Temperature-Controlled Hand-Foot Cooling Prevents Chemotherapy-Induced Polyneuropathy (CIPN): A Real-World Data Collection in 500 patients

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Introduction

Advancements in oncology have significantly improved overall survival rates for cancer patients, particularly those with breast cancer. Consequently, long-term chemotherapy side effects on quality of life (QoL), a remaining cancer treatment cornerstone for a great number of patients, are gaining increasing attention.

Chemotherapy-induced peripheral neuropathy (CIPN) is a common adverse effect of taxanes (paclitaxel, nab-paclitaxel, docetaxel), which can significantly reduce QoL and may lead to dose delays, reductions, or even treatment discontinuation. Reported incidence rates of grade 2–3 CIPN reach up to 50% with three-weekly and up to 30% with weekly taxane-based regimens, which are frequently used in breast cancer.

Despite numerous clinical trials, there is currently no evidence-based standard of care for the prevention of CIPN, and therapeutic options remain limited and largely symptomatic. Clinical trials have reported encouraging data with reduced rates of CIPN using cryotherapy or compression. Temperature-controlled hand-foot cooling (Hilotherapy®, **Fig. 1**) has shown preventive potential against grade ≥ 2 CIPN.

At our oncology department, temperature-controlled Hilotherapy® has been implemented since 2018 as supportive standard of care during chemotherapy using initially 1st and later 2nd generation cuffs, combining cooling with mild compression, with (+) or without (-) 30 minutes postcooling.

We here present the results of our prospectively collected real-world dataset including 500 breast cancer patients, evaluating the efficacy, including follow-up outcomes for the prevention of CIPN.

Results using Hilotherapy®

503 breast cancer patients were treated with a taxane-based chemotherapy **(Table 1)**.

During chemotherapy, a total of 455 (90,5%) developed none or mild symptoms (highest grade: grade 0 = 32,2%, grade 1 = 58,3%). Grade 2 CIPN occurred in 47 patients (9,3%), while two patients reported grade 3 symptoms (0,4%) **(Table 2a; Fig. 2a)**. At end of treatment (EOT), 479 patients (95,2%) continued to show none or mild symptoms (grade 0 = 50,5% and grade 1 = 44,7%), whereas 28 patients (5,6%) reported grade 2 toxicity **(Table 2a, b)**. Two patients reported Grade 3 symptoms (0,4%). Follow-up data demonstrated sustained preventive efficacy of Hilotherapy. The incidence rate of CIPN > grade 1 decreased continuously from 6% at EoT to 4,8% at 12 months **(Table 3 & Fig. 2).**

Treatment regimens	1st gen. (+)	2nd gen. (+)	2nd gen. (-)
q1w	**n= 129**	**n=102**	**n=174**
12x Paclitaxel 80 q1w	100	61	48
12x Paclitaxel 80 q1w + Carboplatin AUC 2 q1w	-	31	10
12x Paclitaxel 80 q1w + Carboplatin AUC 1,5 q1w + Pembrolizumab q3w	21	32	22
12x Paclitaxel 80 q1w + Trastuzumab q3w	-	7	9
12x Paclitaxel 80 q1w + Trastuzumab + Pertuzumab q3w	-	32	10
12x nabPaclitaxel q1w	7	-	-
12x nabPaclitaxel 125 q1w + Carboplatin AUC 2 q1w	1	3	-
6x nabPaclitaxel 100 d1,8,15 q4w + Pembrolizumab q3w	-	3	1
6x nabPaclitaxel 100 d1,8,15 q4w + Atezolizumab d1,15 q4w	-	1	-
4x Paclitaxel 80 → 8x nabPaclitaxel + Carboplatin AUC 1,5 q1w + Pembrolizumab q3w	-	1	-
2x Paclitaxel → 10x nabPaclitaxel + 11x Carboplatin AUC 2 q1w	-	1	-
18x Paclitaxel 80 q1w + Trastuzumab + Pertuzumab q3w	-	2	-
18x Paclitaxel 80 q1w + Bevacizumab q3w	-	-	2
q3w	**n=11**	**n=20**	**n=67**
6x DC q3w	5	4	28
6x TCbH+P q3w	1	16	38
6x Docetaxel q3w + Trastuzumab + Pertuzumab q3w	5	-	1

Table 1: Chemotherapy regimens applied

Summary and discussion

The use of temperature-controlled hand-foot cooling (Hilotherapy®) regardless of 1st or 2nd generation cuffs effectively prevented CIPN toxicity ≥ grade 2 in 90,5% of patients receiving neurotoxic chemotherapy. At EOT, 95,2% of the patients remained free of grade ≥ 2 CIPN, and only two patients experienced grade 3 neuropathy, who had the individual risk factor of diabetes mellitus. Follow-up data confirmed the sustained preventive effect of Hilotherapy®, with no evidence of a coasting phenomenon up to 12 months post-therapy.

