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Original article

Satisfaction with a therapeutic sleeve for arm lymphedema secondary to breast cancer treatment: Controlled crossover trial

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ABSTRACT

Secondary arm lymphedema is a feared late iatrogenic side effect of breast cancer survivors with a negative impact on patient's self-image and quality of life. Its reported incidence is extremely variable, from 6% to 80%, as well as the effectiveness of the multimodal decongestive lymphedema therapy.

In their daily life breast cancer survivors with lymphedema have few alternatives but to use a compressive sleeve. Concerned with the well-known low compliance to the daily use of traditional sleeves, we conducted a comparative study in a subgroup of our patients with lymphedema secondary to breast cancer treatment for the subjective assessment of PRADEX®, an innovative class 1 compression sleeve. Secondarily, we aimed to assess the non-inferiority of PRADEX® regarding subjective and objective measures of the severity of lymphedema.

We studied 46 women with grade 1 secondary arm lymphedema, who used their usual sleeve and PRADEX® daily for 2 weeks each, in a crossover design.

The new therapeutic sleeve was classified as having a better design and a better usability and comfort (more comfortable, thinner, fresher, softer, more flexible, comfortable, resistant to dirt and easier to dress and to wear). Women's subjective opinion about the severity of lymphedema favored their usual sleeve in detriment of PRADEX®, but this subjective feeling was contradicted by objective measurements of different perimeters of the arm at the beginning and at the end of the study.

We concluded that the PRADEX® sleeve, not being worse in its compressive therapeutic efficacy, is much better with regard to patient comfort.

Introduction

Arm lymphedema secondary to treatment is the most feared late iatrogenic side effect for long-term survivors of breast cancer, with a negative impact on patient's self-image and quality of life and usually irreversible.[1,2] The incidence reported in numerous publications is extremely variable, from 6% to 80%.[3,4] A 25–30% incidence should serve as a basis for benchmarking in quality-assurance at Breast Units.[5,6]

The huge paradigm shift in the axillary approach of breast cancer created by the sentinel node biopsy in the last 20 years, and even the most recent randomized trials in which radiotherapy emerges as an alternative to an axillary clearance after a positive sentinel node, kept the lymphedema incidence as a cornerstone in the analysis of axillary morbidity.[7–9]

A careful approach to arm lymphedema secondary to breast cancer treatment remains up-to-date by the increasing number of longer survivals as well as the recent achievements in axillary treatment.[1,5,7,9] The decongestive lymphedema therapy should be multimodal, involving skin care, manual massage, rehabilitation arm exercises, compression elastic sleeves or intermittent pneumatic compression and associated with a personalized careful explanation of preventive measures and psychosocial support to patients.[1,3,4,10] However, high quality evidence on the individual effectiveness of preventive or therapeutic attitudes is scarce.[2,5,11]

In their daily life breast cancer survivors with lymphedema have few alternatives but to use a compressive elastic arm sleeve, an unpleasant, tough, hot, very poorly tolerated and socially

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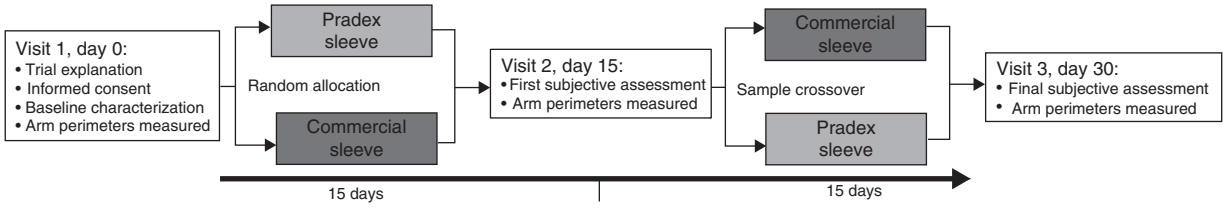

Fig. 1. Study design.

stigmatizing garment. The proportion of patients with lymphedema reporting the use of a compression garment is lower than 30%.[5] Concerned with the well-known low compliance to the daily use of traditional compression sleeves, we conducted a comparative study in patients with lymphedema secondary to breast cancer treatment for the subjective assessment of PRADEX®, a new compression therapeutic sleeve designed to overcome previous usability limitations of commercially available sleeves. Secondarily, we aimed to assess the non-inferiority of PRADEX® regarding subjective and objective measures of the severity of lymphedema.

