





Hilotherapy for the Prevention and Treatment of Chemotherapy-Induced Neuropathy (CIPN)

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Chemotherapy-Induced Peripheral Neuropathy (CIPN)

- Peripheral nerve damage is a possible side effect of taxanes, platinum derivatives, 5FU and other chemotherapy drugs used to treat cancer. This is known as chemotherapy-induced peripheral neuropathy (CIPN).
- CIPN is particularly prevalent in hands and feet and can cause severe pain and discomfort; affecting patients' ability to walk, balance and pick things up.
- CIPN prevalence with taxanes Grade 1-2: 20-50% (AGO 2018).
- CIPN prevelence with taxanes Grade 3-4: 6-20% (AGO 2018).
- Risk factors: type and dose of chemotherapy, BMI, reduced physical activity (AGO 2018).
- Individual risk factors: Diabetes mellitus, nutritive-toxic compounds part. alcohol, renal failure, hypothyroidism, vitamin deficiency etc (AGO 2018).

Symptoms of Polyneuropathy

- Severe pain
- Acroparesthesia
- Hypersensitivity
- Numbness
- Loss of balance
- Inability to sense cold, heat or pressure

The Impact of CIPN on Patients

- Up to 10% of patients receiving chemotherapy develop severe polyneuropathy and hand-foot syndrome.
- > Patients suffering from CIPN may need to reduce their dosage, make changes to their treatment plan or stop chemotherapy altogether.
- > CIPN symptoms are often not reversible and patients may continue to suffer years after their treatment ends.

<u>Hand-Foot Syndrome</u>

Level 1



Mild symptoms including tingling, painless swelling and erythema of hands and/or feet. Difficulties which do not impact on everyday life.

Level 2



Moderate symptoms including painful swelling and erythema of hands and/or feet. May impact patients' everyday lives.

Hand-Foot Syndrome (Cont.) Level 3





Severe symptoms including desquamation, ulceration, blistering and intense pain on hands and/or feet. Likely to have a great impact on patients' lives and cause immense discomfort.

Hilotherapy in Oncology



- ➤ Hilotherapy is a form of physical thermo-therapy that involves applying constant temperature within the range 5 to 25 in a localized and targeted manner.
- It reduces blood flow in the hands and feet throughout the entire chemotherapy process, thus limiting the amount of chemotherapeutic agents reaching the extremities.
- ➤ Hilotherapy prevents the development of HFS and polyneuropathy, giving patients a better quality of life and eliminating the need for lengthy, follow-up treatment.

<u>Practical Application of Hilotherapy</u>



- Continuous cooling at 10°C
- > 30 minutes pre-cooling
- Cooling during chemotherapy
- > 30 minutes post-cooling









Hilotherapy Trial Details

Combined total of 140 patients across two clinics:

European Breast Centre Dr. Rezai at the Luisenkrankenhaus in Düsseldorf (n=60)

Three observation groups

Medical practice specializing in gynecological oncology Dipl. med. Rene Schubert (n=80)

Comparison of conventional cooling with ice gloves/booties vs. Hilotherapy at 12°C



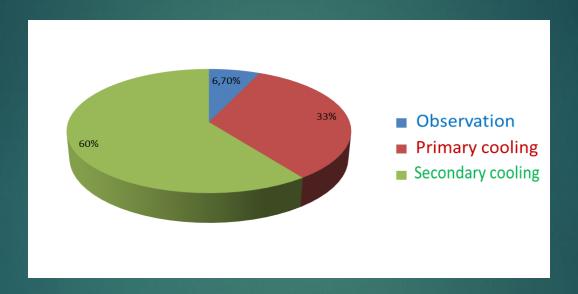
Evaluation of 60 Patients at The Luisenkrankenhaus

Three observation groups were formed:

- Group 1: Observation Patients received chemotherapy without cooling their hands and feet.*
- Group 2: Primary cooling Patients cooled their hands and feet from their first chemotherapy cycle.*
- Group 3: Secondary cooling Patients cooled their hands and feet when the symptoms of HFS had developed.*

