enables treatment of both scapulohumeral/spaculothoracic pain and lymphedema effortlessly, at several points on the arm. For positioning of the transducers, we have used acupuncture sites along the meridians of the edematous arm *(Fig. 1)* according to principles of Chinese Traditional Medicine (11) and from earlier studies on treatment of edema by HeNe laser (12). The selection of acupuncture sites derives from work carried out by Chinese and Italian colleagues who as acupuncturists worked in our Department (since 1987) and rests on the following reasons: 1) acupuncture stimulation influences the balance of all body fluids (both intra- and extracellular); 2) the impression that patients treated by acupuncture for chronic edema showed improvement; and 3) acupuncture sites are readily determined anatomically.

The efficacy of UST was evaluated by determining the size and firmness of the edematous arm, prolonged benefit with and without concomitant use of an elastic sleeve (ES), and relief of scapulohumeral and intercostobrachial pain syndrome. The data were compared to a group of patients undergoing standard MPT (controls).

CLINICAL EXPERIENCE

One hundred and fifty consecutive women with chronic arm lymphedema after surgery on the breast including axillary node dissection for treatment of cancer were selected from 1991 onward. Those patients who underwent regional radiotherapy (chest wall, axilla, and/or supraclavicular region) though unusual at our institute were excluded.

The criteria for admission to this pilot phase were broad and patients were not excluded because of age, weight, hormonal state, size, firmness, or time of onset of edema after operation. Lymphedema was quantified as percent size difference (SIZE%) between the edematous arm and the nonedematous contralateral arm. This size differential in circumference was measured in both arms at 5 standard sites (1). A SIZE% equal to or less than 6.5 (SIZE%) was deemed "slight" edema; one equal to or higher than 13 (SIZE%) was designated "severe" edema, and a SIZE% between these two values was taken as "moderate" edema.

Ultrasound Therapy

Fifty patients received 2 UST cycles at 4

TABLE 1
Therapeutic Protocol for Iatrogenic Chronic Edema*

Time	Ultrasound	Mechanical Pressure
0	Measuring arms and treatment (30 min per day for 10 consecutive days) at 2 Watt/cm^2 power, at a frequency of 3 MHz. Cycle of 5 sec cycle corresponding to a 0.5 sec time during which sound pulse remains on each transducers **1st cycle**	Measuring arms and treatment (6 hours per day for 5 consecutive days) at a pressure of 40 mmHg **1st cycle**
After 4 Months	Measuring arms and repetition of treatment **2 cycle**	Measuring arms and repetition of treatment **2 cycle**
After 8 Months	Arm measurements	Arm measurements and repetition of treatment **3rd cycle**
After 12 Months	Arms measurements	Arm measurements

*Arm lymphedema after axillary dissection in treatment of breast cancer.

month intervals and followed for up to 1 year. UST consisted of 10 sessions, each of them lasting 30 minutes, using stimulation modes and power as shown in *Table 1.* UST was performed with the aid of a LIPOSONIC 10 equipment, fitted with 10 fixed transducers to be connected to the arm by means of suitable straps and sequenced so as to maintain a power of 2 watt/cm^2 with no risk of tissue injury (Joule effect, interference phenomena and wave node formation). These 50 patients were randomized into 2 subsets: 1) 25 patients regularly wore an ES measured to limb size between the 2 treatment cycles and thereafter during follow-up over 12 months; 2) the other 25 patients did not use an ES and had no other treatment. Seventeen of these patients underwent modified radical mastectomy without radiotherapy and 33 underwent a quadrantectomy with axillary dissection with radiotherapy only to ipsilateral mammary tissue ("conservative" operation) according to the Veronesi technique (12).

Mechanical Pressure Therapy

One hundred other patients with "post-mastectomy lymphedema" (control group) underwent MPT according to our optimized protocol: 1 cycle (consisting of 6 hours a day for 5 consecutive days at a pressure of 30-40mmHg) at 4 month intervals (3 cycles in a year) (3). After the first cycle of therapy, the patients were randomized—half wore a prescribed ES between this cycle and the subsequent ones over the year, whereas the

TABLE 2
Edema Evaluation Scale

Firmness	normal	soft	medium-hard	hard	cellulitic
Degree	0	1	2	3	4
Pitting	(+) or (-)	(+) or (-)	(+) or (-)	(+) or (-)	(+) or (-)

TABLE 3

Group	N	SIZE%						H	P
		time 0	4 mos	8 mos	12 mos	MEAN reduction	SD reduction		
UST+ES	15	8.4	5.6	6.5	6.7	1.7	1.48	0.33	0.56
UST	16	9.0	7.1	6.8	7.0	2.0	1.39		
MPT+ES	35	9.5	8.5	8.2	7.6	1.9	1.32	17.35	0.0001
MPT	30	8.6	8.1	7.9	7.4	1.1	1.25		

UST=Ultrasound Therapy; ES=Elastic Sleeve; MPT=Mechanical Pressure Therapy; SIZE%=Percent difference of circumference between the edematous arm and the nonedematous contralateral arm

other half did not wear an sleeve. In the MPT group, 24 patients underwent modified radical mastectomy without radiotherapy and 76 "conservative" operations. MPT was accomplished using a uniform pneumatic sleeve (Jobst Extremity Pump) which produced high pressures and was fitted with a regulatory valve.

