The Breast 47 (2019) 22–27

Contents lists available at ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst

Original article

Effectiveness and safety of surgical glove compression therapy as a prophylactic method against nanoparticle albumin-bound-paclitaxel-induced peripheral neuropathy

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ARTICLE INFO

Article history:
Received 2 May 2019
Received in revised form
11 June 2019
Accepted 29 June 2019
Available online 3 July 2019

ABSTRACT

Background: We have developed a surgical glove (SG)-compression therapy and reported that this method significantly reduced the overall occurrence of grade 2 or higher nanoparticle albumin-bound-paclitaxel (nab-PTX)-induced peripheral neuropathy (PN) from 76.1% to 21.4%. In this multicenter single-arm confirmatory study, we investigated the efficacy and safety of SG-compression therapy for the prevention of nab-PTX-induced PN, compared with the incidence of grade 2 or higher PN in published literature as controls.

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https://doi.org/10.1016/j.breast.2019.06.008

Keywords:
Surgical glove
Compression therapy
Nab-paclitaxel
Peripheral neuropathy

Patients and methods: Primary breast cancer patients who received 260 mg/m^2 of nab-PTX were eligible for this study. Patients wore two SGs (one size smaller than the tight-fitting size) in each hand for 90 min. PN was evaluated at each treatment cycle using the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 and the Patient Neurotoxicity Questionnaire (PNQ). The temperature of each fingertip was measured using thermography.
Results: Between October 2016 and June 2017, 58 patients were evaluated. The incidence of CTCAE grade 2 or higher PN was as low as 13.8% following SG-compression therapy. A goodness-of-fit test proved that the overall incidence of 13.8% grade 2 or higher PN in this study was comparable to the hypothesis-predicted value (13%). No adverse events, including compression intolerance or skin disorders caused by use of SG, were observed. SG-compression therapy significantly reduced the temperature of each fingertip by 1.3°C-2.3 °C compared to pre-chemotherapy level.
Conclusions: This study suggested the safety and efficacy of SG-compression therapy for the amelioration of CIPN.
Clinical trial number: UMIN 000024836.

Introduction

Chemotherapy-induced peripheral neuropathy (CIPN) is a frequent and a hard-to-treat adverse event of many commonly used Chemotherapeutic agents, including taxanes and platinum agents [1–3], and may persist for several years, and impair quality of life [4]. According to the 2014 American Society of Clinical Oncology (ASCO) guidelines, there are no established effective therapies for prophylaxis against CIPN [5].

We have developed a new feasible method to prevent CIPN that entails the use of surgical gloves (SGs) with the objective to compress the whole hand, including the fingers. In our previous self-controlled phase 2 study, SG-compression therapy significantly reduced the overall incidence of grade 2 or higher nanoparticle albumin-bound-PTX (nab-PTX)-induced PN from 76.1% to 21.4% compared with that in control hands, because SG decreased microvascular flow to the fingertips [6].

Given the limitations of our previous study (self-controlled phase 2 trial), we performed this study to confirm the efficacy and safety of SG-compression therapy for the prevention of CIPN in patients with breast cancer.

Patients and methods

Study design

This was a multicenter prospective single-arm study of patients with primary early breast cancer. The enrolled patients wore SGs in both their hands. The objective was to confirm the efficacy and safety of SG-compression therapy for the prevention of CIPN and to assess its impact on long-term residual CIPN. The primary endpoint was the overall incidence of grade 2 or higher nab-PTX-induced sensory PN in the SG-compression-protected hands by using the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0. The incidence of nab-PTX-induced PN in published literature was used as the control group. Secondary endpoints included nab-PTX-induced PN as assessed by PNQ, changes in the temperature of the tip of each finger by using thermography, the incidence of withdrawal from SG use due to compression intolerance, and the incidence of skin disorder associated with use of SGs. This study was performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from all patients prior to their enrollment. The ethics committees of all participating institutions approved the study protocol. This study was registered with the University Hospital Medical Information Network (UMIN) Clinical Trials Registry managed by the National University Hospital Council of Japan (UMIN 000024836).

