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Update on DCIS Outcomes from the American Society of Breast Surgeons Accelerated Partial Breast Irradiation Registry Trial

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Abstract

Background—Since the initial reports on use of MammoSite accelerated partial breast irradiation (APBI) for treatment of ductal carcinoma in situ (DCIS), additional follow-up data were collected. We hypothesized that APBI delivered via MammoSite would continue to be well tolerated, associated with a good cosmetic outcome, and carry a low risk for recurrence in patients with DCIS.

Materials and Methods—From 2002–2004, 194 patients with DCIS were enrolled in a registry trial to assess the MammoSite. Follow-up data were available for all 194 patients. Median follow-up was 54.4 months; 63 patients had at least 5 years of follow-up. Data obtained included patient-, tumor-, and treatment-related factors, and recurrence incidence.

Results—Of the 194 patients, 87 (45%) had the MammoSite placed at lumpectomy; 107 patients (55%) had the device placed postlumpectomy. In the first year of followup, 16 patients developed a breast infection, though the method of device placement was not associated with infection risk. Also, 46 patients developed a seroma that was associated with applicator placement at the time of lumpectomy ($P = 0.001$). For patients with at least 5 years of follow-up, 92% had favorable cosmetic results. There were 6 patients (3.1%) who had an ipsilateral breast recurrence, with 1 (0.5%) experiencing recurrence in the breast and axilla, for a 5-year actuarial local recurrence rate of 3.39%.

Conclusions—During an extended follow-up period, APBI delivered via MammoSite continued to be well tolerated for patients with DCIS. Use of this device may make lumpectomy possible for patients who would otherwise choose mastectomy because of barriers associated with standard radiation therapy.

Although optimal treatment for ductal carcinoma in situ (DCIS) continues to be debated, general treatment recommendations include lumpectomy followed by radiation therapy for patients eligible for breast conservation, and mastectomy for patients who are not candidates for local therapy.[1] Importantly, the mortality rate associated with DCIS is very low (1%–2%) and is related to the noninvasive nature of this disease.2 Thus, the primary concern

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regarding the initial treatment of DCIS is avoidance of local failure. For those patients treated with lumpectomy and subsequent radiation, a local failure typically leads to a recommendation for mastectomy, as reirradiation is generally associated with an unacceptably high level of toxicity targeted to the breast tissue and neighboring organs.3

The beneficial impact of radiation therapy in conjunction with lumpectomy for treatment of DCIS was established by 3 prospective randomized trials, NSABP B-17, EORTC 10853, and the UK Coordinating Committee on Cancer Research trial.[4] These trials, reported in 1993 and 2000, demonstrated a significant reduction (>40%) in local recurrence facilitated by use of radiation therapy inthe setting of breast conservation. The more recent SweDCIS trial confirmed these results.[5] At the same time, while radiation therapy reduces the local recurrence rate, a corresponding survival benefit has not been shown.6 This finding has led to questions regarding the absolute benefit of radiating all patients with DCIS.

Whole-breast radiation has been historically well tolerated, though it does pose an inherent risk of morbidity. Radiation-induced skin changes include fibrosis, discoloration, and telangiectasas. Though rare, severe effects include organ damage to the heart and lungs.[7] The risk of radiation-induced secondary malignancy, including angiosarcoma, is low.[8,9] These radiation-induced risks have been examined in conjunction with the risk of breast cancer recurrence after surgical excision of DCIS with lumpectomy alone. As stated, when lumpectomy is combined with radiation therapy, the recurrence risk is significantly reduced. Thus, the risk–benefit ratio when comparing lumpectomy alone to lumpectomy with radiation has generally favored use of whole-breast radiation.6 At the same time, the majority of local recurrences after breast-conserving therapy occur in the vicinity of the tumor bed.[10,11] The notion that radiation therapy could be tailored to treat only the area of the breast at greatest risk for recurrence led to development of accelerated partial breast irradiation (APBI). Use of APBI may provide a more appropriate balance between treatment-associated benefit and risk of radiation exposure. In addition to limiting radiation exposure, APBI also shortens the duration of therapy from 6 weeks typically required for whole-breast radiation to approximately 6 days.

In 2005, the National Surgical Adjuvant Breast and Bowel Project (NSABP) and the Radiation Therapy Oncology Group (RTOG) opened the randomized B-39 trial to examine the efficacy of whole-breast radiation therapy versus APBI. Methods of APBI included in the trial were MammoSite balloon-based brachytherapy, 3D conformal external-beam radiotherapy, and multicatheter brachytherapy. While results and analysis of this trial will not be available for several years, the American Society for Radiation Oncology (ASTRO) has recently published a consensus statement regarding the use of APBI, and APBI is currently being actively incorporated into the care of a selected group of patients with breast cancer.[12] Updates from trials such as the American Society of Breast Surgeons (ASBS) MammoSite registry trial are important to inform clinicians regarding the outcomes of new technologies, before formal prospective data becomes accessible. The current study confirms initial findings presented by the ASBS in 2005 regarding the use of MammoSite for treatment of DCIS. This study also includes data on 5-year recurrence that are consistent with data reported for patients treated with whole-breast irradiation, and supports the use of MammoSite in selected patients with DCIS.

