An IRB approved, multicenter clinical trial (NCT01478438) was designed to determine the efficacy and outcome of percutaneous laser ablation (PLA) in treatment of invasive ductal carcinoma (IDC). Secondarily, post-ablation MRI was evaluated as an alternative to surgical pathology in predicting residual post-ablation invasive cancer and ductal carcinoma in situ.

Patients with a single focus of biopsy proven IDC measuring ≤20 mm by pre-ablation MRI were treated with image-guided PLA using a 805 nominal nanometer wavelength laser diode source. Thermal ablation was documented with thermal sensors placed at the tumor periphery, measuring predefined temperature levels indicating successful ablation. Patients were evaluated at 4 weeks post-ablation with mammogram, ultrasound and MRI, after which they underwent surgical resection. Cell viability criteria were applied to pathology specimens by evaluation of pre- and post-ablation H&E, CK 8/18, estrogen receptor (ER) and Ki67 staining patterns. Complete tumor ablation was defined pathologically as no residual viable breast cancer cells at the targeted ablation site. Patients were seen in follow up at designated intervals.

Mean laser time was 15.8 minutes.

Complete tumor ablation was confirmed in 85% of patients by both pathology and MRI.

NPV of MRI for IDC < 20mm was 92.2%
NPV of MRI for IDC < 15mm was 97.7%

Percutaneous laser therapy is a possible alternative to traditional breast cancer conservation surgery for treatment of early stage invasive breast cancer. A strong correlation exists between post-ablation MRI findings and pathologic alterations in CK 8/18, Ki67 and ER staining. Clinical trials which evaluate PLA efficacy and outcome in the absence of subsequent surgical resection are necessary to further determine the potential of this breast cancer therapy.

**RESULTS**

Sixty-one patients (mean age 64 years) treated with PLA were reported in this series (June 2012 - May 2015. The mean tumor size was 11.3 mm. The mean laser time was 15.8 minutes. There were no serious adverse events. Complete tumor ablation was confirmed in 51 patients (85.0%) by pathologic analysis. Nine patients (15.0%) were found to have residual invasive cancer by both post-ablation MRI and pathologic analysis. A post-ablation discordance between MRI and pathology was found in evaluation of 8 pts with 4 pts (6.7%) being false positive and 4 pts (6.7%) being false negative. Forty-six of the 47 pts (97.9%) with pre-ablation tumors < 15mm were completely ablated using PLA. Good to excellent patient satisfaction was reported by 56 of 58 patients (96.6%).There have been no PLA associated sequelae.

**CONCLUSIONS**

ID 403876: Phase II Open-Label Trial Investigating Percutaneous Laser Ablation for Treatment of Early Stage Breast Cancer: MRI, Pathology and Outcome Correlations


Principal Investigator: Barbara S. Schwartzberg MD FACS  
Contact Information: scmiba@gmail.com