Cryotherapy Combined with Compression Gloves and Socks Therapy Reduce Nab-Paclitaxel-Induced Peripheral Neuropathy in Breast Cancer Patients Undergoing Neoadjuvant Chemotherapy: A Multicenter Randomized Controlled Trial

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Lize Wang, MD[1]; Yingjian He, MD[1]; Jinfeng Li, MD[1]; Xinying Yu, RN[1]; Hongjuan Sun, RN[1]; Jie Zhang, RN[1]; Bin Hua, MD[2]; Zhaoqing Fan, MD[1]

[1]Beijing Cancer Hospital, [2]Beijing Hospital, China

Background

- Chemotherapy-induced peripheral neuropathy (CIPN) is a frequent and dose-limiting toxicity of nab-paclitaxel in the treatment of breast cancer.
- Effective strategies to mitigate CIPN remain limited.
- Cryotherapy and compression therapy have shown promise in reducing CIPN, but prospective randomized data are scarce.
- We investigated whether the combined use of cryotherapy and compression gloves/socks could alleviate nab-paclitaxel–induced neuropathy in patients receiving neoadjuvant chemotherapy.

Methods and Materials

- This multicenter, prospective, randomized controlled trial enrolled patients with stage ≥T2, hormone receptor–positive node-positive or triple-negative breast cancer (TNBC).
- The primary endpoint was the incidence of grade ≥3 neuropathy. Secondary endpoints included pathological complete response (pCR) rate, quality of life and the incidence of grade ≥2 neuropathy.
- All patients received dose-dense anthracycline-based chemotherapy (90–100 mg/m²) for 4 cycles followed by nab-paclitaxel (260 mg/m²) every 2 weeks for 4 cycles.
- Patients were randomized (1:1) to either standard care (control) or cryotherapy with compression gloves and socks worn during nab-paclitaxel infusion (intervention).
- Peripheral neuropathy was assessed by Common Terminology Criteria for Adverse Events (CTCAE) criteria, version 5.0 (sensory and motor neuropathy score), the Patient Neurotoxicity Questionnaire (PNQ) and the EORTC QLQ-CIPN20.

Results

- A total of 102 patients were enrolled. Three participants withdrew, and 99 were included in the final analysis-50 in the intervention

Figure 1. Study schema.

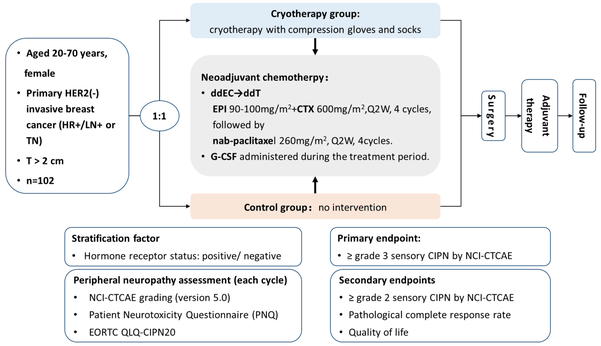


Figure 2. Demonstration of cryotherapy with compression gloves and socks.



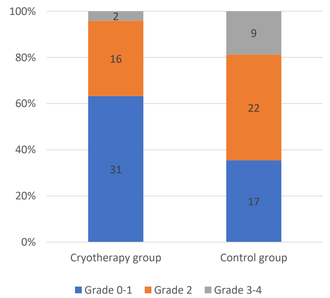
Results

group and 49 in the control group. One patient in each group had incomplete assessment data.

Results

- Among the 99 patients included in the analysis, 57 patients were hormone receptor–positive (HR+) and 42 patients were triple-negative (TN).
- The incidence of grade ≥3 sensory neuropathy was significantly lower in the cryotherapy group compared with the control group (4.1% vs. 18.8%, P =0.023).
- Similarly, grade ≥2 sensory neuropathy occurred less frequently in the cryotherapy group, indicating a consistent reduction in neurotoxicity (36.7% vs. 63.8%, P =0.008).
- Patients in the cryotherapy group also reported significantly lower scores on CIPN20 assessments (P =0.008).
- According to PNQ, the incidence of grade D or E showed no statistically significant difference between groups (P = 0.475).
- Among all patients receiving biweekly nab-paclitaxel, the total pCR rate was 25.8%.
- In the TNBC subgroup, the total pCR rate achieved 50.0%.
- The rate of treatment discontinuation or dose reduction due to adverse events was 20.4% in the control group versus 10.0% in the cryotherapy group.

Chart 1. Assessment of sensory neuropathy by CTCAE V 5.0.



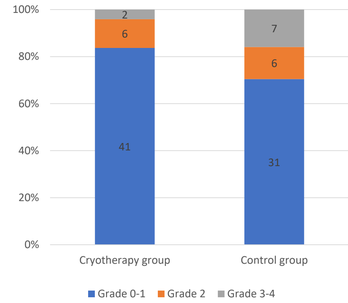
≥ grade 3 sensory CIPN
- Cryotherapy group: 4.1%
- Control group: 18.8%

P = 0.023

≥ grade 2 sensory CIPN
- Cryotherapy group: 36.7%
- Control group: 63.8%

P = 0.008

Chart 2. Assessment of motor neuropathy by CTCAE V 5.0.



≥ grade 3 motor CIPN
- Cryotherapy group: 4.2%
- Control group: 14.6%

P = 0.098

≥ grade 2 motor CIPN
- Cryotherapy group: 16.7%
- Control group: 33.3%

P = 0.159

Table 1. Pathological complete response by groups

pCR	Entire group	HR+ group	TN group
ypT0/is ypN0	25.8%	7.3%	50%
ypT0/is ypN0/+	27.8%	10.9%	50%

Conclusions

- Cryotherapy combined with compression therapy significantly reduced the incidence and severity of nab-paclitaxel–induced CIPN in the neoadjuvant setting, while improving patient quality of life and treatment tolerability.
- Biweekly nab-paclitaxel yielded an acceptable pCR rate, especially in patients with triple-negative breast cancer.
- These findings support cryotherapy combined with compression therapy as a safe, non-pharmacologic strategy to mitigate CIPN in breast cancer patients.

- Clinical trial information: NCT05341141.

Contact

First author: Lize Wang, MD, lize2010@163.com
Corresponding author: Zhaoqing Fan, MD, zhqfan@bjmu.edu.cn
Beijing Cancer Hospital

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