

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/ijns



Associations between the treatments and outcomes of patients with upper and lower lymphoedema in Japan: A cross-sectional observational study



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ARTICLE INFO

Article history: Received 10 July 2014 Received in revised form 14 November 2014 Accepted 20 January 2015

Keywords: Cross-sectional studies Lymphoedema Outcome assessment Therapy

ABSTRACT

BACKGROUND: Lymphoedema is not currently curable, and it is important that symptoms are alleviated by appropriate treatment. Treatments aim to delay the progression of swelling and to improve patients' quality of life (QOL). There are many objective and subjective outcomes of lymphoedema, but it is unclear which outcomes should be used to evaluate lymphoedema treatments.

OBJECTIVE: This study aimed to examine the associations between lymphoedema treatments and outcomes.

DESIGN: A cross-sectional observational study.

SETTING: Lymphoedema outpatient clinics in Japan.

PARTICIPANTS: A total of 170 patients with lymphoedema were recruited from four outpatient clinics.

METHODS: The data were collected from medical records, physical assessments, and interviews. The following objective outcomes were evaluated: circumference measurements, Stemmer sign, cellulitis, and skin hardness. The following subjective outcomes were evaluated: satisfaction with treatment, subjective symptoms, EuroQol-5 dimensions, and a quality of life measure for limb lymphoedema (LYMQOL). Multiple regression analysis was performed to examine the associations between lymphoedema treatments and their outcomes.

RESULTS: Secondary lymphoedema was present in 158 patients (92.9%), and 91 patients (53.5%) had lower lymphoedema. The patients using compression garments were 2.63 times more likely to have a positive Stemmer sign and 2.85 times more likely to be satisfied with their treatment than those who were not using compression garments (p = 0.02 for Stemmer sign, p < 0.01 for satisfaction). The patients treated with simple lymphatic drainage (SLD) exhibited a 2.26-fold greater level of satisfaction with treatment than those not receiving this treatment (p < 0.01). The patients treated with complete decongestive therapy (CDT) had higher QOL than did those not receiving this therapy ($\beta = -0.19$, p = 0.04).

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CONCLUSIONS: The progression of swelling can be evaluated using the Stemmer sign with regard to compression therapy. The degree of satisfaction can be evaluated as the patient's satisfaction with their lymphoedema regarding compression garments and SLD, and improvements in QOL can be evaluated using the LYMQOL with regard to CDT. The subjective outcomes were not associated with every lymphoedema treatment in this study, and the effectiveness of lymphoedema treatment can be evaluated using several different outcomes.

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What is already known about the topic?

- 1. One of the goals of lymphoedema treatment is to reduce or delay the progression of swelling. The objective outcomes that are currently used to assess progress toward this goal are circumference measurement, water displacement, Perometer® measurement (a device that was designed to measure limb volumes; Pero-System, Wuppertal, Germany), and bioimpedance. However, it is unclear which outcomes should be used to evaluate lymphoedema treatments.
- 2. The other goal of lymphoedema treatment is to improve the patients' quality of life. The subjective outcomes that are currently used to assess progress toward this goal include health-related quality of life tools. The shortform 36-item survey instrument is the most appropriate tool for the evaluation of compression in the SF-36, the Barthel scale, the McGill pain questionnaire, and the Euroqol 5 dimensions (EQ-5D). However, which outcomes should be used to evaluate other lymphoedema treatments remains unclear.

What this paper adds?

- 1. The progression of swelling can be evaluated using the Stemmer sign with regard to compression garments.
- 2. The degree of satisfaction can be evaluated as the patient's satisfaction with their lymphoedema regarding compression garments and SLD, and improvements in QOL can be evaluated using the LYMQOL with regard to CDT. Subjective outcomes were not associated with every lymphoedema treatment in this study, and the effectiveness of lymphoedema treatments might be evaluated with several different subjective outcomes.

1. Introduction

Lymphoedema is a chronic condition with a number of causes. Primary lymphoedema entails oedema caused by abnormalities or disease originating in the lymphatic system due to either congenital or acquired conditions (Sitzia et al., 1997) and accounts for 8% of new diagnoses of lymphoedema (Sitzia et al., 1998). Secondary lymphoedema entails oedema caused by surgery, trauma, or disease that does not originate in the lymphatic system, and its causes include filariasis, neoplastic disease, radiation injury, and surgical lymph node excision (Sitzia et al., 1997). The incidence of secondary lymphoedema is 27.2% among Japanese ovarian and uterine cancer patients (Toda et al., 2009) and ranges from 6% to 30% among breast cancer patients (Petrek and Heelan, 1998).

Many patients suffer from lymphoedema worldwide. Lymphoedema is not currently curable, and it is important that the symptoms are alleviated by appropriate treatments.

Treatments aim to reduce or delay the progression of swelling and to improve the patients' quality of life (QOL). There have been thirty-six English-language randomised controlled trials (RCTs) and observational studies regarding this issue that have assessed several outcomes (Oremus et al., 2012). However, the methods to evaluate lymphoedema treatments were different from each study, and only one observational study included lower lymphoedema patients. Moreover, few of these studies focused on outcomes. Franks et al. (2006) found that the short-form 36-item survey instrument (SF-36) is the most appropriate QOL tool for evaluating compression therapy in the SF-36, the Barthel scale, the McGill pain questionnaire, and the Eurogol 5 dimensions (EQ-5D). However, it is unclear which outcomes should be used to evaluate the progression of swelling, and it is also unclear which outcomes should be used to evaluate other lymphoedema treatments. Lohr (1998) stated that the outcome measures comprise "the five D's": death, disease, disability, discomfort, and dissatisfaction. With respect to lymphoedema treatment, these D's can indicate objective outcomes that can be evaluated by health care providers and subjective outcomes that can be evaluated by the patients themselves.

Many objective and subjective outcomes have been used to assess lymphoedema treatments. Objective outcomes are used to evaluate the progression of swelling and currently include a circumference measurement, water displacement, Perometer measurements (this device was designed to measure limb volume; Pero-System, Wuppertal, Germany), and bioimpedance spectroscopy. The subjective outcomes that are currently used are QOL tools. To evaluate lymphoedema treatments, the outcomes should be easily assessed in the clinical setting. The evaluation of lymphoedema treatments with inappropriate outcomes might result in the incorrect evaluations of the effects of treatment.

This study aimed to examine the associations between lymphoedema treatments and outcomes. The clarification of the associations between lymphoedema treatments and outcomes will enable the correct evaluation of treatments and contribute to the construction of evidence-based lymphoedema treatments.

2. Methods

2.1. Participants

This study had a cross-sectional, observational design. All patients who met the following inclusion criteria were

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