Patients

Women with pathologically proven primary breast cancer during the period from October 2016 to June 2017 who were willing undergo neoadjuvant chemotherapy or adjuvant chemotherapy were eligible for this study. They were recruited from 15 participating institutions. Inclusion criteria were as follows: age range, 20–75 years and Eastern Cooperative Oncology Group performance status, 0–1. Patients were excluded if they had Raynaud's phenomenon or grade 1 or higher PN according to CTCAE.

Treatment

Nab-PTX (260 mg/m^2) was administered as a 30-min intravenous infusion every 3 weeks for four cycles as neoadjuvant chemotherapy or adjuvant chemotherapy. Patients with human epidermal growth factor receptor 2 (HER2)-positive breast cancer received trastuzumab (initial dose, 8 mg/kg; loading dose, 6 mg/kg) subsequent to the administration of nab-PTX during each cycle.

During each nab-PTX infusion, all patients wore two SGs of the same size on both hands for 90 min that included 30 min before the administration of nab-PTX, during the 30 min of nab-PTX infusion, and for 30 min after the end of the infusion. This protocol was identical to that used in our phase 2 study [6].

The SGs were one size smaller than the size that would normally fit the patient's hand. Non-latex SGs were used at all institutions to avoid cutaneous allergic reaction. However, the manufacturers of the SGs were different at each institution: Senti-Touch (Toray Medical, Tokyo, Japan), DermaTex II (JSS, Osaka, Japan), Protexis Latex Micro (Cardinal Health, IL, USA), and Tradition Surgical Gloves (Medline Industries Japan, Tokyo, Japan). We evaluated the comparative incidence of PN associated with the use of these SGs. Preventive medication for CIPN was prohibited. For patients who developed CTCAE grade 2 or higher PN, the use of supportive medicines, such as duloxetine, was allowed based on the discretion of the treating physician.

Determining the optimal size of compression SGs

The method to determine the optimal size of SGs was the same as that employed in the previous phase 2 trial [6]. In brief, the surgeons placed their palm over the patient's palm to determine the patient's estimated tight-fitting size. The tight-fitting size was confirmed by asking the patient to wear the SGs. Once the size was

determined, one size smaller SG was used in the study.

Evaluation of PN

Evaluation of PN was as described in our previous study [6]. In brief, PN was assessed by the breast surgeons or physicians using the CTCAE version 4.0 at the following time-points: pretreatment (baseline), before each treatment cycle, and at day 22 after the completion of four cycles. Simultaneously, the patients were also asked to independently complete PNQ at all time-points. PNQ is composed of two questions about sensory and motor neurotoxicity [7]. In this study, PNQ grades were coded on an ordinal scale of 1 (no neurotoxicity) to 5 (very severe neurotoxicity).

During evaluation of the grade of PN with CTCAE and PNQ in each cycle, the highest grade observed in both hands of each patient was used. The highest level of PN observed during any of the patient's chemotherapy cycles was used for calculation of the overall incidence of CTCAE grade 2 or higher PN.

Evaluation of the temperature of the tip of each finger

To confirm the decrease in microvascular flow of each fingertip, the temperature of each fingertip was measured by thermography at the first cycle of nab-PTX. Measurement of the temperature of each fingertip was as described in our previous study [6]. In brief, to measure the temperature of each fingertip compressed by the glove 30 min after the end of the nab-PTX infusion, the top of the SG of each finger was cut and removed by scissors, and each fingertip was exposed to the thermographic camera. A thermographic camera (INFRA-EYE 2000, Fujitsu, Tokyo, Japan, TH5108ME, NEC San-ei Instruments, Tokyo, Japan, and FLIR i3, FLIR system, Tokyo, Japan) was available at three of the included institutions.

