Category II — Clinical Care, Treatments and Processing
B. Breast Surgery
2. New Approaches

Wide-Field Focused Microwave Thermotherapy in Combination with Neoadjuvant Anthracycline-Based Chemotherapy to Increase Local Response for Improved Breast Conservation Potential: Updated Phase III Clinical Trial Progress Report

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Objectives: Breast conservation is a challenge for patients with large tumors, and may require the addition of neoadjuvant chemotherapy to downsize tumors and convert patients from mastectomy to a lumpectomy. Thermotherapy enhances anthracycline chemotherapy commonly used in neoadjuvant therapy along with other patient-specific chemotherapy. Microwaves can provide selective heating of high-water, high-ion content breast carcinomas. Wide-field focused microwave thermotherapy is an approach that has been used in clinical studies to treat invasive breast carcinoma in the intact breast [Dooley WC, Vargas HI, Fenn AJ, Tomaselli MB, Harness JK. Focused microwave thermotherapy for preoperative treatment of invasive breast cancer: a review of clinical studies, Ann Surg Oncol, 2010;V17(4):1076-1093]. In a small randomized study, two treatments of focused microwave thermotherapy demonstrated the ability to provide a statistically significant increase in median ultrasound-measured tumor volume reduction for T2, T3 large invasive breast cancer tumors when used in combination with neoadjuvant AC (Doxorubicin, Cyclophosphamide) chemotherapy compared to chemotherapy alone (tumor volume reduction 88.4% n=14 vs. 58.8% n=10, p=0.048). A Phase III multicenter randomized clinical study of preoperative focused microwave thermotherapy in combination with preoperative chemotherapy in the treatment large breast cancers has been designed to confirm the above findings.

Methods: Patients with T2, T3 invasive breast cancer, 3.5 cm or greater, are planned to be treated with focused microwave energy using opposing applicators with the breast compressed in the prone position (Microfocus APA-1000 Breast Thermotherapy System, Medifocus, Inc.). To focus the microwaves and monitor the tumor temperature, a single catheter with feedback sensors is placed within the tumor under ultrasound guidance. This study will be a 1:1 randomized study of 238 breast cancer patients who are candidates for mastectomy and are not candidates for lumpectomy at enrollment. The study will compare neoadjuvant thermochemotherapy to neoadjuvant chemotherapy alone. The primary study aim is to determine if the addition of thermotherapy to patient-specific chemotherapy increases ultrasound-measured tumor volume reduction (primary end point), with the goal of increasing the option to perform breast conservation (secondary end point). Patients in the new arm will receive three treatments of preoperative focused microwave thermotherapy in combination with standard neoadjuvant anthracycline-based chemotherapy and standard of care. In the control arm, patients will be treated with standard neoadjuvant anthracycline-based chemotherapy and standard of care. Results: Initial patients have been enrolled and treated at University of Oklahoma and VM Medical Center in this Food and Drug Administration Investigational Device Exemption (FDA-IDE) and Health Canada Investigational Testing Authorization (HC-ITA) approved study. The ClinicalTrials.gov identifier for this study is NCT01204801. Conclusion: A Phase III clinical study (USA Principal Investigator: W.C. Dooley; Canada Principal Investigator: J.R. Keyserlingk) of wide-field focused microwave thermotherapy in combination with neoadjuvant anthracycline-based chemotherapy, for breast cancer patients with large invasive breast cancer tumors, is in progress.