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# Peglopraside-Based Ratiometric Fluorescence Imaging Detects Intraoperative Positive Margins in Real-Time

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| | | | | |
|---|---|---|---|---|
| Benign | 2 (20.0) | 2 (28.6) | 0 (0.0) | 1.000 |
| Malignancy | 3 (30.0) | 2 (28.6) | 1 (33.3) | 1.000 |

## 38 – Pegloprastide-Based Ratiometric Fluorescence Imaging Detects Intraoperative Positive Margins in Real-Time

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*Background/Objective*: Positive margins detected after breast conservation surgery can result in the need for a re-excision or completion mastectomy. We hypothesized that pegloprastide combined with a ratiometric fluorescence imaging system would allow surgeons to detect positive margins in real time.

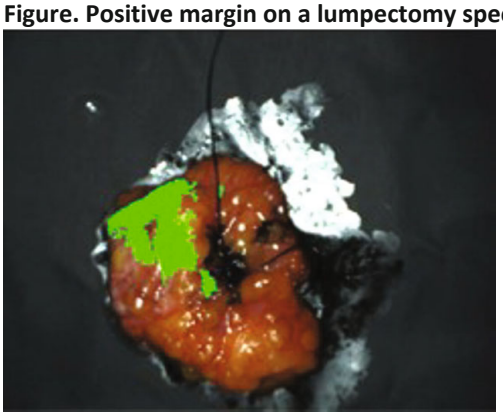
*Methods*: Pegloprastide (AVB-620) was to be administered to patients 3-20 hours before the start of surgery. During the operation, initial primary tumor removal was performed unaided. Following primary resection, a fluorescence imaging system optimized for use with pegloprastide was used to assess the primary specimen and the cavity. Cavity shaves were taken when fluorescence above pre-specified thresholds were noted. Additional cavity shaves for areas negative by imaging were also sampled. Comparisons were made between images and final pathology results to assess the correlation between pegloprastide-mediated imaging and margin status. Pathologic margins were deemed to be positive if invasive cancer showed tumor on ink (0mm) or DCIS was within 2mm of the surface or a positive shave margin was identified. Preplanned subgroup analysis was performed based on dose timing, comparing Day before Surgery (DBS) versus Same Day as Surgery (SDS).

*Results*: Ninety-two patients received pegloprastide. There were no drug-related serious adverse events recorded. The average age was 59.5 (40-81), 85% of patients were ER-positive, and 9% of patients were HER2-positive. Ninety-six percent of patients underwent a lumpectomy. Of the 92 patients, 87 were evaluable and were divided into 2 groups based on the timing of the pegloprastide dose, either DBS (n=47) or SDS (n=40). Overall, the positive margin rate as measured at the end of the primary resection was 46% (40/87). The overall patient level positive margin sensitivity and specificity were 45% and 70% respectively. When measured by dosing subgroup, there was a significant difference (p=0.005) in sensitivity with DBS showing a 65% true positive rate (13/20), compared to 25% (5/20) for SDS group. Beyond that, in the DBS patient group, an additional 10% of patients (2/20) with positive margins, who did not have the positive margin area detected by fluorescence (a false negative), had a close margin (defined as invasive tumor within 2mm of the surface) fluorescently detected, such that 75% (15/20) of margin positive patients actually had a positive fluorescent signal seen. Specificity was 78% in the DBS

group and 60% in the SDS group. Sample level accuracy was 82% for DBS and 79% for SDS. Re-excision rates in the trial were 6%.

*Conclusions*: Pegloprastide is well tolerated. When infused the day before surgery, pegloprastide demonstrates the ability to identify positive margins in at least 65% of patients. Utilization of pegloprastide, particularly when dosed the day before surgery, may aid in allowing surgeons to identify and resolve positive margins in real time in a substantial proportion of patients.

**Figure. Positive margin on a lumpectomy specimen highlighted by pegloprastide-based imaging**



## 40 - Experience with Intraoperative Radiation Therapy in an Urban Cancer Center

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*Background/Objective*: Intra-operative radiation therapy (IORT) is a relatively newer means of delivering radiation (RT) directly to the lumpectomy cavity at the time of surgery and has been shown to be as safe and effective as adjuvant whole breast RT, as published in the TARGIT-A trial. We started enrolling patients on our IORT registry trial in 2018 and aim to report our early results thus far, hypothesizing that they will match those seen in the larger published studies.

*Methods*: We instituted an IORT practice using Intrabeam® low-energy 50kVp x-rays for selected early stage clinically node-negative breast cancer cases in 2018. Patients were enrolled on our institutional registry protocol which allowed for IORT in ER+ patients with grade 1-2 DCIS ≤ 2.5 cm or invasive disease ≤ 3.5 cm in patients ≥ 45 years of age. We report our experience to date herein. Our cohort of patients seen in radiation oncology consultation for possible IORT was reviewed. Demographic information was recorded and analyzed, as was clinical and pathologic information, work-up, subsequent treatment strategies, and outcomes.

*Results*: Between January 2018 and March 2020, 110 patients with clinical Stage 0-I ER+ breast cancer were seen for possible IORT. Ninety-six patients ultimately received IORT to 99 sites. Reasons for not proceeding with IORT were: MRI and biopsy findings of additional lesions (5/14; 36%), patient preference (7/14; 50%), technical issues (1/14; 7%), and surgery pending due to other co-morbid