Evaluation of skin disorders caused by wearing SGs

Potential skin disorder was assessed by surgeons or physicians using CTCAE version 4.0 at the same times as the assessment of PN. Skin disorder caused by wearing of SGs was defined as lesions that appeared only in the hands without affecting other skin areas.

Statistical analysis

To calculate the sample size for this study, we used data pertaining to the incidence of CTCAE grade 2 or higher sensory PN from four previous studies that involved administration of nab-PTX to patients with breast cancer [8–11]. In our phase 2 study, the incidence of nab-PTX-induced sensory PN in hands treated with SG-compression therapy was 28.1% (21.4/76.1) of that in the control hands. Therefore, we set the overall incidence of greater than CTCAE grade 2 sensory PN in control hands at 44.1% from prior literature and hypothesized that the incidence of SG-compression-protected hands will be 13%.

Considering α error of 5% and a power of 95%, a sample size of 51 patients was required; assuming 10% dropout, the final patient number was established at 57. A significance level of 0.05 (double-sided) was predicted. We set a power of 95% to achieve more robust results by increasing the sample size because this study was a single-arm trial. The Chi-square test was used to assess the difference in the overall incidence of CTCAE grade 2 or higher between the control group (from prior literature) and data obtained from this study. The goodness-of-fit test based on Chi-square test was used to assess whether the actual overall incidence of grade 2 or higher sensory PN observed in this study was the same as the predicted value. The Wilcoxon matched-pairs signed-rank test was used to determine the magnitude of difference in terms of the temperature of the fingertips before and after wearing the SGs.

Results

Patients

In total, 61 patients with breast cancer (median age, 59 years) were enrolled in this study from 15 institutions. However, 3 patients were excluded because of the following reasons: the first patient developed drug eruption after the first dose of nab-PTX, which was directly attributed to nab-PTX; the second patient developed grade 2 fatigue and muscle pain; and the chemotherapy regimen was changed for the third patient because of the detection of liver metastasis (Fig. 1). Nab-PTX was used as neoadjuvant chemotherapy in 31 patients and as adjuvant chemotherapy in 27 patients. The median size of the glove was 5.5 (range, 5.5–7.0) (Table 1).

Efficacy of the SG-compression therapy

In total, 58 patients who received nab-PTX in combination with SG-compression therapy were evaluated for PN. As shown in Table 2, the overall incidence of sensory PN with CTCAE grade 2 or higher by SG compression therapy was low, i.e., 13.8%, which was significantly lower than that of the control group of the prior literature (44.1%; $P < 0.001$). Similarly, the overall incidence of grade 2 or higher motor PN was lowered to 3.4%. Consistent with the CTCAE-based results, there was a low incidence of sensory and motor grade 4 or higher PNQ, which indicates interference with activities of daily living, in SG-compression-protected hands (sensory: 10.6%; motor: 10.6%).

The goodness-of-fit test using the Chi-square test proved that the overall incidence of CTCAE grade 2 or higher sensory PN (13.8%) obtained in this study was comparable to the hypothesized value of 13%. ($P = 1.0$). The result demonstrated that the primary endpoint was met in this study.

The temporal changes in CTCAE and PNQ grades during nab-PTX treatment are shown in Figs. 2 and 3. SG-compression therapy helped to maintain a low incidence of CTCAE grade 2 PN (sensory PN, 10.3% and motor PN, 3.6% at day 22 after 4 cycles) with a complete absence of grade 3 over time, despite the increase in nab-PTX treatment cycles (Fig. 2).

Similar to the results of CTCAE grade, SG-compression therapy helped maintain a low incidence of PNQ grade 4 PN with complete absence of grade 5 over time, despite the increase in nab-PTX treatment cycles (sensory PN, 5.4% and motor PN, 3.6% at day 22 after 4 cycles) (Fig. 3).

