Outcomes For APBI With Strut-based Brachytherapy: 596 Patients With 39-month Median Follow-up

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PURPOSE/OBJECTIVE(S)

†The SAVI Collaborative Research Group (SCRG) created a retrospective database to study the long-term outcomes of women receiving accelerated partial breast irradiation (APBI) using strut-based applicators.

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

MATERIALS/METHODS

Patients for this analysis were required to have reported dosimetry data and follow up of at least 12 months post-APBI. 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 oncologist and outcomes were 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.

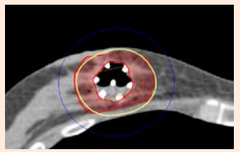

Figure 2 – SAVI 6-1 device with typical PTV-Eval in red and 100% isodose curve in yellow.

RESULTS

596 total patients were included in this analysis (69% invasive histology). The median age was 63.0 yrs (range 40-88 yrs), with 88% post-menopausal. Median tumor size was 11.0 mm (range 0.0-60 mm) with 89% being estrogen receptor positive. Hormone therapy was administered to 63.7% and 20.2% received chemotherapy. 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 (1.0%), seroma (3.0%) and fat necrosis (0.8%). Good/excellent cosmesis was seen in >94% of subjects at all times of follow up (6 months to 60 months).

Table 1 – Patient Characteristics

Characteristic	≥1 Yr F/U All	≥1 Yr F/U Invasive	≥1 Yr F/U DCIS
Subjects	596	414	175
Breasts	598	415	176
AGE			
Median (Range) (years)	63 (40,88)	64 (40,88)	61 (41,85)
≥60 years N (%)	355 (59.7%)	262 (63.4%)	90 (51.4%)
≥50-<60 years N (%)	160 (26.9%)	98 (23.7%)	59 (33.7%)
≥40-<50 years N (%)	78 (13.1%)	51 (12.3%)	26 (14.9%)
<40 years N (%)	2 (0.3%)	2 (0.5%)	0 (0%)
Menopausal Status N (%)			
Pre-menopausal	59 (10.3%)	39 (9.8%)	19 (11.6%)
Peri-menopausal	10 (1.8%)	9 (2.3%)	1 (0.6%)
Post-menopausal	502 (87.9%)	352 (88%)	144 (87.8%)
Tumor Size (mm)			
Median (Range)	11 (0,60)	12 (0.4,58)	8 (0,60)
≤ 5	76 (14.2)	38 (9.7)	36 (25.9)
>5 - ≤10	140 (26.2)	97 (24.9)	42 (30.2)
>10 - ≤20	253 (47.4)	206 (52.8)	45 (32.4)
>20	65 (12.2)	49 (12.6)	16 (11.5)
AJCC Tumor Status N (%)			
Tis	164 (28.7%)	0 (0%)	163 (100%)
T1A	57 (10%)	54 (13.4%)	0 (0%)
T1B	126 (22%)	124 (30.8%)	0 (0%)
T1C	180 (31.5%)	179 (44.5%)	0 (0%)
T2	45 (7.9%)	45 (11.2%)	0 (0%)
AJCC Nodal Status N (%)			
N0	502 (91.6%)	374 (96.1%)	123 (80.4%)
NX	38 (6.9%)	7 (1.8%)	30 (19.6%)
N(+)	8 (1.5%)	8 (2.1%)	0 (0%)
Margins N (%)			
Negative	498 (94%)	344 (93.5%)	149 (94.9%)
Positive	5 (0.9%)	4 (1.1%)	1 (0.6%)
Close A (≤ 1mm)	12 (2.3%)	12 (3.3%)	0 (0%)
Close B (>1mm - ≤ 2mm)	15 (2.8%)	8 (2.2%)	7 (4.5%)
ER Status N (%)			
Positive	502 (88.8%)	353 (89.1%)	142 (87.7%)
Negative	63 (11.2%)	43 (10.9%)	20 (12.3%)
Last Follow-up (months)- All Breasts (Time since RT Stop)			
N	597	414	176
Median	38.8	39.3	38.1
Mean (SD)	38.6 (15)	39.2 (15)	37.6 (15)
Range	2.4,79.8	2.4,79.8	9.2,73.4

Local control† was excellent with a true recurrence/marginal miss rates of 1.3% (n=8), 0.96% (n=4) and 2.3% (n=4) for all subjects, invasive and DCIS subgroups, respectively. The ipsilateral/elsewhere recurrence rate was 1.0% (n=6), 0.96% (n=4) and 1.1% (n=2) for all subjects, invasive and DCIS subgroups, respectively. The 3-yr actuarial rates for TR/MM were 1.3%, 0.85% and 2.4% for all subjects, invasive and DCIS subgroups, respectively.

†) Breast recurrence only. Also note there was a single (invasive) subject with simultaneous breast/regional failures that is not included in the ipsilateral/elsewhere numbers for all subjects and invasive groups. This was not a TR/MM location.

Table 2 – Recurrence Rates

Raw Rates 39 Mos. med FU	All	Invasive	DCIS
Subjects	596	414	175
Breasts	598	415	176
IBTR (N/%)	17 (2.84%)	10 (2.41%)	7 (3.98%)
TR/MM (N/%)	8 (1.34%)	4 (0.96%)	4 (2.27%)
Ipsilateral/Elsewhere (N/%)	6 (1.00%)	4 (0.96%)	2 (1.14%)

CONCLUSIONS

For this large (n=596) population of patients, with 39 months of median follow up, strut-based brachytherapy appears to be a well-tolerated and effective treatment. Local control in this large population is similar to that seen with other brachytherapy techniques for APBI at this duration of follow up.

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†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.