We opted to compare UST and MPT therapy excluding a subgroup with no therapy because we deemed it unethical not to treat patients with symptomatic chronic arm lymphedema. Besides dimensional data, we subjectively determined the "firmness" of lymphedema based upon the scoring system shown in *Table 2*.

Variations in arm size and firmness of edema were assessed after each treatment cycle and every 4 months until 1 year.

RESULTS

The data thus far comes from 96 patients, 31 of whom belonged to the UST group and 65 to the MPT group. Twelve patients (5 and 7, respectively, in the two groups) were removed from the trial either because of recurrence of cancer (2 patients in the MPT group) or non-compliance with the protocol. Follow-up continues for the remaining 42 patients.

In the UST group 11 patients underwent radical mastectomy modified according to Patey, without radiotherapy, and 20 were submitted to quadrantectomy with axillary dissection and radiotherapy to ipsilateral mammary tissue (QU.A.RT) according to Veronesi (13); in the MPT group 19 radical and 46 "conservative" operations were performed.

The interval between operation and onset of arm edema ranged from 3 to 52 months in the UST group and from 5 to 57 months in the MPT group. In the two groups overall, at time 0 (i.e., onset of therapy) mean arm size difference was 8.78% in the UST group and 9.13% in the MPT group; after 12 months, the SIZE% was 6.88 in the UST group and 7.55 in the MPT group—non-significant difference (Kruskal Wallis analysis of variance by ranks,

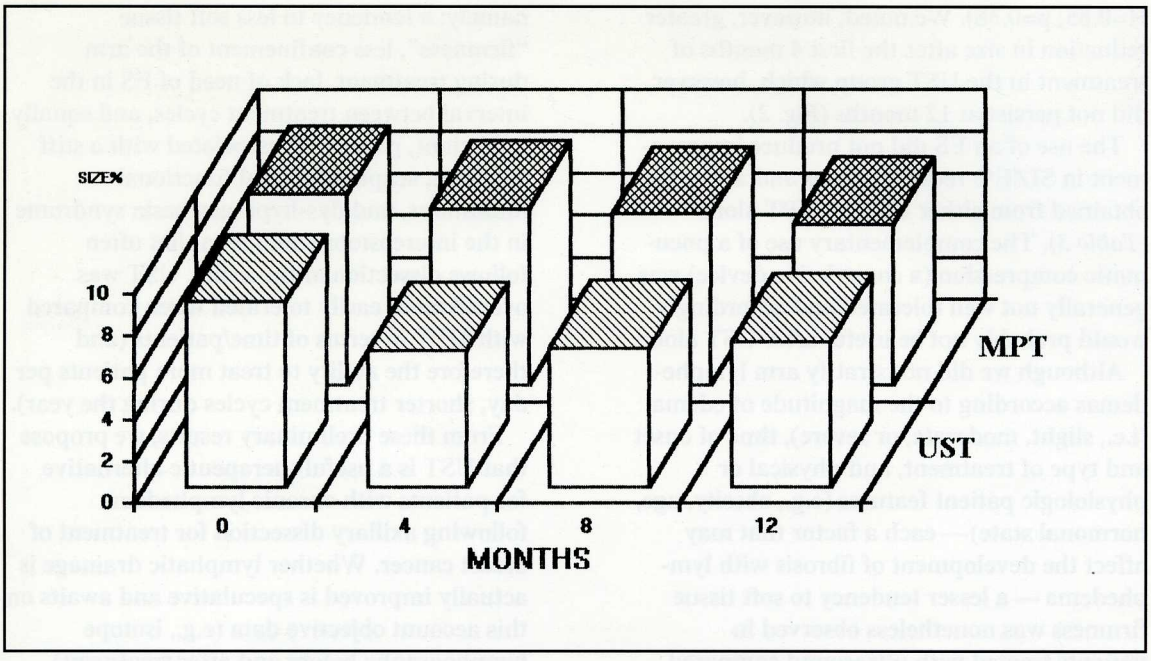

Fig. 2. Degree of arm lymphedema (SIZE%) in the two patient subgroups undergoing therapy. MPT: mechanical pressure therapy; UST: ultrasound therapy.