During administration of nab-PTX, 14 patients (24.1%) were permitted to take additional medications, such as goshajinkigan, pregabalin, and/or duloxetine, because of development of grade

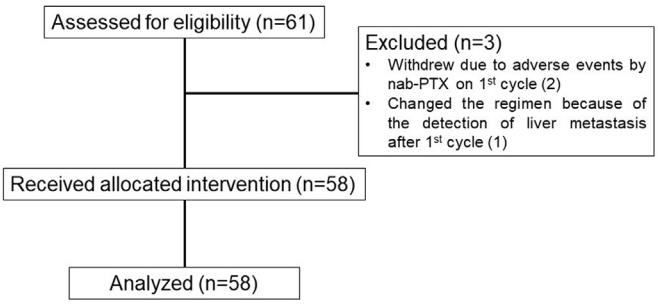

Fig. 1. Schematic illustration of the study design and the patient-selection criteria.

Table 1
Patient characteristics.

Median Age	59 (33-73)
ECOG performance	
0	58
1	0
Location of primary tumor	
R : L	35:23
Glove size	
5.5	37
6.0	17
6.5	3
7.0	1
Treatment	
Neoadjuvant chemotherapy	31
Adjuvant chemotherapy	27
Relative dose intensity (median)	101.20% (50.00-101.20)
Subtype of primary tumor	
ER+HER2-	18
ER+HER2+	10
ER-HER2+	8
ER-HER2-	22

2 PN affecting the feet.

Changes in the temperature of fingertips

Thermography demonstrated decrease in the temperature of each fingertip due to SG-compression therapy, which is similar to the results of our phase 2 study. We measured the temperature of each fingertip of both hands before and after chemotherapy in 21 patients. As shown in Fig. 4, the use of SGs significantly decreased the temperature of each fingertip by 1.3°C-2.3 °C, as compared to measurements obtained before wearing SGs ($P < 0.0001$).

Adverse events associated with SGs

All patients completed this study because of good tolerance to SG-compression therapy. In addition, no dermatological adverse effects related to the use of SGs were observed.

Discussion

In this study, the use of SG-compression therapy decreased the overall incidence of CTCAE grade 2 or higher sensory PN to 13.8% by decreasing the microvascular flow to each fingertip. This result is consistent with the results of our phase 2 study and further indicates there were some the efficacy and safety of SG-compression therapy in reducing CIPN, particularly nab-PTX-induced PN.

Two studies, retrospective and prospective, demonstrated the efficacy of frozen gloves and stockings for preventing taxane-induced PN [12,13]. However, the preparation of frozen gloves is time consuming and costly. Frozen gloves have to be dried overnight after use and then frozen overnight or longer in a special freezer. The cost of frozen gloves is as expensive as 28,000 Japanese Yen/pair of gloves. Therefore, it is often difficult to use frozen gloves in clinical practice at many hospitals.

Table 2
Overall incidence of peripheral neuropathy (PN), as evaluated using the CTCAE version 4.0 (a) and PNQ (b) (N = 58).

a)			b)		
CTCAE v4.0	Sensory (%)	Motor (%)	PNQ	Sensory (%)	Motor (%)
Grade 0	22 (37.9)	44 (75.9)	Grade 1	19 (32.8)	33 (56.9)
Grade 1	28 (48.3)	12 (20.7)	Grade 2	27 (46.6)	17 (29.3)
Grade 2	8 (13.8)	2 (3.4)	Grade 3	6 (10.3)	2 (3.4)
Grade 3	0	0	Grade 4	6 (10.3)	6 (10.3)
Grade 4	0	0	Grade 5	0	0

CTCAE, Common Terminology Criteria for Adverse Events; PNQ, Patient Neurotoxicity Questionnaire

