

# Abstract from Clinical Trials

## Modulated Electro-Hyperthermia as Palliative Treatment for Pancreatic Cancer: A Retrospective Observational Study on 106 Patients

**This is a retrospective observational multicentric study on the efficacy and safety of mEHT for advanced pancreatic cancer therapy. Patients were included in the study if they had diagnosis of advanced stage (III-IV) pancreatic adenocarcinoma**

The selected upper abdominal quadrant was treated for a median of 3 sessions per week, for a total of 8 weeks, increasing the power applied and length of each session.

The median overall survival of the mEHT group was 18.0 months (range = 1.5-68.0 months) and 10.9 months (range = 0.4-55.4 months) for the non-mEHT group.

Non-resected patients had a significant higher OS in the mEHT group than in the no-mEHT group with a median OS of 17.0 months versus 9 months of the no-mEHT group (P = .00094).

The tumor response analysis showed a response rate (RR = PR + SD) of 94.1% for the mEHT group and 36.1% for the non-mEHT group.

A recent review on hyperthermia efficacy in pancreatic cancer therapy reported the results of 14 studies including a total of 395 patients. This article reported an overall RR of 43.9% for hyperthermia and 35.3% for the control group.

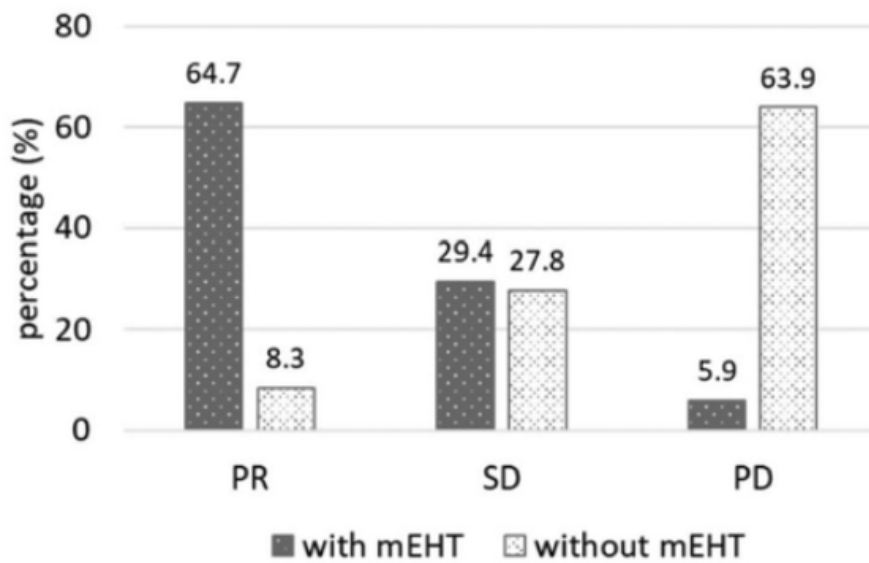


Fig 1. Tumor response at 3 months. PR, partial response; SD, stable disease; PD, progressive disease; mEHT, modulated electro-hyperthermia.

A total of 499 mEHT sessions were delivered in this study, resulting in a limited number of adverse events (20/499 4%) correlated to mEHT. These adverse events (pain, burns, or discomfort) had a low intensity (G1-G2) and short duration.

The outcomes from mEHT treatments are comparable to other hyperthermia methods, with fewer adverse events, lower costs and improved safety.

### The clinical benefit of hyperthermia in pancreatic cancer: a systematic review

In a review of 14 studies and 395 patients by van der Horst et al (2019), 248 patients were treated with hyperthermia. Prior treatments included: resection (10%), chemotherapy (23%), chemoradiotherapy (1%), and 66% of patients did not receive prior treatment.

Hyperthermia was combined with radiotherapy for 17 patients (7%, two studies) with chemoradiotherapy for 82 patients (33%, four studies) and with chemotherapy

## Response Rates

For the three studies that included a control group,[3,4,8] and reported local response, the response rate for 41 patients treated with HT was 43.9% (1 CR, 17 PR), compared with 35.3% (18 PR) in the 51 control patients.

For the six studies with a control group, reporting survival, the weighted estimate of the population median overall survival was 11.7 months for the HT patients (median OS range 6-18.6

months), compared with 5.6 months for the control patients (4-11 months). All six studies with control patients showed a longer median overall survival with HT treatment than without.

These results suggest that HT, when added to chemotherapy and/or radiotherapy, may positively affect response and overall survival for patients with pancreatic cancer.

Please note that treatment options for this unfortunate diagnosis are limited and adjunctive treatments proven to improve quality of life and treatment efficacy must be considered.

In the South African setting, mEHT was proven successful in a Phase 3 clinical trial for an unrelated tumor type, Cervical Cancer, using the EHY2000 device in Gauteng. The number of patients who were disease free at 3 years was 32% more in the hyperthermia group than in the chemoradiation group alone, more than double the amount of disease free patients after 3 years. Level 1 evidence. (C Mienaar, et al. 2022). Preliminary data suggests a >30% increase in 5 year survival when mEHT is combined with standard CRT for Cervical Ca, and which would result in PMB cover.

Patients reported an improved quality of life in the hyperthermia group, and with increased compliance to treatment verse the patients receiving only chemoradiation. Hyperthermia treatment revealed no increased toxicity whilst improving outcomes and enhancing the system anti-cancer immune response (abscopal effect).

Oncologic Hyperthermia has been included into the ESMO and NCCN guidelines for certain cancers.

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