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A safety and efficacy pilot study of acupuncture for the treatment of chronic lymphoedema

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ABSTRACT

Background Lymphoedema is a distressing problem affecting many women after breast cancer surgery. There is no cure and existing treatments are marginally beneficial, rarely reducing arm swelling in any meaningful way. Needling and even lifting of objects using the affected arm has been prohibited, but our clinical experience and that of others suggested that acupuncture was safe and that it might be a useful treatment for lymphoedema.

Objective We sought to conduct a pilot study of the safety and effectiveness of acupuncture in women diagnosed with chronic lymphoedema for at least 6 months and less than 5 years.

Methods Women with chronic lymphoedema (affected arm with >2 cm circumference than unaffected arm) after breast cancer surgery received acupuncture twice a week for 4 weeks. Response was defined as at least a 30% reduction in the difference in size between the affected and unaffected arms. Monthly follow-up calls for 6 months following treatment were made to obtain information about side effects.

Results Study goals were met after nine subjects were treated: four women showed at least a 30% reduction in the extent of lymphoedema at 4 weeks when compared with their respective baseline values. No serious adverse events occurred during or after 73 treatment sessions.

Limitations This pilot study requires a larger, randomised follow-up investigation plus enquiries into possible mechanisms. Both are in development by our group.

Conclusion Acupuncture appears safe and may reduce lymphoedema associated with breast cancer surgery.

BACKGROUND

A primary cause of lymphoedema, or swelling of a limb, is surgery or radiation treatment for breast cancer. The accumulation of fluid occurs when lymph nodes are removed. In a study of 251 women who had surgical treatment for breast cancer involving sampling, excision or biopsy of axillary nodes, 39 (20.7%) had developed lymphoedema at 3 years postsurgery. Risk factors for development of lymphoedema in this study included mastectomy and body mass index ≥26.[1] Lymphoedema is considered a chronic, life-long condition as there are no curative treatments.[2] While uncommon when axillary surgery is restricted to sentinel lymph node biopsy (6.9% of patients),[3] a study of 109 patients with mild lymphoedema found that the unpredictable rate of progression from mild to more severe lymphoedema was 79% at 1 year, 66% at 3 years and 52% at 5 years.[4]

Physical problems and emotional distress are commonly reported by breast cancer survivors with lymphoedema. Impaired quality of life, limitations to daily activities, the constant protection required to avoid activities feared to exacerbate or cause lymphoedema, and the body image issues associated with having one abnormally enlarged limb are reported in numerous publications.[5–14] A study of the economic burden of breast cancer-related lymphoedema includes greater risk of infections and higher medical costs.[15]

Little research has been published on acupuncture for lymphoedema. In the USA, this is due in large part to the prohibition against needling and to other efforts to protect the affected arm. However, studies from Japan and USA on acupuncture for lymphoedema found neither infection nor other side effects.[16 17] Acupuncture is a safe treatment when performed by qualified practitioners. After 760 000 treatments in 97 733 patients receiving acupuncture in Germany, only six cases of serious adverse events (SAEs) were reported.[18] In another study from Germany, 229 230 patients received over 2.2 million acupuncture sessions. Adverse effects occurred in 8.6% of the sampled patients, however, most were minor events such as bleeding and bruising. Of all adverse effects, 0.1% was indicative of negligence or malpractice (broken or forgotten needle, pneumothorax, burns after moxibustion).[19]

This study sought to obtain preliminary evidence of the effects of acupuncture on chronic lymphoedema due to breast cancer treatment and to further evaluate the safety of acupuncture in this setting.

METHODS

After approval of the protocol by the institutional review board, patients were identified

and screened by an Integrative Medicine Service research assistant. After obtaining informed consent and following approval from the beast cancer physicians at the Memorial Sloan-Kettering Cancer Center (MSKCC), patients were accrued to the study. Inclusion criteria were women aged 18 years or older; lymphoedema in an arm as a result of surgery and/or radiation therapy for breast cancer; clinical diagnosis of lymphoedema for at least 6 months and no more than 5 years; and affected arm with >2 cm circumference than the unaffected arm. Previous acupuncture treatment for lymphoedema and the current use of diuretics were the sole exclusion criteria.

Upper extremity measurements were performed in a standard fashion: the circumference of the patient's upper arms and forearms was measured, in both the affected and unaffected limbs, before and after each treatment. The upper arm was measured at 10 cm above the olecranon process; the forearm was measured at 5 cm below the olecranon process. The site with the greater difference between affected and unaffected arms (either the forearm or the upper arm) was used to determine baseline and outcome assessment for each patient. Changes in each patient's arm circumference were compared against her baseline measures.

Response was defined as at least a 30% reduction in the difference in size between the affected and unaffected arms after 4 weeks of treatment.

Traditional Chinese Medicine acupuncture treatment was given by certified acupuncturist members of the MSKCC Integrative Medicine Service. All Integrative Medicine Service acupuncturists are licensed, credentialed employees of MSKCC. They selected the point prescription by consensus, based on historical context plus their relevant professional experience. The same point prescription was used for all patients; needle stimulation was a manual gentle rotation with lift and thrust. Needles were inserted bilaterally, in the affected as well as the unaffected limb. The acupuncturists were not intentionally seeking de qi sensation.

