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Meeting abstract

Intraductal therapy of DCIS with liposomal doxorubicin: a preoperative trial in rural California

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Thirty women with ductal carcinoma-in-situ (DCIS) diagnosed by minimally invasive biopsy techniques are being recruited for an IRB approved study testing the effects of neoadjuvant pegylated liposomal doxorubicin (Doxil) delivered through the affected duct on histology and imaging. Pre-procedure MRI and mammography are obtained on consenting women with a core biopsy demonstrating DCIS. The affected duct is cannulated and a ductogram performed to document both absence of perforation and presence of dye in the diseased duct. 20 mg (10 cc) of Doxil is then instilled into the duct. Patients are observed for one hour, and examined in about 24 hours. They have continuous access to study staff to report symptoms, and periodic contact is made with them to verify their status. Four to six weeks later, just prior to surgery, the mammogram, MRI and CBC are repeated. At operation, ductoscopy is performed and the duct identified for the pathologist. India ink gel is instilled immediately after the tissue is removed in order to identify the treated duct on histology. Three of the thirty patients will be randomized to receive normal saline instead of Doxil in a blinded fashion.

To date, six women have consented to the study. The first was not treated because of technical difficulties with the ductogram. Of the remaining five women two sustained perforated ducts and were not treated; two received the full dose of drug into the correct duct and one had a smaller dose into an adjacent duct. The treatment has been very well-tolerated. One fully treated patient had an inflammatory reaction in the treated area three weeks after Doxil administration. The episode lasted about 24 hours and responded to anti-inflammatory medication. Subsequent histology at the time of lumpectomy surgery 6 weeks later verified the presence of inflammation, squamous metaplasia and fat necrosis.

This study, sponsored by the Dr. Susan Love Research Foundation (DSLRF) and funded by the California Breast Cancer Research Program (CBCRP), is taking place in an isolated, economically-challenged and medically-underserved area. The presence of high-level original research in the local area has been a source of pride to the community as a whole, and the work validates the ideals of the CBCRP and the DSLRF. Support from local clinicians has been substantial, and the work maintains high visibility.

In summary, this research is feasible in a community setting. We are testing the concept of using the ductal system itself as a drug delivery system to affect the natural history of a disease confined to the duct. We are testing our ability to correctly identify the orifice of the affected duct by inspection of the mammogram. The treatment appears to be well-tolerated by the patients, and does not appear to affect the mammographic appearance of the breast despite documented cell death.