Gastrointestinal Cancer Series Treated with Modulated Electro-Hyperthermia (mEHT) -- a single center experience

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Background
mEHT is a relatively new kind of hyperthermia in oncology. It is a further development of the conventional heating methods.

Aim
Our objective in this presentation is to summarize our knowledge about the utilization of mEHT therapy from the practical perspective in gastrointestinal (GI) cancers and summarize our experience in our GI cancer patients treated with mEHT.

Methods
Thirty-four patients with advanced GI cancer (23 pancreatic, 7 colorectal, 3 hepato-biliary, 1 esophageus, 1 neuroendocrine carcinoma) were treated in a 20-month period at the Cancer Center of Semmelweis University, with the instruments EHY-2000 and EHY-2030 (Oncotherm Ltd., Budaörs, Hungary). One patient also developed breast cancer, and one patient (with esophageal cancer) only attended one session, thus, these were omitted from further analysis.

Results
All patients had inoperable and metastatic disease. The most common metastatic sites were lymph nodes (15), liver (12), peritoneum (8), lung (4), bone (1) and the kidney (1). The average time in treatment was 32.8 weeks (range: 1.0-95.0). Various chemotherapeutic protocols were applied, mostly gemcitabine alone or in combination and FOLFIRINOX containing regimina, but also platinum, tegafur, mitomycin C were administered. A two-week break in therapy was necessary in seventeen cases due to fever (8) and local discomfort or pain (6), pneumonia (2), and intolerance (1). Fifteen patients are still under treatment: 11 pancreas, 2 hepatic, 1 neuroendocrine, 1 rectal cancer patient. Those, who finished treatment were mostly due to progression with fluid formation in the cavities or thromboembolism.

Conclusion
Complementary mEHT treatment of GI cancer patients is feasible and easy to administer. Most durable responses were seen in oligometastatic pancreatic cancers. Prognostic factors were not apparent based on analysis of clinicopathological properties.

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Introduction

mEHT is a relatively new kind of hyperthermia in oncology. It is a further development of the conventional heating methods. It has shown improved local control and prolonged survival in advanced pelvic cancers and selected regions in the body, e.g. brain tumors, pancreatic carcinomas. Here we analyzed our cases from the gastrointestinal system.

Patients and methods

Thirty-four patients with gastrointestinal cancer (23 pancreatic, 7 colorectal, 3 hepato-biliary, 1 esophageal and 1 neuroendocrine carcinoma) were treated in a 20-month period at the Cancer Center of Semmelweis University, with the instruments EHY-2000 and EHY-2030 (Oncothermia Ltd., Budaörs, Hungary).

One patient also developed breast cancer, and one patient (with esophageal cancer) only attended one session, thus, these were omitted from further analysis. All cases were locally advanced or metastatic at time of presentation and recruitment into our pilot study. The inclusion criteria was declared by a tumor board in all cases, and the patients then underwent mEHT therapy twice or three times per week until further progression or discontinuation of treatment.

Results

All patients had inoperable and metastatic disease. The most common metastatic sites were lymph nodes (15), liver (12), peritoneum (8), lung (4), bone (1) and the kidney (1).

The average time in treatment was 32.8 weeks (range: 1.0-95.0). Various chemotherapeutic protocols were applied, mostly gemcitabine alone or in combination and FOLFIRINOX containing regimina, but also platinum, tegafur, mitomycin C were administered.

A two-week break in therapy was necessary in seventeen cases due to fever (8) and local discomfort or pain (6), pneumonia (2), and intolerance (1). Fifteen patients are still under treatment: 11 pancreas, 2 hepatic, 1 neuroendocrine, 1 rectal cancer patient. Those, who finished treatment were mostly due to progression with fluid formation in the cavities or thromboembolism.

Discussion and future directions

The treatment of locally advanced pancreatic cancer is currently investigated in the HEAT trial (NCT01077427): gemcitabine+cisplatin+regional hyperthermia, comparator arm gemcitabine+capetabine but the outcomes are not yet available. Another study in pancreatic cancer is the HEATPAC study (NCT02439593), a phase II randomized study of concurrent thermochem radiotherapy versus chemoradiotherapy alone. Both studies recruiting patients suffering from locally advanced cancer.

The German Study II, a retrospective study, included 25 patients with locally advanced or metastatic adenocarcinoma of the pancreas. All patients received gemcitabine-based standard chemotherapy combined with a loco-regional hyperthermia of 1 h duration twice a week. The median overall survival showed 12.2 months (versus expected 6–7 months). Cancer control (CR+PR+SD) was 65 % and 1-year survival was 51 % (versus expected 25 %). Negative side effects due to adding hyperthermia have not been found. Though not systematically documented, pain reduction in some patients was observed.

We initiate a single center, open label, randomized phase 2/3 clinical study (MEHYPOP at clinicaltrials.gov) based on our pilot and observational studies in pancreatic carcinoma. The study protocol was developed and audited, IRB approval is in place.

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