



Feasibility, safety and efficacy of cryotherapy for prevention of paclitaxel-induced peripheral neuropathy in breast cancer patients: A pilot study

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Introduction

Chemotherapy induced peripheral neuropathy (CIPN) is an adverse side-effect of certain chemotherapeutic agents (e.g. Paclitaxel) causing permanent nerve damage and pain. Studies showed 73.4% of patients have reported wanting to reduce or stop treatment because of CIPN. It has been proposed that combining medicine and cryotherapy may effectively prevent CIPN. However, research on feasibility, safety and efficacy of cryotherapy is still lacking. Therefore this study was undertaken to ascertain if cryotherapy is feasible, safe and effective in reducing paclitaxel induced peripheral neuropathy

Methods

A quasi-experimental self-controlled trial design with twenty patients receiving chemotherapy treatment with paclitaxel as a single agent or multimodal treatment protocols were selected using non probability purposive sampling technique. Frozen gloves and socks (-10 – 20°C) was to applied experimental arm, 15 minutes prior to, and after completion of paclitaxel infusion (total duration of 1^{1/2} hour). Data was collected using Visual Analogue Scale (VAS), Subjective Tolerance Scale (STS), Shivering Assessment Scale (SAS) and the incidence/severity of peripheral neuropathy was assessed using CTCAE version 5. Data was analyzed using descriptive and inferential statistics.

Results

Age ranged from 31-64 years with majority (n=13, 65%) in age group of 41-50 years. Only thirteen participants completed 12 cycles.. Most (n=3 23%) participants received 140 mg of Paclitaxel while one (7.6%) received a low dose of 100mg. . Among the 13 participants who completed the 12 cycle, one participant had a VAS and STS score of 1 during 1-8 cycle and SAS score was 1 in 10-11 cycle. Only three (15 %) participants developed grade one peripheral neuropathy. There was no statistical significance in mean score of comfort level and grades of peripheral neuropathy.

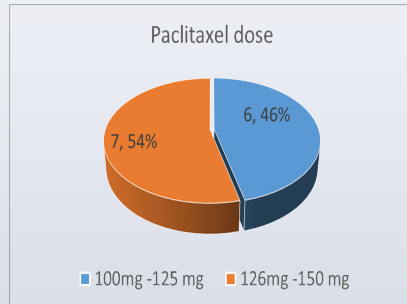


Figure 1: Paclitaxel dose

Reason	Count
Completed treatment	13
Discontinued	7
Reason	
VAS score was 6	1
Refused due to intolerance	1
Migrated to another place	3
Protocol changed	2

Table 1: Reason for discontinuing

(n=13)	Freq	Percent	Weeks
VAS (Score 1)	1	8	(1st, 4th-8th week)
STS (Score 1-3)	1	8	(3rd, 5th - 8th week)
SAS (Score 1)	1	8	(10th and 11th week)
CTCAE- V5, Grade 1	3	23	(1st, 6th and 10th week)

Table 2: Scoring of Parameters



Figure 2. Elasto frozen gloves

Discussion

According to K J Ruddy et al, only one patient in the cryotherapy arm had documentation of extremity pain of grade 2, which is similar to this study, where 1 patient reported pain score of 1. The three patients who developed grade 1 neuropathy had received paclitaxel dose of 150 mg. Severity as measured by CTCAE.v5 score in DH and NDH, showed that 3 participants had grade 1 peripheral neuropathy. As per Shigematsu and colleagues The cryotherapy group had a lower incidence of CTCAE ≥Grade 2 peripheral sensory neuropathy (9% vs. 54%; p=0.001) and motor peripheral neuropathy (5% vs. 32%; p=0.01).

This study assessed and found that it was feasible, safe and effective. Cryotherapy is a good option to consider in preventing CIPN in patients receiving paclitaxel. Therefore the study can be conducted on a larger scale with an adequate sample.

References

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