Methods

Trial design

The study has a crossover design with two experimental series of sequential treatment and comparator, and random allocation of patients at initial treatment.

Sample selection

The study sample included women with grade 1 arm lymphedema due to axillary surgery and/or radiotherapy for breast cancer treatment, with wrist circumference 170–230 mm, who already used a compression class 1 sleeve on a daily basis, prescribed in our institution by a physiatrist and provided by the hospital free-of-charge, as a technical aid.

From a total of 71 patients of our database registered as having lymphedema grade 1 and to whom a compressive sleeve was prescribed, 22 women were excluded at initial recruitment: 3 had already died, 1 was in a terminal stage, 5 never used the prescribed sleeve, 4 progressed in lymphedema severity, 7 could not be reached and finally 2 refused to participate. After the beginning of the study, 3 more women were excluded for not fulfilling the established times for the use of sleeves, defined below. Finally, 46 women had available data for analysis.

Study settings

Fig. 1 illustrates the study design. Two breast nurses of Breast Center of Centro Hospitalar São João interviewed personally all 46 women. In the first visit an initial interview was made to explain the trial and start the first intervention, a second interview was made on day 15 at the time of exchange of the sleeves and a last interview was made at the end of the consecutive second period of 15 days, without any wash out period. Information concerning sociodemographic characteristics, anthropometry, presence of comorbidities and lymphedema characterization were collected. Body mass index (BMI) was measured and categorized according to the standard World Health Organization definition.[12] The perimeters of the wrist, forearm and arm were measured, with a tape, at baseline and days 15 and 30. The patients had to record in a written diary the usage time of the sleeves. Satisfaction was assessed by a structured questionnaire applied by nurses. Women were encouraged to make personal suggestions for improving the sleeves used.

Outcomes

The primary outcome was satisfaction with the sleeve, as assessed by 11 items, each measured in a 10-point Likert scale (higher score meaning lower satisfaction), covering esthetics, comfort, usability and static electricity dimensions. Secondary outcomes were subjective assessment of severity of edema and measured upper limb perimeters. All outcomes were assessed at days 15 and 30.

The PRADEX® sleeve

PRADEX® is an innovative medical device designed for the treatment of upper limb lymphedema secondary to breast cancer treatment, ranked as class 1 according to the Quality Assurance RAL-GZ 387/2 standard Medical Compression Arm Sleeves. This medical device conveys class 1 compression (15–21 mmHg), leaving the shoulder sleeveless, and is recommended for patients with wrist perimeters between 170 and 208 mm.[13–15]

PRADEX® sleeve designed to overcome previous usability limitations of commercially available sleeves is produced using double cylinder circular knitting technology, using a 1×1 rib knitted structure. This knitted fabric is composed by two materials: textured multifilament polyamide yarns and elastane filaments covered with multifilament polyamide yarns. The use of these materials, along with the type of loops interlacement, provides a very comfortable medical device keeping the therapeutic performance based on graduated compression. Arm sleeves have been tested, according to established international standards, for properties related to usability, comfort and compression performance.[14,15]

Statistical analysis

Statistical analysis was performed using the statistical software Stata 11.0 (College Station, TX, 2009). Sample characteristics are presented as counts and proportions for all categorical variables and median and interquartile range (IQR) for non-normally distributed continuous variables. Wilcoxon signed rank tests were used to compare median differences between paired observations for continuous variables. Differences between categorical variables were computed using the McNemar test. A p-value lower than 0.05 was considered statistically significant.

Ethics

The study protocol was approved by the Ethics Committee of Centro Hospitalar São João and written informed consent was obtained from all participants.

Financial support was offered to patients to cover the expenses related with hospital visits. At the end of the trial the new sleeve was offered to patients.

Results

The patient's characteristics are presented in Table 1. The median (IQR) age of women was 54.0 (47.0–63.0) years and more

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