*Taxane-based chemotherapy used

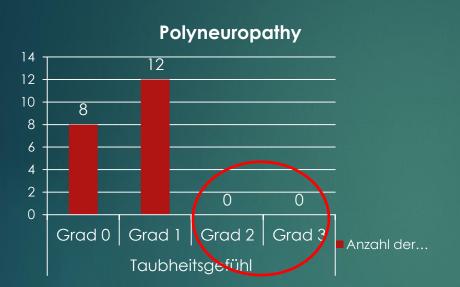
Patient Group Breakdown – Luisenkrankenhaus n = 60		
Observation	Primary Cooling	Secondary Cooling
4	20	36

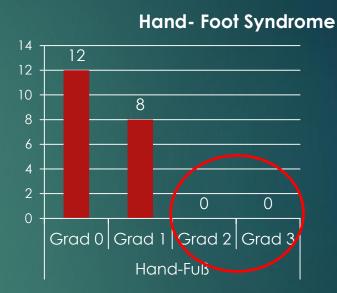


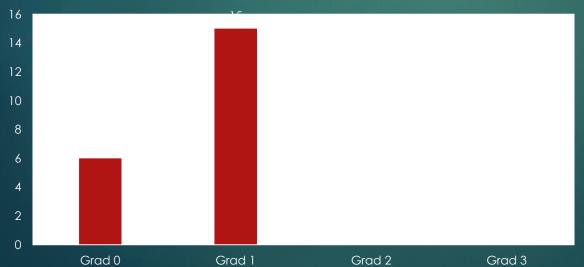
- ➤ Just 6.7% of the patients (n = 4) do not develop appreciable side effects and remain in the observation group. They are not using Hilotherapy.
- > 33% of the patients (n = 20) use Hilotherapy for primary cooling (preventative).
- ➤ 60% of the patients (n = 36) develop HFS/polyneuropathy symptoms (without using Hilotherapy for primary cooling) and Hilotherapy is used for secondary cooling (reactive).

Results of Primary Cooling

20 patients cooled their hands and feet during their first taxane-based chemotherapy.



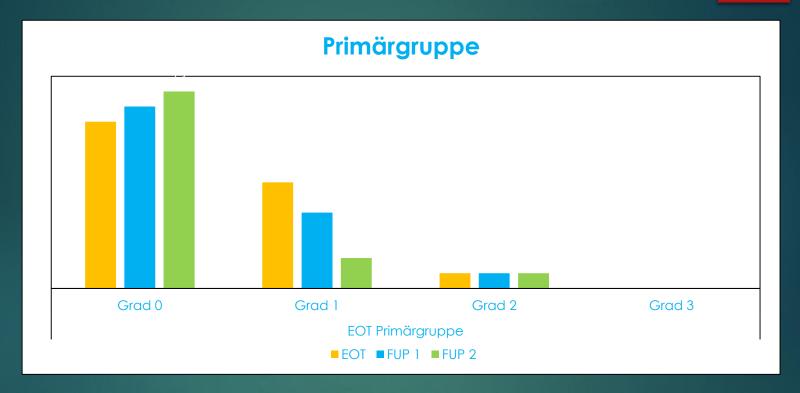




None of the patients who were treated with Hilotherapy developed Level 2 (moderate) or Level 3 (severe) symptoms.

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Follow-Up Results After Primary Cooling



EOT: 4 weeks after the last cycle of chemotherapy (n = 19)

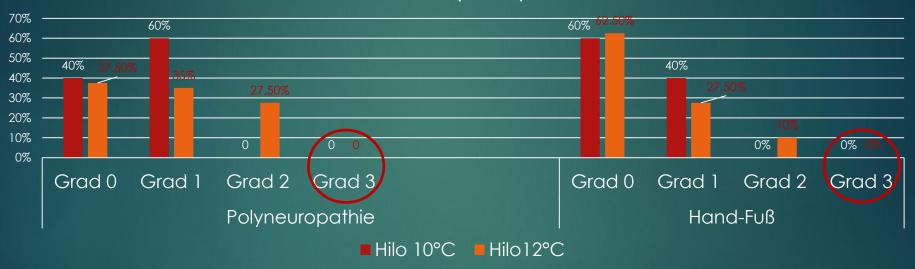
FUP 1: 4 months after the last cycle of chemotherapy (n = 18)

FUP 2: 7 months after the last cycle of chemotherapy (n= 16)

Symptoms continue to improve after treatment is complete. Ca. 95% of the patients do not show any adverse effects 4 weeks after their last cycle of chemotherapy (Level 0-1).

