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ORIGINAL ARTICLE

Safety and tolerability of Kinesio® Taping in patients with arm lymphedema: medical device clinical study

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Abstract
Purpose The aim of this study is to assess the safety and tolerability of Kinesio® Taping (KT) in patients with arm lymphedema.
Method Medical device clinical study in women with arm lymphedema. Kinesio® Tex Gold bandage was applied by the KT technique. Assessments and interviews were carried out both at the beginning and 4 days after intervention. Skin disorders, reported tolerance and modification of limb volume and function after intervention were assessed. Changes in limb volume and functionality before and after intervention were compared by the Student's *t* test and the Wilcoxon Signed-Rank test, considering significant p value <0.05.
Results Twenty-four women were studied. After intervention, no patient had cutaneous lesions, vesicle or limb hyperthermia, and 4.2 % presented skin peeling and redness. Most patients reported no change in social life and that they felt safer in the daily activity and were very pleased with the treatment. The patients presented improvement of upper limb functionality after intervention ($p<0.001$). No difference of limb volume was found after intervention ($p=0.639$).
Conclusions Kinesio® Tex Gold bandage by the KT technique proved to be safe and tolerable in patients with lymphedema, with improved functionality and no change of the affected limb volume.

Keywords Kinesio Taping · Bandage · Lymphedema · Physiotherapy · Breast cancer

Introduction

Lymphedema is a very common morbidity after breast cancer treatment. It is a chronic and progressive disease, characterised

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by an abnormal accumulation of macromolecules in the tissue space [1]. Its incidence varies according to the study design and population, type of axillary approach, method of diagnosis and follow-up time after surgery. In a meta-analysis including 72 studies, the incidence was 16.6 % (IC 95 % 13.6–20.2) [1]. In a previous study carried out in a series from our service, 30.3 % of women undergoing axillary lymphadenectomy developed lymphedema after 5 years of follow-up [2].

Lymphedema is a chronic condition. The treatment with complex decongestive treatment (CDT) has been effective and has an important role in reducing symptoms and improving limb function [3, 4]. In a clinical trial performed in our population, the group submitted to CDT (manual lymph drainage, skin care, bandaging and remedial exercises) had a volume excess reduction of 15 % after the treatment. Although the treatment was able to reduce the volume of the limb, other therapies have been studied in order to maximize the therapeutic response obtained by the CDT [3].

In this sense, another approach currently discussed in secondary lymphedema after breast cancer is Kinesio® Taping (KT) [5–11]. The tape is applied to the skin, and the area will form convolutions that lead to enlargement of the interstitial space, improving the absorption and the lymphatic flow [5, 11].

Moreover, few studies have analysed this procedure's safety and tolerability in relation to its application directly on the skin in patients with lymphedema and the risk of complications in the affected limb. In this context, this study aims to evaluate the safety and tolerability of KT in patients with arm lymphedema secondary to breast cancer treatment.

Materials and methods

A single-centre, nonrandomised medical device clinical study was carried out in women with secondary lymphedema after breast cancer treatment. The women included had a circumference with ≥2.00-cm difference in at least one point of the affected upper limb compared to the contralateral, and they wore the compression garment and with limb volume stabilisation for the previous 30 days before recruitment. Patients with active local or systemic cancer disease, bilateral breast cancer, ongoing chemotherapy or radiotherapy, presence of skin alterations, reported autoimmune diseases or reported musculoskeletal disease unrelated to the breast surgery in ipsilateral limb to surgery, and illiterate or with difficulty in reading were excluded.

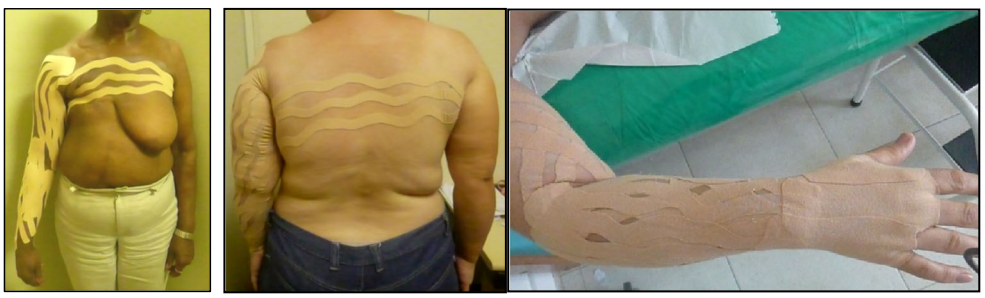
The sample size was calculated estimating 30 % of skin alterations with absolute precision of 20 and the significance level of 5 %. Patient inclusion in the study occurred from 6 November to 18 November 2014, consecutively, among those being in routine physiotherapeutic follow-up. During this period, 24 eligible patients were interviewed and evaluated both at the beginning and 4 days after intervention, when the bandage was removed.