At our institution, Hilotherapy® has therefore been integrated into the standard supportive care pathway for all patients receiving neurotoxic chemotherapy as CIPN prophylaxis, representing a simple, well-tolerated, and easily implementable supportive strategy, requiring minimal workload for nursing staff. Data collection is ongoing, and prospective multicenter studies are currently being conducted in Germany and Spain to further validate these real-world findings.

Conflicts of Interest: A. Kostara: advisory boards, congress and travel expenses Hilotherm GmbH, not related to this investigation; T. Schaper: lecture fees, advisory boards, consulting contract Hilotherm GmbH

SABCS 2025 - PS1-01-18

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1at generation cuffs.
Skin surface is cooled down to approximately 25°C.



2nd generation cuffs.
Skin surface is cooled down to approximately 17° - 18°C.

Fig. 1: Hilotherm ChemoCare[CIPN] device with 1st and 2nd generation cooling cuffs.

Patients and methods

Temperature-controlled hand-foot cooling (Hilotherapy®) was implemented as standard supportive care during each neurotoxic chemotherapy session. Data were prospectively collected from 345 patients with breast cancer treated with Hilotherapy®. Patients received taxane-based chemotherapy either in weekly (q1w, n = 405) or three-weekly (q3w, n = 98) regimens.

Hilotherapy® is a processor-controlled, temperature-regulated cooling system using the Hilotherm ChemoCare[CIPN] device, designed for continuous, precise cooling. The system uses distilled water through designated hand and foot cuffs, maintaining a set temperature of 15°–17°C, corresponding to a skin surface temperature of approximately 18–20°C (**Fig. 1).** The standard protocol includes cooling for 30 minutes prior, throughout the infusion, and 30 minutes post-infusion.

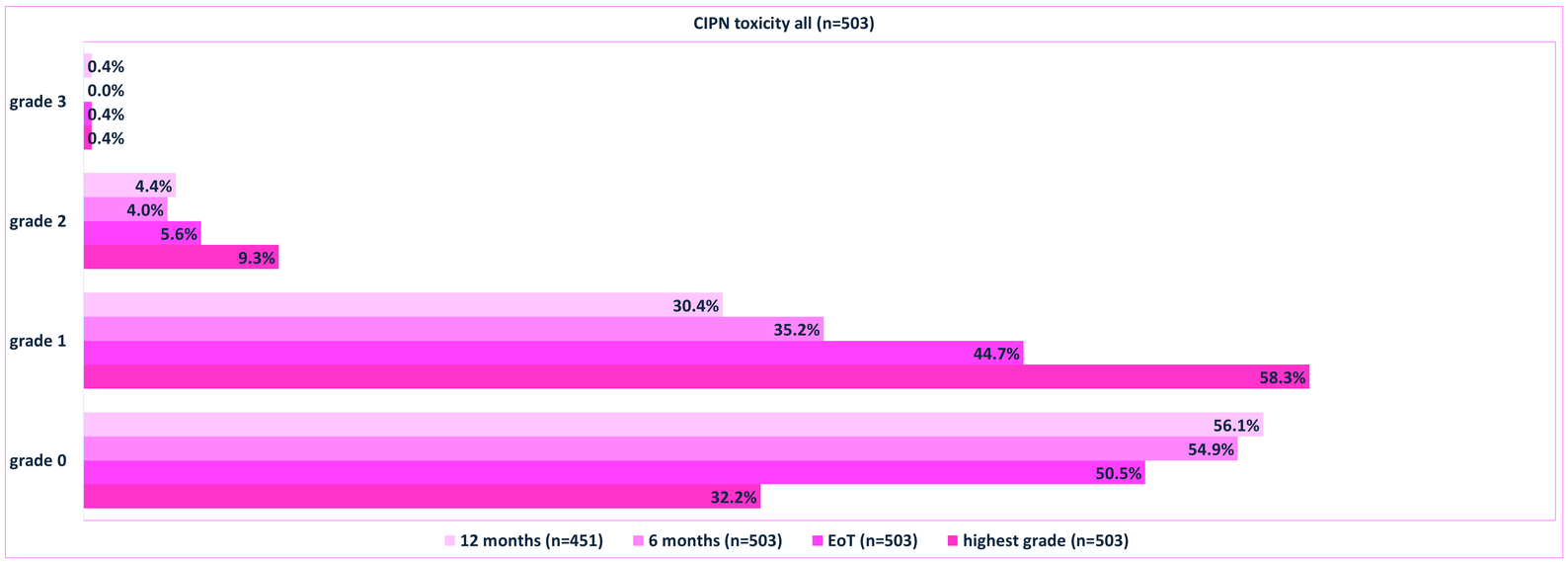
CIPN symptoms was assessed by treating physicians at each cycle using CTCAE-V5 criteria, quantifying the severity of CIPN in grades 1-5. To distinguish asymptomatic patients from those with mild symptoms, a further differentiation was applied: Grade 0: no symptoms and grade 1: mild symptoms not interfering with activities of daily life (AdL).

