Background: Background: electroporation, an effective drug delivery system, enhances the uptake of chemotherapeutic agents by means of short electrical fields which open transient pores on the cell membrane. Electrochemotherapy (ECT) has proven to be an effective local therapy for patients with superficial (i.e., cutaneous and subcutaneous), small-size metastases. The development of new equipments (i.e., dedicated electrodes and pulse generators) could allow for the electroporation of more challenging tumors. The aim of this study was to assess the feasibility and safety of ECT performed by means of new, 20-cm long, freely-implantable needle electrodes. Further outcome measures were tumor response, response duration and toxicity. This preliminary report is based on the outcome of the first 24 patients (out of the 38 planned). Methods: a phase I/II study enrolling patients with deep (max 20 cm) and / or large (max 6 cm) unresectable soft tissue metastases which were unresponsive to chemotherapy or radiation. The needle electrodes were inserted percutaneously under US or CT guidance. Their number and disposition was chosen according to a pre-treatment planning based on radiological imaging. Chemotherapy consisted of a bleomycin bolus, followed by the application of electric voltages according to the European Standard Operative Procedures of Electrochemotherapy (ESOPE). Results: out of 24 patients, tumor histotypes were as follows: melanoma, n=10; soft tissue sarcomas, n=10, others, n=4. The electric pulses were successfully applied to all patients, the median time of the procedure being 35 min (range, 20-75). No serious adverse event were reported during hospital stay, which lasted on average 1 day (range, 1-3). Soft tissue toxicity was mild and all patients were followed on an outpatient basis. Among the melanoma patients, local response rate was 100% (complete, 40%), in patients with soft tissue sarcomas local response rate was 90% (complete, 30%). The remaining 4 patients achieved a partial response. Overall, the median local progression-free survival was 13.1 months (range, 3-24). Conclusions: thanks to recent technological advances (i.e., variable geometry electric pulse generators and long needle electrodes) ECT may be successfully applied also to deep-seated and large soft tissue tumors.

Trial design: Phase I/II study

Disclosure: All authors have declared no conflicts of interest.