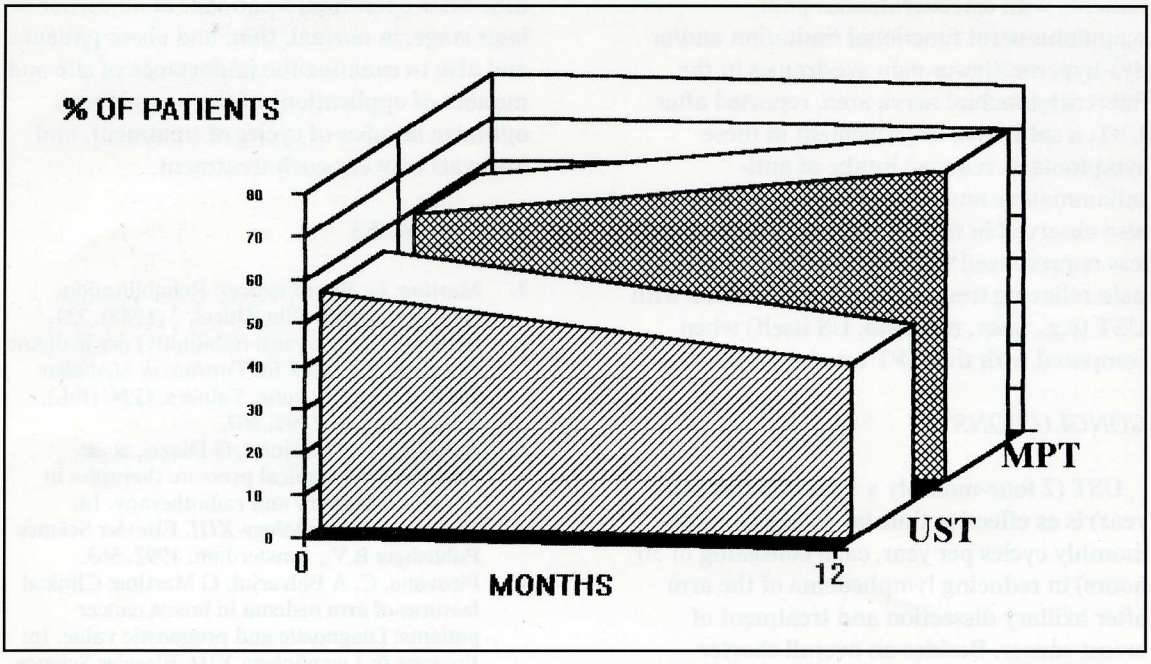

Fig. 3. Subjective degree of soft tissue firmness (tendency to fibrosis) in the two patient subgroups with arm lymphedema. MPT: mechanical pressure therapy; UST: ultrasound therapy.

H=0.85, p=0.36). We noted, however, greater reduction in size after the first 4 months of treatment in the UST group which, however, did not persist at 12 months *(Fig. 2)*.

The use of an ES did not produce improvement in SIZE% reduction over and above that obtained from either UST or MPT alone *(Table 3)*. The complementary use of a pneumatic compression (a constrictive device) was generally not well tolerated and accordingly would probably not be useful after UST alone.

Although we did not stratify arm lymphedemas according to the magnitude of edema (i.e., slight, moderate, or severe), time of onset and type of treatment, and physical or physiologic patient features (e.g., obesity, age, hormonal state)— each a factor that may affect the development of fibrosis with lymphedema — a lesser tendency to soft tissue firmness was nonetheless observed in patients treated with ultrasound compared with those undergoing mechanical pressure therapy *(Fig. 3)*.

In confirmation of the anticipated "anti-inflammatory" action of UST, 90% of patients with osteomyofascial pain, scapulohumeral functional limitation and/or dys-hyperaesthesia-pain syndromes in the intercostobrachial nerve area, reported after UST, a subjective improvement in these symptoms. A reduced intake of anti-inflammatory and mild analgesic drugs was also observed in the UST group, together with less request/need from these patients for other pain relieving treatments often combined with UST (e.g., laser, magneto, US itself) when compared with the MPT treated group.

CONCLUSIONS

UST (2 four-monthly x 5 hour cycles per year) is as effective thus far as MPT (3 four-monthly cycles per year, each consisting of 30 hours) in reducing lymphedema of the arm after axillary dissection and treatment of breast cancer. Besides an overall shorter length of treatment, UST has several other advantages when compared with MPT, namely: a tendency to less soft tissue "firmness", less confinement of the arm during treatment, lack of need of ES in the interval between treatment cycles, and equally important, pain relief associated with a stiff shoulder, scapulohumeral functional limitations, and dys-hyperaesthesia syndrome in the intercostobrachial area that often follows dissection of the axilla. UST was overall more easily tolerated when compared with MPT in terms of time/patients (and therefore the ability to treat more patients per day, shorter treatment cycles during the year).

From these preliminary results, we propose that UST is a useful therapeutic alternative for patients with chronic lymphedema following axillary dissection for treatment of breast cancer. Whether lymphatic drainage is actually improved is speculative and awaits on this account objective data (e.g., isotope lymphography before and after treatment).

Our trial is ongoing and will be extended to assess the efficacy of UST on slight, moderate, and more severe lymphedemas including those swellings that appear either promptly or sometime after operation, treatment at an earlier or later stage, in normal, thin, and obese patients, and also to examine the importance of site and number of applications of the transducers, optimize number of cycles of treatment, and intervals between each treatment.

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Gemma Martino, M.D.
Director, Department of Physical Therapy and Rehabilitation
Istituto Nazionale per lo Studio e la Cura dei Tumori Milano
via Venezian, 1
20133 Milan, ITALY