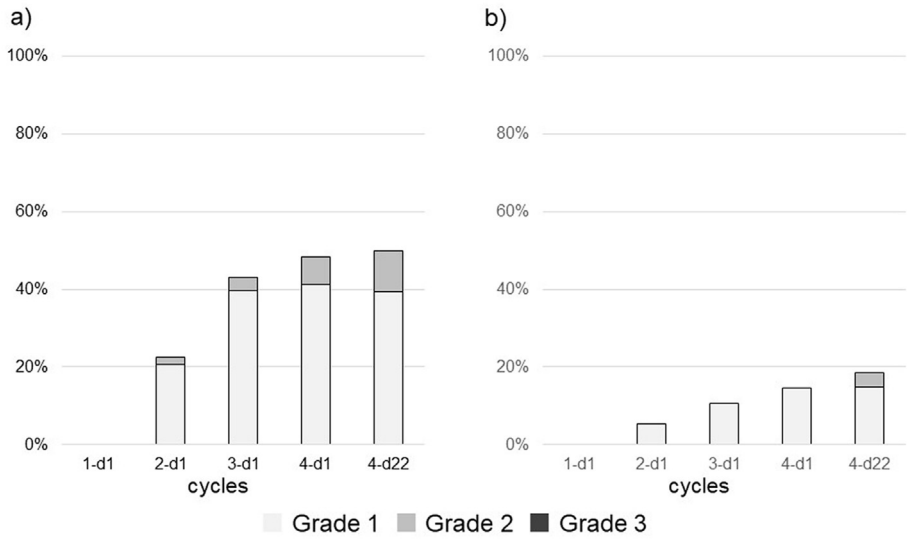

Fig. 2. Changes in the grades of PN evaluated using CTCAE version 4.0. Results are shown for each cycle of nab-PTX treatment. a) sensory neuropathy, b) motor neuropathy. SG-compression therapy helped maintain a low incidence of CTCAE grade 2 PN with a complete absence of grade 3 over time, despite the increase in nab-PTX treatment cycles. CTCAE, Common Terminology Criteria for Adverse Events; nab-PTX, nanoparticle albumin-bound-paclitaxel; PN, peripheral neuropathy; SG, surgical gloves.

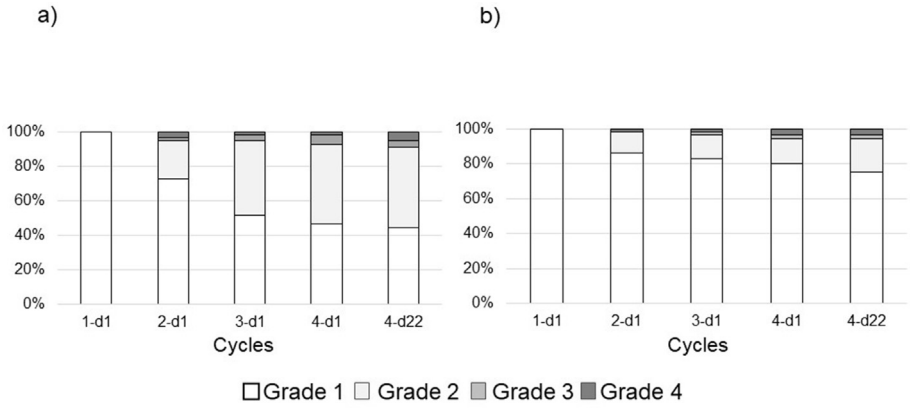

Fig. 3. Temporal comparison of the peripheral neuropathy grade using PNQ during nab-PTX treatment a) sensory neuropathy, b) motor neuropathy. Similar to the results of CTCAE grade, SG-compression therapy helped to maintain a low incidence of PNQ grade 4 PN with a complete absence of grade 5 over time, despite the increase in nab-PTX treatment cycles.

