Prospective, randomized trial on efficacy and safety of cryotherapy and cryocompression therapy as prevention of chemotherapy-induced peripheral neuropathy

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#1079

Background:

- Due to improved overall survival for gynecological cancers, impact on patients' Quality of Life (QoL) and longtime effects of therapy gain importance in treatment planning
- Chemotherapy-induced peripheral neuropathy (CIPN) is one of the most detrimental side effects of taxane-based chemotherapy (CT)
- According to recent literature, up to 87% of patients receiving taxane-based CT suffer from CIPN grade two or above
- Symptoms include sensory and motor deficits, which often lead to dose reduction or discontinuation of the taxane-based CT
- Some studies with small patient populations indicated that adding compression to cryotherapy could increase its preventative effect regarding CIPN
- The aim of our randomized study was to evaluate whether compression added to cryotherapy could improve the efficacy in the prevention of CIPN

Methods:

- This prospective randomized study was conducted between May 2020 and January 2023 at the Department of Obstetrics and Gynecology, Medical University of Innsbruck
- Patients who met the inclusion criteria were randomized 1:1 to either receive cryotherapy or cryocompression therapy on their upper extremity during CT
- We performed a wide range of tests and assessments during their course of treatment and follow-up that lasted up to 9 months
- Tests included temperature measurements, two QoL questionnaires and neurological tests like nerve conduction velocity and sensory tests

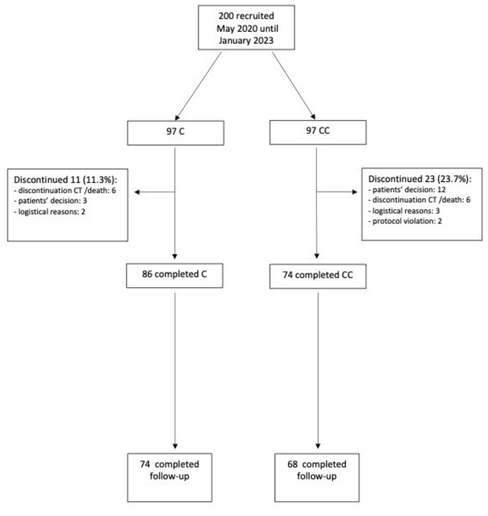

Figure 1. Consort diagram.

C = cryotherapy; CC = cryocompression.

The trial did not demonstrate superiority of cryocompression over cryotherapy.

Compared to recent literature participants treated with cryotherapy as well as cryocompression therapy developed substantially less CIPN.

Our study suggests that cryotherapy as well as cryocompression therapy is a safe way to cool patients' extremities to prevent CIPN.

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Results:

- A total of 200 participants were recruited for this study
- At their end of CT assessment 13.7% of participants in the cryotherapy group (C) had grade two polyneuropathy. In comparison, in the cryocompression therapy group (CC) there were 17.2% with grade two polyneuropathy. Six to nine months after CT, in the C 14.7% of participants presented with grade two polyneuropathy, compared to 21.8% in the CC
- There was no significant difference between the two groups regarding occurrence of grade two or above polyneuropathy
- In the C 11.3% of participants discontinued therapy and in the CC 23.7% did so
- No participants discontinued the study due to adverse events caused by cryotherapy or cryocompression therapy. In both groups a significant reduction of temperature was observed
- With regards to the neurological tests and QoL questionnaires, there was no significant difference between the two groups

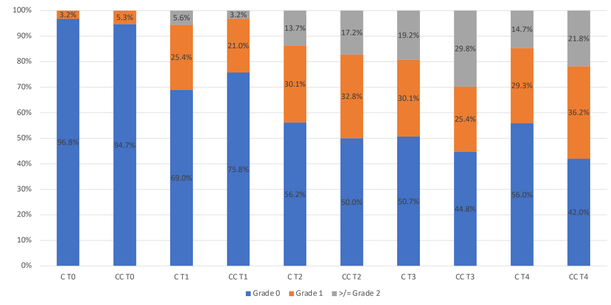

Figure 2. CTCAE CIPN during chemotherapy and follow up.
C= cryotherapy; CC= cryocompression; T0= start of CT; T1= midway CT; T2= end of CT; T3= 3 months after CT; T4= 6-9 months after CT.

Future Directions for research:

- Larger multicenter studies are necessary to assess the efficacy of cryotherapy/ cryocompression and the impact of factors like cumulative dose, duration of exposure, scheduling and combination of different agents on the occurrence of CIPN
- More precise and even more important standardized scores to evaluate CIPN are needed to enable clinicians to realistically and distinctly evaluate a patient's CIPN
- This is necessary for explicit benefit-harm trade-offs to inform treatment decision-making (especially regarding the discontinuation of CT or dose reductions) as well as to make research results comparable