The application of the KT lymphatic method [9] was conducted by one independent physiotherapist. During the intervention with KT, the compression garment was removed. The skin was cleaned, dried, and grease-freed. The tape was applied to the skin in the anterior and posterior axillo-axillary anastomosis, and from proximal to distal in the upper limb, opposite to the physiological direction of the lymph flow. The bandage was applied to the back of the hand only in those women who had edema in this region (Fig. 1).

Kinesio® Tex Gold bandage, 5 cm wide, beige, was used maintaining a base of 4-cm diameter and three strips, according to the limb's size. Guidelines on bandage handling and care were provided, to be used at home, as well as a self-assessment questionnaire.

Patients' sociodemographic and clinical data was collected. The impaired range of motion in the arm was definied by the limited movement on flexion or abduction of shoulder which was testified through active range of motion of the limb. The body mass index (BMI) was collected using a structured questionnaire (self-reported data).

The following outcomes were assessed: dermal alterations after intervention, tolerance reported by the patient, and



(A) Kinesio® TexGold in anterior axillo-axillary anastomosis

(B) Kinesio® TexGold in posterior axillo-axillary anastomosis and from proximal to distal in the upper limb

(C) Kinesio® TexGold in the upper limb and hand

Fig. 1 Kinesio® Tex Gold application

changes in functionality and in the limb volume. The occurrence of skin exfoliation, skin lesions, blisters, redness and hyperthermia in the affected limb were considered dermal alterations. Tolerance reported by the patient on the use of KT was assessed through a questionnaire that included questions about partial or complete bandage detachment, itching, burning, discomfort, tightness and/or subjective worsening of lymphedema, interference in social life, the report of feeling safe about the volume control, difficulty in carrying out activities of daily living and satisfaction with the treatment.

The Quick DASH Outcome Measure questionnaire, translated and validated for the Brazilian population [12], was used to evaluate the functionality of the upper limbs. It is an instrument that contains 11 questions designed to measure physical function, symptoms and social function. The Quick DASH score has two components: the section of disorders/symptoms (11 items, with scores 1 to 5) and two optional modules: musical or sport performance and work (four items, scores from 1 to 5). At least 10 of the 11 items must be answered. Each answered question had a maximum value of 5. These values were transformed into a 100 score by subtracting 1 and multiplying by 25. This transformation intends to compare the scores with other scales from 0 to 100. A high score indicates a major disorder. The same procedure applied to the disorder/symptom scores was applied to calculate the four items of the optional modules.

The indirect volume was calculated from the circumference of the limb that was measured 14 and 7 cm above, and 7, 14 and 21 cm below the elbow articular line (including it), delimiting each segment of the limb by a pair of circumferences and using the truncated cone formula was used to obtain the volume of the arms, were $V=h\times(C^2+Cc+c^2)/(\pi\times 12)$, where V is the volume of the limb segment, C and c are the circumferences, and h is the distance between the circumferences (C,c). The sum of the difference between each point corresponds to the final volume estimated in each segment. The evaluation of the volume change after intervention was obtained by the formula IV(initial volume)−FV (final volume) [2].

This project was approved by the Ethics in Research Committee of the National Cancer Institute (INCA) and registered under number CAAE: 35091214.4.0000.5274.

A descriptive analysis of the selected variables and major outcomes was performed through the analysis of central tendency, dispersion and frequency distribution measures. Functionality and limb volume alterations were evaluated by the mean difference (Student's t test), considering a confidence interval of 95 % and the Wilcoxon signed-rank test. The SPSS version 20 software was used for data analysis.

Results

The sample was composed of 24 women with a mean age of 64.7 years (±11.9), after 9.8 years (±7.9) from breast cancer

Table 1 Demographic and clinical characteristics of the population at baseline (n=24)

Variables	Number[a]	%
Age		
<65 years old	14	58.3
≥65 years old	10	41.7
Marital status		
Married and stable union	09	37.5
Separated and widowed	15	62.5
Education		
<8 years	13	54.2
≥8 years	11	45.8
Self-reported skin color		
White	11	45.8
Non-white	13	54.2
Occupation		
Home	20	83.3
External work	04	16.7
Obesity		
No	13	54.2
Yes	11	45.8
Current smoking		
No	24	100
Yes	0	0
Alcoholism current		
No	17	70.8
Yes	7	29.2
Health		
Very good or good	16	66.7
Regular	08	33.3
Clinical staging (TNM)		
Advanced (≥IIB)	11	50.0
Initial (<IIB)	11	50.0
Neo adjuvant treatment		
No	11	45.8
Yes	13	54.2
Type of breast surgery		
Modified radical mastectomy	20	83.3
Conservative	04	16.7
Status of axillary lymph nodes		
Negative	09	37.5
Positive	15	62.5
Adjuvant treatment[b]		
Chemotherapy	13	54.2
Radiotherapy	16	66.7
Hormone therapy	15	62.5