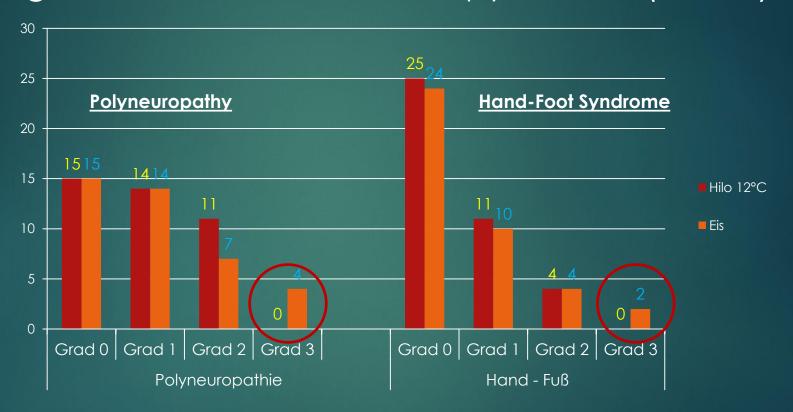
How do different cooling temperatures affect the results?

Comparison of Hilotherapy at 10°C (n=20) vs. Hilotherapy at 12°C (n=40)



- Both temperature approaches prevented the development of severe Level 3 symptoms.
- Hilotherapy at 10°C proved to be more effective, as no patients receiving this treatment reported Level 2 or 3 symptoms.
- ➤ Level 2 symptoms were found in some patients using Hilotherapy at 12°C (27.5% and 10%).

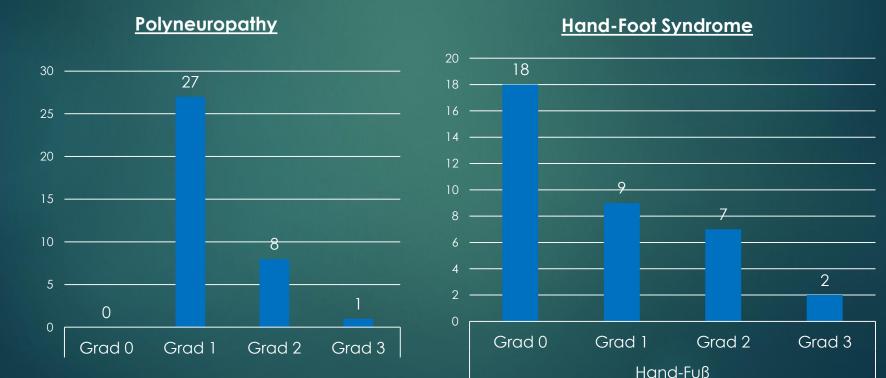
Prophylactic cooling in comparison: Ice gloves/booties vs. Hilotherapy at 12°C (N = 80)



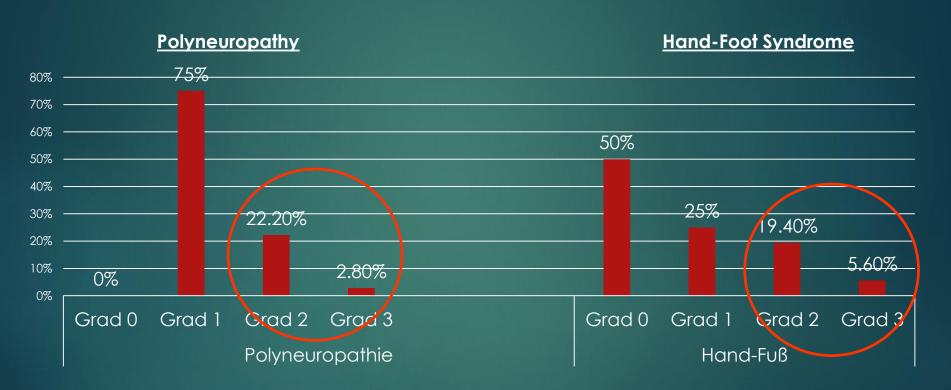
- No severe, Level 3 symptoms were prevalent in patients who cooled with Hilotherapy.
- However, patients who cooled with ice gloves and booties did develop Level 3 symptoms.

