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Preclinical survival study demonstrating safe and effective heating of in-vivo porcine pancreas with novel multi-applicator coil inductive thermal treatment system (TTx)

Pierre Floriano[1], Randall Jones[2], Yong Pang[2], William Riehle[2], Paul Stauffer[3], Kelly Lechtenberg[4], Teresa Schieber[4], Robin Schroeder[4], Charles Anderson[1]

[1]NeoTherma Oncology, Wichita, KS, USA, [2]ScanMed, Omaha, NE, USA, [3]Thomas Jefferson University, Philadelphia, PA, USA, [4]Midwestern Veterinary Services, Inc., Oakland, NE, USA

Background

Pancreatic cancer patients are faced with dismal odds and little improvement in survival and quality of life using conventional therapies. Thermal treatment has been shown in clinical trials to increase the effectiveness of radiation and chemotherapy in an array of tumors. But effective therapeutic hyperthermia (HT) of deep tissues has proven difficult to achieve safely. A novel radio-frequency (RF) inductively coupled TTx was evaluated in a pre-clinical pilot study for its ability to non-invasively, safely heat the pancreas of Yucatan mini-pigs (YMP) to a target range of 39.5°C-43°C. Surgically implanted thermal probes were used to monitor treatment and blood was drawn for standard liver, kidney, CBC and chemistry panels to assess pig health and organ damage.

Methods

Four healthy YMP (~53kg each) were anesthetized for probe placement and heat treatment. RFHT treatment was performed in three animals while one served as a sham control. Probes were placed on the skin and in subcutaneous (SQ) tissue, between right and left medial liver lobes, between pancreas and duodenum, at the periphery of the right kidney and in the rectum. The RFHT procedure consisted of a ramp-up period at high power followed by 60 minute 'hold' time at lower power once the deep tissue target temperature was achieved. The procedure was repeated four times with >48 hours between surgeries to allow recovery. Blood was collected before, after and 24hrs post-treatment and 3-lead ECGs were taken every 15 min. Three days after the final thermal treatment, the YMP were euthanized, necropsied and histopathologically examined.

Results

The system produced a rapid temperature ramp in all three heated pigs, achieving peri-pancreas temperatures of 39.5°C as fast as 7 min, and 41°C in 21 min, though variability was seen in heating rate and baseline organ temperatures between animals. The pancreas target temperature was safely maintained for the desired 60 min during treatments with skin and SQ tissues kept below the specified limit (<44°C). No organ damage was indicated by blood work, necropsy or histology results.

Conclusions

In this YMP model, rapid, controlled and safe deep tissue heating was demonstrated with cool surface temperatures using a novel air-coupled multi-applicator coil inductive TTx. Based on these successful results, the sponsor is integrating the TTx with magnetic resonance imaging to provide real-time non-invasive thermal monitoring to be combined with advanced treatment planning. These efforts will culminate with initiation of a first-in-human feasibility study in pancreatic cancer patients in 2017.