Modulated electro-hyperthermia in Pancreatic Cancer Patients: initial experience and clinicopathologic evaluation

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Modulated Electro-Hyperthermia in Pancreatic Cancer Patients: initial experience and clinicopathologic evaluation

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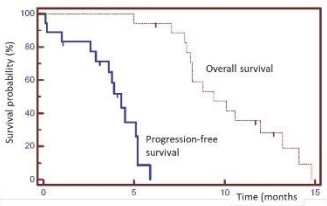
Intoduction

Modulated electro-hyperthermia (mEHY) as a complementary treatment has gained support in the treatment of cancer patients as supplementary method besides the standard treatment or for those who exhausted conventional treatment. Pancreatic cancer is one of the neoplastic diseases with poor outcome, and we aimed at reviewing available evidence and evaluating our own cohort receiving mEHY treatment.

Metastatic Pancreas; Phase II study (n=26)

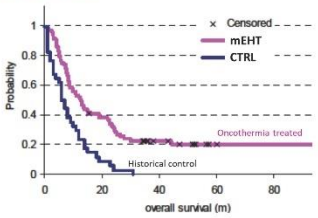
Second-line chemotherapy in combination with Oncothermia for patients with refractory metastatic (progressive in liver) pancreatic cancer.
The treatment protocol was intravenous chemotherapy (gemcitabine, 1000 mg/m2 IV and oxaliplatin 100 mg/m2 [GEMOX]) on day one combined with mEHT (days1, 3 and 5); and the protocol repeated by every two weeks.

Volovat et al.; (2014); *Romanian Reports in Physics, 66:165–17*



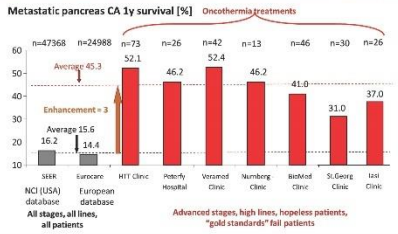
Phase II study of advanced, metastatic pancreas cancer (n=99) Dani A, et al. (2006) Forum Hyperthermie 1:13–2

Phase II clinical trial, double center (A & B), single-arm in comparison to historical control from the same hospital, same doctors. 40+% of patients had multiple metastases. The trial includes a cohort of heavily pretreated patients (3+ lines), and due to the refractory or another fail of the conventional therapies oncothermia was applied as monotherapy. The first and subsequent year survivals were: 1st:50.5%, 2nd: 27.3%, 3rd:15.2%, 4th:8.1%, 5th:3%. These values are significantly higher than the values from the large databases (SEER and Eurocare).



1st year survival comparison of pancreas studies in different hospitals using oncothermia protocol

The achieved results of 1st year survival is compared to the same time achieved results in USA and EU, according to the relevant databases; SEER and EuroCare. The weighted average is nearly 3 times higher for oncothermia treated patients than the general expectation. This result is despite the fact, that the general statistics contain all the patients, while patients treated with oncothermia are all in high-line treatment advance stages, where the "gold standards" fail.



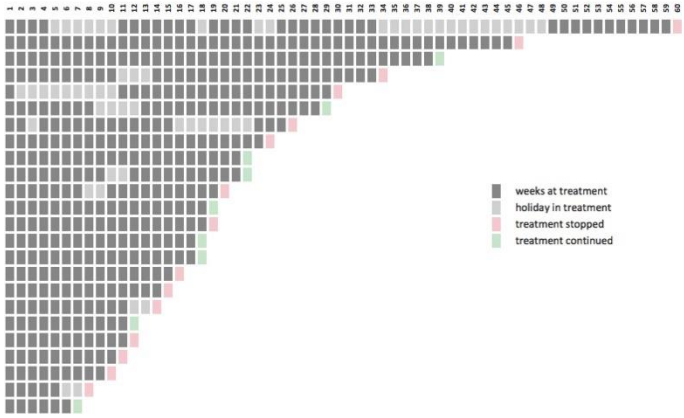
Patients and methods

Twenty-four eligible patients were recruited based on clinical rounds decision since SEP-2, 2016. Primary tumors of patients originated from the pancreas (head and body). Surgical procedure due to advanced stage was not feasible. EHY-2000 and EHY-2030 instrument (Oncothermia Ltd., Budaörs, Hungary) were used and initial power of 50 W was applied. The increments were set to 5-10 W in 5 minute steps until 150 W was reached.

Results

The patients' data was evaluated on APR-01, 2018. The patients attended mEHY treatment in a range of 7 to 86 occasions (1-14 months). ECOG status: 0-2. Average number of metastases of the tumors were two: 12 lymph node, 8 liver, 7 peritoneal, 1 kidney and 1 pulmonary metastasis was detected. Various chemotherapeutic protocols were administered to the patients as per guideline recommendations, most often Gemcitabine, platinum and 5-FU based regimens. Average treatment time of each mEHY occasion was 59.5 minutes. From the initial power to the final power on average 50W power increment was reached. Nine patients (42,8%) had to temporarly hold therapy due to neutropenic fever (5), pain (2), rush (1), pneumonia (1) and thrombophlebitis (1). Fourteen of the patients eventually stopped or finished the treatment as depicted in the chart below. CEA and CA19-9 levels in pancreatic cancer patients are not predictive for response to mEHY therapy.

	gender/age	session	weeks	adjuvant t/x	reason for stopping/break
1					
2	F68	85	60	GEM/B, Folfirinox	fever
3	M68	86	46	wek.Gemzar/B	intolerance
4	M71	79	39		
5	M58	82	34	Folfirinox	
6	F63	22	30	Gemzar5FU+LV	neutropenia
7	M71	54	29	weekly CDDP+Gemzar	pneumonia
8	M26	42	26	10x irrad	fever
9	F69	52	24	C0 GEM+CDDP	progression, ileus
10	F67	41	22	GEM+CDDP	
11	M64	39	22	GEM-Tax.	urticaria
12	F57	24	20	Gemzar	intolerance
13	F76	34	19	Tegafur	
14	M72	8	19	GEM+CDDP	pain
15	M63	29	18	GEM+CDDP	
16	F72	33	18	gemzar	
17	M61	51	16	Folfirinox	progression, ascites
18	F62	28	15	Folfirinox	cholangitis, jaundice, ascites
19	M56	30	14	GEM+CDDP	progression, ascites
20	F66	42	12	GEMox, majd GEM mono	
21	M68	16	12	Folfirinox	progression
22	M48	23	11	wek. Gemzar	jaundice, hyperkalaemia
23	F65	12	10	Folfirinox	pain
24	M56	14	8	Folfirinox	pain, ascites
25	F75	15	7	GEM/B	



Conclusion

Twenty-four pancreatic cancer patients were treated at our mEHY therapy unit. Patients with oligometastatic/inoperable tumors are likely the target population of this treatment approach, especially supplementing systemic therapy. CEA and CA19-9 levels in are not predictive for response to mEHY therapy in our cohort. Identification of better biomarkers is warranted.

Acknowledgements

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