

P-01: Giammaria Fiorentini, Carlo Milandri, Patrizia Dentico, Paolo Giordani, Vincenzo Catalano, Feissal Bunkeila (2012) Deep electro-hyperthermia with radiofrequencies combined with thermo-active drugs in patients with liver metastases from colorectal cancer (CRC): A phase II clinical study

**DEEP ELECTRO-HYPERTHERMIA WITH RADIOFREQUENCIES
COMBINED WITH THERMO-ACTIVE DRUGS IN PATIENTS WITH LIVER
METASTASES FROM COLORECTAL CANCER (CRC):
A PHASE II CLINICAL STUDY.**

Giammaria Fiorentini¹, Carlo Milandri², Patrizia Dentico², Paolo Giordani¹,
Vincenzo Catalano¹, Feissal Bunkeila²

¹Dept. of Oncology Azienda Ospedaliera Marche Nord, Pesaro, Italy
²Dept. of Medicine, General Hospital Empoli, Florence, Italy

Purpose

- Increase palliation in patients with liver metastases from CRC
- Evaluate capacitatively coupled low-frequency 13.56 MHz deep hyperthermia combined with thermo-active drugs

Patients and methods

From April 2006 to February 2010, 60 heavily pretreated patients at advanced stage of CRC with not operable liver metastases have been cured with deep hyperthermia at an applied adsorbed power of 80-150 Watt equivalent to 41°- 47° for 60-75 minutes, 3 times/w for 3 weeks in combination with thermo-active drugs.

Thermo active drugs were:

cisplatin 30 mg/sqm on D 1,8, 15 in the first subset of 28 patients (Group A) then with oxaliplatin 50 mgr/sqm on D 1,8,15 in a second subset of 32 patients (Group B). Hyperthermia was achieved by arrangements of capacitative electrodes with a radiofrequency field of 13.56 Mhz (RF-DHT).



RESULTS OF HYPERTHERMIA AND THERMO- ACTIVE DRUGS (60pts)

	Group A (cisplatin) 28pts	Group B (oxaliplatin) 32 pts	TOTAL 60 pts	%
Partial responses	1	5	6	10%
stabilizations	1	5	6	10%
CEA reductions	4	12	16	27%
Increasing performances	11	19	30	50%
Reduction analgesics	5	15	20	33%
Better Q of L	16	34	50	83%

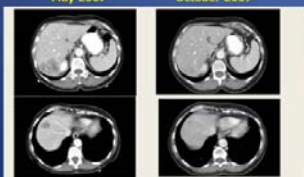
RESULTS OF HYPERTHERMIA AND THERMO- ACTIVE DRUGS (60pts) -TOXICITY

	Group A (cisplatin) 28pts	Group B (oxaliplatin) 32 pts	TOTAL 60 pts	%
Stom G2	3	4	7	12%
Leukopenia G2	1	5	6	10%
Nausea & V. G2	5	4	9	15%
Hemotoxicity G2	4	0	4	7%
Neurotoxicity G2	1	5	6	10%

RESULTS OF HYPERTHERMIA AND THERMO- ACTIVE DRUGS (60pts)

Group A (cisplatin) 28pts	Group B (oxaliplatin) 32 pts	TOTAL 60 pts	%

**Metastases from CRC:
PR lasting 22 weeks
May 2007 October 2007**



MEDIAN SURVIVAL TIME

33 weeks (range 19-45)

MEDIAN DURATION OF RESPONSE

19 weeks (range 9-27)

**Metastases from CRC:
PR lasting 29 weeks
November 2007 March 2008**



Conclusions

Capacitatively coupled low-frequency 13.56 deep-HPT is feasible for chemo-refractory malignant liver involvement from CRC. Significant increase of QoL was shown. 12 pts reported a control of disease. Oxaliplatin showed a more effective thermo-enhancement respect cisplatin in liver metastases from CRC. Based on these results and on ethical reasons we abandoned cisplatin and we are planning a further randomized trial comparing FOLFOX 4 plus hyperthermia versus FOLFOX 4. These interesting results deserve to be confirmed in further clinical studies.