METHODS

Between May 4, 2002 and July 30, 2004, 97 institutions participated in a prospective registry trial designed to collect data on the use of MammoSite to deliver APBI. A total of 1449 breasts treated with APBI (1440 treated subjects) were submitted for analysis, and 194 subjects enrolled in this study had DCIS as their primary pathology. Patients enrolled in the

study were required to give informed consent, and patients treated on or after April 14, 2003, were required to sign a Health Insurance Portability and Accountability Act (HIPPA) agreement. Trial enrollment was closed in July 2004, with all enrolled patients required to return for follow-up annually for 7 years. Because data entry and processing were a continuous process for the registry trial, a cutoff date of January 31, 2010 for submission of patient data for this update analysis was chosen to allow for auditing and analysis.

Clinical Research Participants/Organization

As previously reported, Synergos, Inc., an independent full-service contract research organization not affiliated with the ASBS, the manufacturer or any of the institutions participating in this trial, was initially hired to collect, manage, and analyze data for the ASBS.[13] BioStat International Inc., Tampa Fl, took over management and statistical analysis of the registry trial for the ASBS in June 2006.

Eligibility Criteria

Recommended criteria for patient enrollment in the protocol included patients with DCIS up to 4.5 cm as measured by mammography, clinically negative lymph nodes, negative surgical margin status (no tumor extending to inked surgical margin), applicator placement within 10 weeks of final lumpectomy procedure, and a postlumpectomy cavity with 1 dimension of at least 3.0 cm.14›15 Patients who received a radiation boost were excluded. Recommended exclusion criteria also included underlying collagen vascular disease. Recommended technical guidelines were established in the protocol to exclude treatment of patients with inadequate device-to-skin distances (recommended minimum of 5 mm; preferably ≥7 mm), excessive cavity size, or poor balloon-cavity conformance. Patients could be enrolled prior to final lumpectomy to allow device placement in an open fashionduring that procedure; other patients were enrolled postlumpectomy and had device placement using a closed technique in the physician's office/clinic.

Cosmetic Outcomes, Adverse Events and Recurrence

Cosmetic outcome was evaluated at each follow-up visit by the treating radiation oncologist or surgeon using the Harvard criteria.[16] Breast infections included mastitis, cellulitis, or abscess occurring at any point during followup. Device-related infections were those that the investigator believed to be secondary to use of MammoSite (no stringent criteria were established). Local recurrence was defined as a pathologically confirmed reappearance of cancer in the treated breast.

Statistical Methods

All time intervals were calculated from the date of MammoSite removal. Nonparametric estimates of survival distribution or recurrence distribution were obtained via life table methods. Associations between clinical-, pathologic-, or treatment-related variables and recurrence were analyzed by logistic regression for continuous measurements, and Fisher exact tests for categorical variables. Associations between dichotomous cosmetic outcomes and treatment-related variables were analyzed using Fisher exact tests for categorical measurements and logistic regression for continuous measurements. All tests were declared statistically significant if the calculated *P* value was less than or equal to 0.05. All tests appear as 2-sided *P* values. Version 8.0 or higher of the SAS statistical software package was used for statistical analyses.

RESULTS

Patient, Tumor, and Treatment Characteristics

The initial study population consisted of 194 subjects (Table 1). Median age for the study population was 62 years (range, 40–88 years). Median tumor size was 8 mm (range, 1–45 mm). The majority of patients (141) had no axillary intervention, whereas 53 patients were found to have no axillary involvement, primarily through sentinel lymph node biopsy. Two patients had positive final surgical margins, 21 patients had close margins, and 171 had negative margins. Nuclear grade for the study population was stratified as follows: grade 1, 34 patients; grade 2, 61 patients; grade 3, 71 patients (information was not available for 28 patients). A total of 82 patients were found to have comedo necrosis. Slightly more than half the study population, 102 patients, underwent hormonal therapy. Thus far in the registry trial, 6 patients have died. One patient died of breast cancer, and 5 patients died of other causes. Median follow-up for the remaining 188 patients was 54.4 months (range, 12 days to 89 months).

MammoSite Device Data

The MammoSite was placed through a closed cavity for 107 patients using ultrasound guidance for 84 patients and the scar-entry technique for 21 patients (insertion technique was unknown for 2 patients; Table 2). The MammoSite was placed using the open technique at the time of lumpectomy for 87 patients. Median device-to-skin distance was 10 mm (range, 2–60 mm). The majority of patients (191) received a partial breast irradiation dose of 34 Gy in 10 fractions, with a dose specification of 100% at 1.0 cm for 180 patients. The time length of catheter implantation was 12 days.