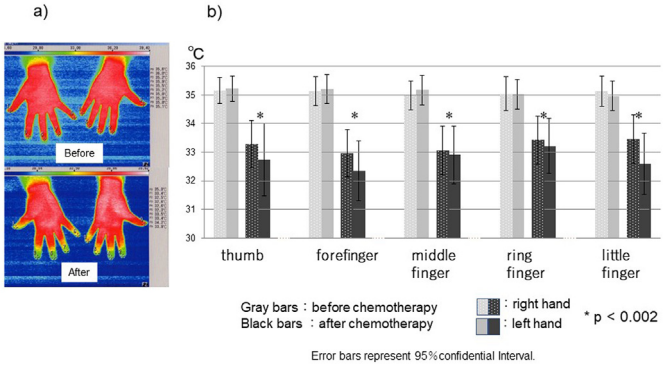

Fig. 4. Changes in the temperature of each fingertip subjected to SG-compression therapy ($N = 21$). a) Thermographic image of the palmar aspects of a patient's hands before and after chemotherapy (upper and lower side, respectively). b) SG-compression therapy significantly reduced the temperature of each fingertip compared to pre-chemotherapy level. ($P < 0.002$). SG, surgical gloves.

We developed SG-compression therapy as a new, low-cost, feasible method for the prevention of PN. Our previous self-controlled phase 2 study demonstrated that SG-compression therapy significantly decreased the incidence of PN by reducing the temperature of the tip of each finger by 1.6°C-2.2 °C. In the present study, the overall incidence of CTCAE grade 2 or higher sensory PN with SG-compression therapy was as low as 13.8%. These results are consistent with our hypothesis that the overall occurrence of PN with CTCAE grade 2 or higher will be 13% by this method. We believe that these findings demonstrate the effectiveness of SG-compression therapy.

This therapy offers some advantages over the use of frozen gloves with respect to the adverse events related to the device itself. All patients completed this study because the compression caused by SGs was well tolerated. There were no skin disorders attributed to the SGs. Conversely, dropout from chemotherapy due to cold intolerance [14] and cold-related injuries are some of the risks associated with the use of frozen gloves. These findings suggest that SG-compression therapy is safe and effective for the prevention of CIPN.

The overall incidence of grade 2 or higher PN (13.8%) in the present study was lower than that in our phase 2 study (21.4%). There are two potential reasons for this difference. One potential reason is the smaller sample size in the phase 2 trial; secondly, the self-controlled study design may have affected the patient's evaluation of the PN.

This study has some limitations. First, the study was not a randomized study. PN is a severe adverse event that impairs the quality of life of the patient for a prolonged period of time after completion of chemotherapy. We noticed a considerable difference with respect to the incidence of residual PN between non-protected hands and SG-compression-protected hands according to follow-up survey data from our phase 2 study. Even 483 days (median follow-up interval) after the administration of nab-PTX, PN was observed in 45% of hands not protected by SG as against only 18.9% of SG-compression-protected hands [15]. Keeping this in mind, we opted for a single-arm confirmatory study to minimize patient suffering caused by CIPN. A second limitation of this study was the use of subjective methods for the evaluation of PN, i.e., CTCAE and PNQ. In this study, 10.6% of patients rated their PN as PNQ grade 4, whereas surgeons and physicians assessed their symptoms as CTCAE grade 2. This discrepancy between the assessment of PN by patients and physicians indicates the limitations of the use of subjective methods for the evaluation of PN. Other methods, such as those used by Hanai et al., may provide a more objective evaluation of PN.

In conclusion, this study suggested that SG-compression therapy was effective to decrease the incidence of nab-PTX-induced PN by reducing the microvascular flow to each fingertip. Our results also indicate the safety of SG-compression therapy as a preventive method because none of the patients dropped out of this study due to compression intolerance or developed any skin disorder associated with use of SGs. This preventive method is inexpensive, easy, and safe for use at any institution.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of interest

The authors have declared no conflicts of interest.

Acknowledgments

We thank the patients and their families for their participation in this study. We also thank our colleagues and medical staff at each institute.

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