Results of Secondary Cooling

Secondary Group n= 36
60% of patients in this group developed symptoms of HFS and polyneuropathy during chemotherapy (without Hilotherapy) and opted for secondary cooling.



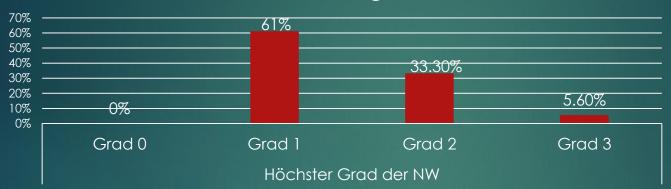
Results of Secondary Cooling (Cont.)



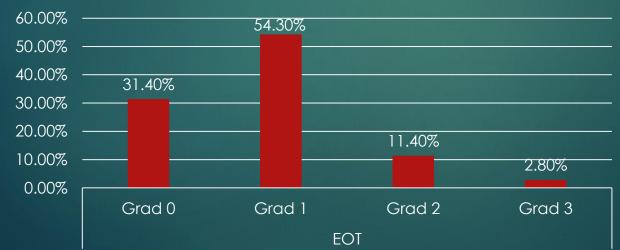
- \triangleright The majority of patients (75%) had either mild symptoms or no symptoms at all.
- ➤ Level 2 and 3 symptoms were prevalent in a handful of patients.

Results of Secondary Cooling (Cont.)

Symptom Severity Levels – Before Secondary Cooling



EOT – After Secondary Cooling

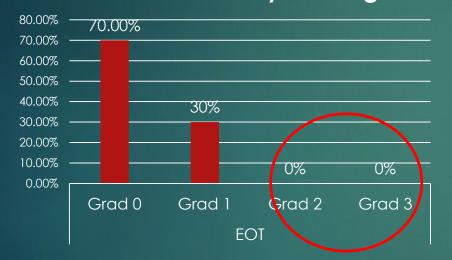


Significant improvement of symptoms, 4 weeks after the last cycle of chemotherapy.

Primary Cooling vs. Secondary Cooling

Comparing Hilotherapy users' symptoms four weeks after their chemotherapy treatment has ended.





EOT – Secondary Cooling



Cooling patients' hands and feet from their first chemotherapy session helped to prevent the onset of Level 2 and 3 HFS symptoms.



Evaluation of 60 Patients at The Luisenkrankenhaus: Results Summary

- Without prophylactic Hilotherapy, just 7% of the patients observed showed no symptoms of HFS/polyneuropathy.
- ➤ Patients who used Hilotherapy as a preventative method did not develop Level 2 (moderate) or Level 3 (severe) symptoms of HFS/polyneuropathy.
- > 70% of patients within the primary group showed no symptoms 4 weeks after their chemotherapy had ended.
- The other 30% of patients in this group, were found to have Level 1 (mild) symptoms.
- ➤ Level 2 and 3 symptoms were greatly reduced in the primary cooling group, demonstrating the value of using Hilotherapy as soon as chemotherapy starts.
- Although primary cooling was more effective, secondary cooling was found to reduce severe symptoms and prevent patients' conditions from worsening.



Gynecological Oncology Scheibenberg

Comparison of Conventional Cooling with Ice Gloves/Booties vs. Hilotherapy at 12°C: Results Summary

- ➤ Hilotherapy at 10°C was found to be more effective than Hilotherapy at 12°C. Hilotherapy at 10°C prevented patients from developing painful Level 2 and 3 symptoms.
- Hilotherapy was found to be more effective than traditional cooling methods, as patients using ice gloves and booties still developed severe Level 3 symptoms and patients being treated with Hilotherapy did not.
- Conventional cooling methods thaw and lose their cooling effect, meaning they have to be changed continuously throughout the treatment process.
- These methods also involve the risk of skin burns due to the nature of the extremely cold temperatures used.
- > The use of Hilotherapy was found to be comfortable for patients and convenient for nursing staff.



Conclusion

The symptoms of HFS and polyneuropathy could be greatly reduced or prevented by using Hilotherapy to cool patients' hands and feet during chemotherapy. For best results, Hilotherapy should be used as soon as a patient commences their chemotherapy treatment.