

Background:

Chemotherapy-induced peripheral neuropathy (CIPN) is an adverse event of many commonly used chemotherapeutic agents (cisplatin, oxaliplatin, more rarely carboplatin, vinca alkaloids, especially vincristine, more rarely also vinblastine and vinorelbine, 5-fluoropyrimides (5-FU, capecitabine). CIPN in breast cancer is often caused by taxane-based regimen (Paclitaxel, nab-Paclitaxel, Docetaxel) carboplatin, eribulin and vinorelbine. Seidman et al (UCO 2008), reported CIPN incidence rates grade 2-3 in 33% for three-week taxol administration and 51% of grade 2-3 toxicities for weekly administration of paclitaxel, one of the standard of care in the treatment of breast cancer. The peripheral neuropathy (PN) induced by taxanes may persist for several years and is negatively associated with quality of life (Blackley et al, 2019). Often the CIPN results in dose delay, dose reduction or even treatment discontinuation which means possible decrease of healthy outcome and worsening of long-term prognosis.

In our study we found that the prophylactic, temperature controlled hand-foot-cooling (Hilootherapy®) using a new processor - controlled cooling device (Hilotherm Chemo Care) prevented chemotherapy-induced-peripheral neuropathy (CIPN) > grade 1 in 93% of our breast cancer patients. The 4-year data from 129 patients prove the sustainability of our results. Compared to previous cooling methods, Hilootherapy® is very well tolerated by patients and involves little stress for nursing staff in everyday clinical practice.

Method and patients:

In our pilot study (January 2018 - May 2019) 151 breast cancer patients used the temperature controlled hand-foot cooling (Hilootherapy® 1. generation). The extremities were cooled with a constant temperature setting (device setting 10-12°C) during each taxane-containing chemotherapy. Cooling took place 30 minutes before to 30 minutes after chemotherapy (Fig. 1a&b). After each chemotherapy treatment, symptoms of CIPN were recorded using CTCAE V.4 criteria, the sustainability of the results were collected by follow-up data (patient contacts every 3 months). Currently, we can present 4-year follow-up data from 129 patients.

42 patients received their chemotherapy treatments without any prophylactic cooling and were mentioned as observing group.

