Outcomes for APBI with Strut-Based Brachytherapy: First 200 Accrued Patients
(5-Year Report)

ASTRO 2014 Annual Meeting
September 14-17, 2014
San Francisco, CA

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PURPOSE/OBJECTIVE(S)

†The SAVI Collaborative Research Group (SCRG), was created to study the long-term outcomes of women receiving accelerated partial breast irradiation (APBI) using strut-based applicators. Five-year outcomes for the first 200 accrued patients in the study (n=200), treated between 11/2006 and 2/2009, are reported for all subjects, as well as stratified by DCIS or invasive histology.

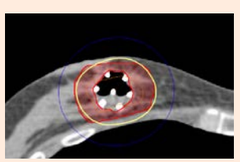
Figure 1 – SAVI applicator sizes 6-1 Mini, 6-1, 8-1, 10-1

MATERIALS/METHODS

Patients for this subset analysis were taken as the initial 200 treated across all participating sites. Median follow-up of this cohort has been updated to 56.9 months since abstract submission. Patients were treated with APBI using the strut-based brachytherapy device with conventional dose and fractionation (3.4 Gy x 10 fx, BID). Treatment planning goals for the planning target volume were a V90≥90%, V150≤50 cc, and V200≤20 cc.

Patients were followed regularly by their radiation oncologists and outcome was graded based on the CTCAE v3.0 (common terminology criteria for adverse events, version 3.0). Recurrence (raw and actuarial) rates were also calculated based on the follow up. Cosmesis was graded using the Harvard Scale.

Figure 2 – SAVI 6-1 device with typical PTV-Eval in red and 100% isodose curve in yellow.



RESULTS

148 patients had invasive disease and 52 had ductal carcinoma in situ. The median age was 62.0 yrs (range 40-85 yrs), with 83% post-menopausal. Median tumor size was 10.5 mm (range 0.0-55 mm) with 88% being estrogen receptor positive. All patients completed APBI as planned with no serious adverse events. All patients met the dosimetric criteria. Late toxicity (grade ≥ 2) rates were low; telangiectasias (1.6%), seroma (3.2%) and fat necrosis (0.5%). Good/excellent cosmesis was seen in >93% of subjects at all times of follow up (6 months to 60 months).

Table 1 – Patient Characteristics

Characteristic	All Patients	Invasive	DCIS
Subjects	200	148	52
Breasts	200	148	52
AGE			
Median (Range) (years)	62 (40,85)	63 (40,84)	58.5 (41,85)
≥60 years N (%)	108 (54%)	84 (56.8%)	24 (46.2%)
≥50-<60 years N (%)	57 (28.5%)	42 (28.4%)	15 (28.8%)
≥40-<50 years N (%)	34 (17%)	21 (14.2%)	13 (25%)
<40 years N (%)	1 (0.5%)	1 (0.7%)	0 (0%)
Menopausal Status N (%)			
Pre-menopausal	25 (13.1%)	16 (11.3%)	9 (18%)
Peri-menopausal	7 (3.7%)	7 (5%)	0 (0%)
Post-menopausal	159 (83.2%)	118 (83.7%)	41 (82%)
Tumor Size (mm)			
Median (Range)	10.5 (0,55)	11.5 (0.7,40)	9 (0,55)
≤ 5	27 (14.2)	13 (9.2)	14 (29.2)
>5 - ≤10	56 (29.5)	45 (31.7)	11 (22.9)
>10 - ≤20	83 (43.7)	67 (47.2)	16 (33.3)
>20	24 (12.6)	17 (12)	7 (14.6)
AJCC Tumor Status N (%)			
Tis	52 (26%)	0 (0%)	52 (100%)
T1A	19 (9.5%)	19 (12.8%)	0 (0%)
T1B	50 (25%)	50 (33.8%)	0 (0%)
T1C	63 (31.5%)	63 (42.6%)	0 (0%)
T2	16 (8%)	16 (10.8%)	0 (0%)
AJCC Nodal Status N (%)			
N0	175 (90.2%)	140 (95.9%)	35 (72.9%)
NX	15 (7.7%)	2 (1.4%)	13 (27.1%)
N(+)	4 (2.1%)	4 (2.7%)	0 (0%)
Margins N (%)			
Negative	184 (97.9%)	135 (97.1%)	49 (100%)
Positive	1 (0.5%)	1 (0.7%)	0 (0%)
Close A (≤ 1mm)	3 (1.6%)	3 (2.2%)	0 (0%)
Close B (>1mm - ≤ 2mm)	0 (0%)	0 (0%)	0 (0%)
ER Status N (%)			
Positive	173 (87.8%)	130 (88.4%)	43 (86%)
Negative	24 (12.2%)	17 (11.6%)	7 (14%)
Last Follow-up (months)- All Breasts (Time since RT Stop)			
N	194	143	51
Median	56.9	55.1	59.1
Mean (SD)	50.7 (20.6)	49.8 (21.4)	53.4 (18.2)
Range	0.3,83.7	0.3,83.5	2.1,83.7

Local control was excellent with a true recurrence/marginal miss rate of 2.5% (n=5) for all patients. Local control for invasive and DCIS subgroups was 2.7% (n=4) and 1.9% (n=1), respectively. The IBTR recurrence rate was 3.0% (n=6) for all patients. IBTR for invasive and DCIS subgroups was 3.4% (n=5) and 1.9% (n=1), respectively. The contralateral recurrence rate was 2.5% (n=5) for all patients. The contralateral recurrence rate for invasive and DCIS subgroups was 2% (n=3), and 3.9% (n=2), respectively.

Note: Between abstract submission and and poster presentation, some patients had additional follow-up with 2 additional recurrences recorded.

Table 2 – Recurrence Rates

Raw Rates 57 Mos. Med FU	All	Invasive	DCIS
Subjects	200	148	52
Breasts	200	148	52
TR/MM (N/%)	5 (2.50%)	4 (2.70%)	1 (1.92%)
IBTR (N/%)	6 (3.00%)	5 (3.38%)	1 (1.92%)
Contralateral (N/%)	5 (2.50%)	3 (2.03%)	2 (3.85%)

CONCLUSIONS

For these initially treated 200 patients with 5-year results, strut-based brachytherapy appears to be a well-tolerated, effective treatment with low rates of toxicities. Local control rates are as good as those for other brachytherapy-based APBI techniques. With APBI an acceptable treatment for many women with early-stage breast cancer, strut-based brachytherapy continues to be versatile, safe and effective.

ACKNOWLEDGEMENTS

†The SAVI Collaborative Research Group includes investigators from the following institutions:

Arizona Breast Cancer Specialists, Phoenix, AZ; Center for Breast Care, Inc., Burbank, CA; The Christ Hospital Cancer Center, Cincinnati, OH; Christiana Care Health System, Newark, DE; Drexel University College of Medicine, Philadelphia, PA; Northwest Community Hospital, Arlington Heights, IL; Kerri Perry, MD; Denton, TX; Schiffler Cancer Center, Wheeling, WV; South Florida Radiation Oncology, Boynton Beach, FL; Texas Oncology, Denton, TX; 21st Century Oncology, Ft. Myers, FL; and 21st Century Translational Research Consortium (TRC), Scottsdale, AZ; Radiation Medicine and Applied Sciences, University of California, San Diego, La Jolla, CA; Virginia Hospital Center, Arlington, VA.