[a] The differences in the size of the sample corresponds to the missing value

[b] The patient may have been subjected to more than one treatment

Table 2 Physical examination pre-intervention (n=24)

Variables	Number	%
Report of pain in the affected arm		
No	12	50.0
Yes	12	50.0
Skin type		
Normal	19	79.2
Dry	04	16.7
Oily	01	4.2
Hand lymphedema		
No	18	75.0
Yes	06	25.0
Winged scapula		
No	16	66.7
Yes	08	33.3
Range of motion		
Full	17	70.8
Functional	07	29.2
Paresthesia in the intercostobrachial nerve		
No	06	25.0
Yes	18	75.0

surgical treatment. Lymphedema had been present, on average, for 64.2 months (±46.0).

Most of the women were divorced or widowed (62.5 %), with less than 8 years of study (54.2 %), and their main occupation was household tasks (88.3 %). Obesity (BMI≥30) was present in 45 %. None of them reported being a smoker, and 29.2 % had consumed at least one alcoholic drink in the last 30 days. Most of them reported good health (41.7 %) (Table 1).

Half of the women had breast cancer in advanced clinical stage, and 12 of them were submitted to neoadjuvant chemotherapy. Only 16.7 % were treated with conservative surgery and all of underwent axillary lymph node dissection, with a mean removal of 19 axillary nodes (±7), with 2 (±3) compromised. As adjuvant treatment, 54.2 % underwent chemotherapy, 66.7 % radiotherapy and 62.5 % hormone therapy (Table 1).

Table 3 Incidence of dermal changes after the intervention (n=24)

Variables	Number	%
Peeling skin		
No	23	95.8
Yes	01	4.2
Wound skin		
No	24	100
Yes	0	0
Lesions with bubbles		
No	24	100
Yes	0	0
Hyperemia arm		
No	23	95.8
Yes	01	4.2
Hyperthermia arm		
No	24	100
Yes	0	0

Table 4 Tolerance referred to by patients regarding the use of Kinesio® Tex Gold

Variables	Number	%
Detachment at the ends of KT		
No	06	25.0
Yes	18	75.0
Total separation of KT		
No	23	95.8
Yes	01	4.2
Pain		
No	23	95.8
Yes	01	4.2
Rash		
No	14	58.3
Yes	10	41.7
Burning sensation		
No	22	91.7
Yes	02	8.3
Discomfort		
No	22	91.7
Yes	02	8.3
Tightness		
No	22	91.7
Yes	02	8.3
Feeling increased edema		
No	22	91.7
Yes	02	8.3
Change in conviviality		
No change	17	70.8
Improvement	06	25.0
Worsening	01	4.2
Sense of safely in control of lymphedema		
No change	06	25.0
Safely	17	70.8
Unsafe	01	4.2
Difficulty in performing daily life activities		
No change	18	75.0
Less difficulty	05	20.8
More difficulty	01	4.2
Satisfaction with treatment with KT		
Little satisfied	01	4.2
Average satisfied	05	20.8
Very satisfied	18	75.0

Before intervention, 50.0 % of the women reported pain in the affected arm, 29.2 % had impaired range of motion in the arm and 75.0 % paresthesia in the intercostobrachial nerve (Table 2).

The bandage was applied on the anterior and posterior axillar-axillary anastomosis area in 95.8 % of the cases. The bandage was applied from shoulder to elbow and from elbow to wrist in all the patients. The hand was treated in six cases (25.0 %).

During the assessment of dermal alterations after intervention, no patient presented cutaneous lesions, blisters or hyperthermia in the limb, and one (4.2 %) patient presented skin peeling and redness (Table 3).

The variables related to tolerance of the use of KT are presented in Table 4. There was no total detachment of the bandage in 95.8 % patients, but 75.0 % presented detachment of the tape ends. Most patients denied a change in social life or in carrying out activities of daily living; they felt safer and were very satisfied with the treatment.

The functionality of the upper limbs improved ($p<0.001$). There was no difference in the volume of the upper limbs after intervention ($p=0.639$) (Table 5).

Discussion

The study sample was composed of 24 women with secondary lymphedema in the upper limb after breast cancer treatment. The patients underwent KT application and remained with it for 3 to 4 days. They presented low incidence of dermal alterations and reported good tolerance to bandage use. The comparison of the parameters measured before and after bandage use showed improvement of the functionality but no alteration of the limb volume. These results suggest that the use of KT might be a safe alternative for the treatment of patients with upper limb lymphedema.