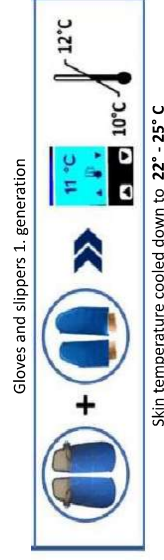


Fig. 1a: Patient in cooling

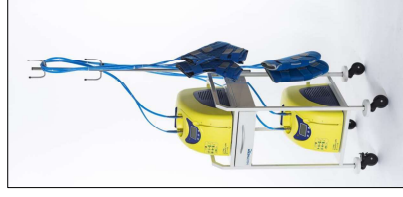


Fig. 1b: Hilotherm Chemo Care device

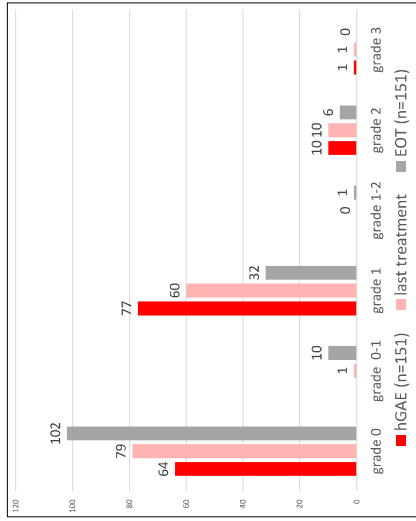


Fig. 3: CIPN-toxicity under Hilootherapy® 1. generation

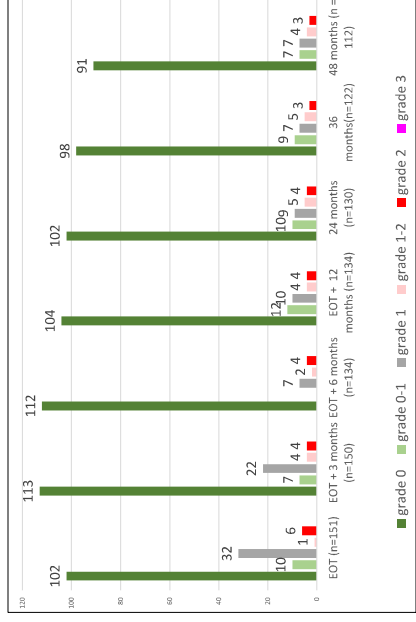


Fig. 4a: 4 Year Follow Up*

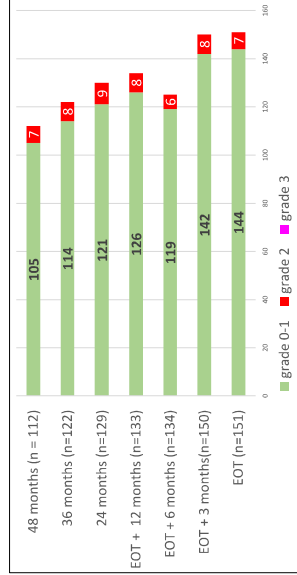


Fig. 4b: 4 years Follow Up*

	grade 0-1	grade 2
EOT	95.4 %	4.6 %
EOT + 12 months	94.0 %	6.0 %
EOT + 24 months	93.1 %	6.9 %
EOT + 36 months	93.4 %	6.6 %
EOT + 48 months	93.75 %	6.25 %

Fig. 4c: 4 years-Follow Up*

Fig. 5: Adverse events without prophylactic cooling compared with prophylactic Hilootherapy®

Conflicts of interest:
M. Darsow: has nothing to declare due to this presentation;
T. Schaper: Lecture fees, advisory boards, consulting contracts
Hilotherm GmbH

DGHO 2023: Poster 727
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Results:

Out of 151 patients using prophylactic HILOOTHERAPY®, 141 patients (93.4%) developed none or mild symptoms of CIPN (grade 0: n = 64, grade 1: n = 77); 10 (6.2%) patients described a grade 2 toxicity, 1 patient grade 3 (0.6%) (Fig. 3). The symptoms were partially reversible: 4 weeks after the last chemotherapy treatment (EOT), none of the patients showed grade 3 toxicity, grade 2 toxicities decreased from 10 patients (6%) to 6 (4%) patients. The number of patients describing none symptoms of CIPN increased from 64 up to 102. At EOT 95.4% of all patients using prophylactic HILOOTHERAPY® are free of severe CIPN symptoms > grade 1.

Out of the 42 patients without prophylactic hand-foot cooling, 38 patients developed symptoms of CIPN (Fig. 5). 19 of the patients (45.5%) without prophylactic HILOOTHERAPY® developed grade 2-3 toxicities (grade 2: n = 17; Grade 3: n=2).

The long-term Follow Up data confirm the sustainability of the results: out of the 151 patients, 129 are currently in the 4-year follow-up. Fig 4a&b shows the distribution of toxicity levels in detail.

4 years after completing chemotherapy treatments, 93.75% of the patients (n= 105) describe no severe grade 2/3 CIPN symptoms. 7 patients still suffering grade 1-2 (6.25%). These data confirm CIPN toxicities of higher grades are long-term complications and last for many years. (Fig. 4a&b). In 10 patients we observed grade 2 toxicities during chemotherapy - at the time of 4 years Follow Up, 7 patients describe grade 2 symptoms.

Conclusions:

Using the prophylactic, temperature-controlled hand-foot cooling (HILOOTHERAPY® 1st generation), higher grade CIPN toxicities (> grade 1) can be avoided in 93.4% during chemotherapy® (Fig. 5).

The long-term data from the pilot project with 151 patients confirm the sustainability of the results (Fig. 4a&b). 4 years after the last chemotherapy infusion, 93.75% of patients continue to be free of grade 2 & 3 CIPN toxicities.

Modern oncological systemic therapies (individualized therapies, immunotherapies, targeted therapies) lead to an improvement in the long-term prognosis of cancer patients - thus the importance of maintaining quality of life for long-term survivors is increasing.

The temperature-controlled hand-foot cooling (HILOOTHERAPY® is a simple and very tolerable supportive therapy for patients to avoid CIPN. The technique is easy for nursing staff to implement and does not have a significant impact on everyday clinical practice.