Alcohol swabs were applied prior to insertion of sterile, filiform, single-use needles (Tai Chi Brand, 32-36 gauge, 1 or 1.5 inch needles; made in China and distributed by Lhasa OMS, Weymouth, Massachusetts, USA) that penetrate 5–10 mm into the skin. The acupoint prescription is given in Table 1.

Study patients received acupuncture twice a week for 4 consecutive weeks at the MSKCC Integrative Medicine Outpatient Center. Thereafter, patients were asked to contact the research assistant should any side effects occur, and monthly follow-up calls were made to study the subjects for 6 months to obtain information about any side effects.

The study design was a Simon's two-stage minimax design with a null and alternative hypotheses of 5% and 20%, respectively. We planned to enroll 13 patients in the first stage of the study; if there was at least one response, we planned to accrue an additional 14 patients, declaring acupuncture worthy of further study if a total of four or more responses occurred in the total of 27 patients.

Table 1 Acupoint prescription

Points	Location
LI15	Anteroinferior to the acromion, on the upper portion of musculus deltoidus
LI4	On dorsum of the hand, midpoint of the second metacarpal bone, in the belly of the first interosseus dorsalis muscle
TE14	Posterior and inferior to the acromion
CV12	Midline of the abdomen, midpoint between umbilicus and xiphoid process
CV3	Midline of the abdomen, four inches below umbilicus
LU5	On the cubital crease, radial side of the tendon of musculus biceps brachii
SP6	Posterior border of the medial aspect of the tibia, three inches above the tip of the malleolus
ST36	Lateral to the tibia's anterior crest, inferior to the lateral side of the patella

Needles were retained for 30 min.

RESULTS

The trial was stopped early when four responses were obtained. Eleven patients had been enrolled. Two withdrew due to time constraints. The nine participants

Table 2 Study patients' demographic and clinical data (the first four patients are the responders)

Patient number	Age	Race/ ethnicity	Surgery	RT	Chemo	Affected limb	Years since lymphoedema Dx	BMI at baseline (lbs)	Baseline difference (cm)	Post-Tx difference (cm)	Responder
1	56	W	Lump	Y	Y	Left	2.3	43.1	2.2	0.9	Y
2	51	A	Mast	Y	Y	Left	2.6	26.7	2.1	0.4	Y
3	54	B	Mast	N	Y	Left	1.7	23.5	2.0	0.9	Y
4	51	B	Lump	Y	N	Left	0.6	28.2	2.5	1.6	Y
5	79	W	Lump	Y	Y	Right	3.0	29.6	8.2	8.5	N
6	46	W	Lump	Y	Y	Left	3.4	30.6	5.9	4.6	N
7	54	B	Mast	N	Y	Left	2.3	29.5	8.3	7.8	N
8	54	W	Mast	Y	Y	Left	1.9	32.4	3.1	3.0	N
9	41	W	Mast	Y	Y	Left	1.4	30.0	6.6	5.8	N

All of the patients had axillary lymph node dissection.

A, Asian/far Eastern/Indian subcontinent; Baseline and Post-Tx difference, difference between affected and unaffected arm; B, Black/African American; BMI, body mass index; Chemo, history of chemotherapy; Dx, diagnosis; Lump, lumpectomy; Mast, mastectomy; RT, history of radiation therapy; W, white.

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Summary points

- Acupuncture is contraindicated in limbs with lymphoedema
- However it may be useful and the evidence on safety is inconclusive
- In this pilot study, we found four responders in nine patients and no adverse events
- Larger studies are needed

ranged in age from 41 to 79 years, with a median age of 54 years. The average difference in affected versus unaffected arm circumference at accrual was 4.5 cm (SD 2.7 cm). All patients were breast cancer survivors with upper extremity lymphoedema; all had axillary lymph node dissection.

This pilot study met its goal after nine subjects were treated: four women showed at least a 30% reduction in the extent of lymphoedema at 4 weeks when compared with their respective baseline values. In 73 treatment sessions, no SAE occurred and no SAE occurred during the 6-month follow-up period. Some patients experienced minor toxicities such as slight bruising or minor pain at the acupuncture site shortly after treatment.

There were no obvious differences between responders and non-responders with respect to age, ethnicity, type of surgery, adjuvant therapy or duration of lymphoedema. Additional details are provided in Table 2, for all the nine study patients.

DISCUSSION

We saw no evidence to the effect that acupuncture for lymphoedema is unsafe. The response rate met our predefined criterion for considering acupuncture worthy of further study. These positive results led to our development of a randomised clinical trial to evaluate the effects of acupuncture on chronic lymphoedema due to breast cancer surgery. The aetiology of lymphoedema, including why it develops in some patients but not in others who received identical treatment, remains unknown. Therefore, we will also conduct laboratory studies of mechanisms that regulate lymphoedema. Hopefully, these studies will shed light on the mechanisms by which acupuncture serves to improve it.

Competing interest None.

Ethics approval This study was conducted with the approval of the Institutional Review Board Committee of MSKCC.

Provenance and peer review Not commissioned; externally peer reviewed.

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Notes