CIPN outcomes were re-evaluated at 6 and at 12 months post-chemotherapy to assess long-term persistence or recovery.

After completion of treatment, patients completed a questionnaire evaluating practicality, satisfaction, tolerability and recommendation intent. Each item was rated on a 5-point Likert (1 = very good to 6 = insufficient).

Study endpoints included:

- incidence rate of CIPN during chemotherapy and at EoT
- incidence rate of CIPN at 3, 6 and 12 months after chemotherapy
- rate of chemotherapy dose reductions due to CIPN
- Patient satisfaction and tolerability



all (n=503)	grade 0	grade 1	grade 2	grade 3	†	lost
highest grade (n=503)	**32,2%** (162)	**58,3%** (293)	**9,3%** (47)	**0,4%** (2)	-	-
EoT (n=503)	**50,5%** (254)	**44,7%** (225)	**5,6%** (28)	**0,4%** (2)	-	-
6 months (n=503)	**54,9%** (276)	**35,2%** (177)	**4%** (20)	**0%** (0)	**1,8%** (9)	**4,2%** (21)
12 months (n=451)	**56,1%** (253)	**30,4%** (137)	**4,4%** (20)	**0,4%** (2)	**2%** (9)	**6,7%** (30)

Table 3 & Fig. 2: CIPN toxicity all

q3w	grade 0	grade 1	grade 2	grade 3
highest grade (all, n=98)	**30,6% (30)**	**59,2% (58)**	**9,2% (9)**	**1% (1)**
1st gen. (+), n=11	36,4% (4)	46,5% (5)	9,1% (1)	9,1% (1)
2nd gen. (+), n=20	30% (6)	65% (13)	5% (1)	0% (0)
2nd gen. (-), n=67	29,9% (20)	59,7% (40)	10,4% (7)	0% (0)
EoT (all, n=98)	**41,8% (41)**	**50% (49)**	**8,2% (8)**	**0% (0)**
1st gen. (+), n=11	27,3% (3)	54,5% (6)	18,2% (2)	0% (0)
2nd gen. (+), n=20	35% (7)	60% (12)	5% (1)	0% (0)
2nd gen. (-), n=67	46,3% (31)	46,3% (31)	7,5% (5)	0% (0)

q1w	grade 0	grade 1	grade 2	grade 3
highest grade (all, n=405)	**32,6% (132)**	**58% (235)**	**9,4% (38)**	**0,2% (1)**
1st gen. (+), n=129	42,6% (55)	52,7% (68)	5,4% (7)	0% (0)
2nd gen. (+), n=102	23,5% (24)	66,7% (68)	9,8% (10)	0% (0)
2nd gen. (-), n=174	30,5% (53)	56,9% (99)	12,1% (21)	0,6% (1)
EoT (all, n=405)	**52,1% (211)**	**42,5% (172)**	**4,9% (20)**	**0,5% (2)**
1st gen. (+), n=129	72,9% (94)	23,2% (30)	3,9% (5)	0% (0)
2nd gen. (+), n=102	36,3% (37)	57,8% (59)	4,9% (5)	1% (1)
2nd gen. (-), n=174	46% (80)	47,7% (83)	5,7% (10)	0,6% (1)

Table 2a, b: CIPN toxicity stratified, q1w vs. q3w