Lymphedema treatment involves a number of therapies aimed at maintaining the balance of the lymphatic system and minimising interstitial fluid accumulation. The treatment defined as gold standard is complex physical therapy (CPT), based on two phases: an initial phase aiming at limb volume reduction and the maintenance phase [13]. The first phase of CPT can be performed daily until edema reduction and normalised tissue texture. It consists of 60 min of manual lymphatic drainage (MLD), multilayer bandaging with low elasticity garments, lymph pumping exercises and skin care. After a maximum volume reduction, a compression garment is fitted [3], and self-care is stressed for volume maintenance. Daily exercise is fundamental for long-term treatment success [14].

One problem in lymphedema control is limb volume maintenance after edema reduction. In this phase, patients are oriented to wear compression garments, but many do not adhere to treatment. They report that its use makes them feel like prisoners to the disease, bringing back negative memories of cancer and its treatment. In a study conducted to assess patient adherence to treatment in relation to self-care behaviours in lymphedema control, a low adherence to the use of compressive therapies was observed in all monitoring periods [15].

In this sense, KT has been used as a new approach in lymphedema treatment and control. The purpose of this bandage is that when applied to the skin, the skin rises, creating a space that contributes to the absorption of interstitial liquid and lymph flow [8, 9, 11, 16]. The Kinesio® Tex Gold bandage is composed of 100 % cotton material with acrylic glue and polyurethane that reacts to heat. It is manufactured by fingerprint technology, characteristic of digital impression, and once applied, it has better adherence than previously used tapes [17].

In our study, no patient had cutaneous lesions, blisters and/or skin hyperthermia, and one presented skin peeling and redness at the application site. Different results were observed by Tsai et al. [5] who reported that the KT caused more skin lesions than the conventional bandage (garments). This difference may be due to different tape materials, since we used a material (Kinesio® Tex Gold) recently introduced in the market.

Related to tolerance of KT use, tape detachment at the ends was observed in 75.0 % of the cases and caused some discomfort when cutting the tape ends. However, all but one patient did not present total detachment of the tape, proving that the therapy is possible. When questioned about social life and daily activities, 70.8 % of patients reported no alteration.

Table 5 Change of volume and functionality of the upper limbs

Score DASH	Start of treatment Average (SD)	After treatment Average (SD)	Difference (post-pre)				Wilcoxon signed-rank test		
			Average	95 % CI		P value[a]	Improves N (%)	Worsening N (%)	Maintained N (%)
Quick DASH	36.27 (21.53)	19.70 (17.89)	−16.57	−24.84	−8.30	<0.001	16 (66.67)	02 (8.33)	06 (25.00)
Difference in volume Upper Limb (ml)	370.32 (201.05)	380.61 (194.81)	10.29	−34.48	55.06	0.639	16 (66.67)	08 (33.33)	0

DASH disabilities of the arm, shoulder and hand; *SD* standard deviation; *N* sample size; *CI* confidence interval

[a] Paired *t* test

Seventy-five percent of the patients were very satisfied with the treatment and safety in the use of Kinesio® Tex Gold, similar to that obtained by Finnerty et al. [6] who reported that the tape was very comfortable when still attached, but when detached, it caused itching and hot skin.

Specific exercises are indicated for lymphedema treatment and maintenance of limb volume reduction, to provide a pumping effect to promote lymph flow [18]. In the present study, the Quick DASH questionnaire showed a significant improvement (p 0.001) on the scores of limb functionality: 66.7 % patients reported a better performance in shoulder, arm and hand use during Kinesio® Tex Gold treatment.

Regarding limb volume, there was no significant alteration after intervention (p=0.639). In a clinical trial with 45 women with lymphedema after breast cancer, randomly separated into three intervention groups (CPT, CPT + KT, KT); after 10-day treatment, limb volume reduction was observed in all groups (p<0.05) [9]. The different results may be due to the short treatment time used in our study.

In patients with secondary lymphedema after breast cancer treatment, the KT technique arose from the need of an alternative in upper limb volume reduction and maintenance; however, there is controversy regarding the application method, the amount of pressure exerted and indication [5–11].

Our results showed that KT may be considered a safe technique when applied on the upper limb with lymphedema. The main limitation of this study is the short time in which the patients were exposed to intervention with KT and the non-inclusion of a control group.

Conclusion

The use of Kinesio® Tex Gold tape in women with secondary lymphedema after breast cancer treatment proved to be safe. There was a low incidence of dermal complications, a feeling of safety in lymphedema control and a low impact on the activities of daily life. Improvement of upper limb functionality and no alteration of limb volume after intervention were reported. Further studies should be conducted to evaluate its long-term effectiveness and security.

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Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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