Cosmesis

Five years or greater follow-up cosmetic information was available for 63 patients (Table 3). Of these patients, 58 (92%) had an Excellent or Good cosmetic result, whereas 5 (8%) were rated as having a Fair or Poor result. Mean device-to-skin distance for patients with an Excellent or Good cosmetic result was 11.9 mm, whereas those patients with a Fair or Poor result had a skin distance of 8.2 mm. Since the original analysis of cosmesis-related factors, optimal skin distance for the MammoSite of ≥7 mm was determined. Of those patients who had a device-to-skin distance of ≥7 mm, 55 (93%) had an Excellent to Good cosmetic result, whereas 4 (7%) had a Fair to Poor result. Of the 4 patients who had a device-to-skin distance of <7 mm, 3 (75%) had an Excellent to Good cosmetic result and 1 (25%) had a Fair to Poor result.

With regard to method of device placement, 36 (97%) patients who had the device placed using the closed-cavity technique had Excellent to Good results, compared with 22 (85%) patients who had the device placed through the open-cavity technique. Incidence of breast wound infection or seroma formation was low, and these events did not contribute to a poor cosmetic outcome. Higher balloon fill (≤50 cc vs>50 cc) also did not negatively affect cosmetic results.

Adverse Events

Device-Related Events—Of the 194 patients enrolled in the registry trial, 16 developed a breast infection in the first year of patient follow-up (Table 4). There was no difference in infection rate between patients who underwent MammoSite placement using the closed-cavity technique (9 patients) or the open-cavity technique (7 patients). At last follow-up, information on cosmesis was available for 12 patients who had sustained a breast infection. Of these patients, 10 patients had Excellent or Good cosmetic results. Telangiectasia

developed in 24 patients. Again, method of device placement was not associated with development of this skin change [open-cavity patients (13) versus closed-cavity patients (11)]. Unlike breast infection, however, incidence of reported telangiectasia persisted after 24 months of follow-up in 5 patients. Development of telangiectasia was associated fair/poor cosmesis ($P = 0.02$). After 24 months of follow-up, fat necrosis was reported in 1 patient who had the device placed using the open-cavity technique. Seroma formation occurred in a total of 46 patients. This event was related to device placement, with the open-cavity technique (26 patients) being more commonly associated with seroma than the closed-cavity technique (20 patients; $P = 0.0013$). Symptomatic seroma occurred in 17 patients, and 15 patients had their seroma drained. There was no association between symptomatic findings or seroma drainage and method of device placement. While seroma formation was reported in 3 patients after 24 months of follow-up, none of these patients experienced symptoms or required drainage.

Recurrence—Thus far, of the 194 patients enrolled in the registry trial, 6 patients have sustained a recurrence. Of these, 5 patients had an in-breast recurrence and 1 patient had a local regional failure; thus, the 5-year actuarial local recurrence rate was 3.39% and disease-free survival rate was 93.20%. The median age range for patients who recurred was 53.9 years (range, 44–77.9 years). Median tumor size was 9.0 mm (range, 4.0–16.0 mm). Also, 3 patients presented with nuclear grade 2 disease and 3 patients had grade 3 DCIS. One patient was found to be N0; 5 patients had no axillary intervention (NX). Margins were found to be close for 3 patients and negative for 3 patients. Two patients received antihormonal therapy. Close margins ($P = 0.02$) and age <50 years at diagnosis ($P = 0.017$) were associated with risk for local recurrence (Table 5). The patient who sustained a local regional recurrence was initially found to have recurred 10 months after the MammoSite was removed. She was found to have grade 3 infiltrating ductal cancer with metastasis to 3 of 11 lymph nodes at the time of her mastectomy and axillary dissection. She has since died, 36 months subsequent to device removal, rendering a cause-specific survival rate of 99.40% for the overall study population.

DISCUSSION

The initial registry trial findings reported in 2005 on the use of the MammoSite device in patients with DCIS showed the device to be well tolerated with favorable cosmetic results. This update largely confirms these initial results and also provides information about recurrence for patients treated with this method of APBI. Of the 63 patients with at least 5 years of follow-up, 92% had excellent to good cosmetic results. As previously reported, favorable cosmesis was associated with larger device-to-skin distance. The majority of adverse events, including infection and seroma, were self-limiting and did not impact cosmetic results. Importantly, the 5-year local–regional recurrence data reveal a 3.39% actuarial rate, which compares favorably with a 5-year recurrence rate of 7.5% associated with whole-breast radiation reported in the NSABP B-17 trial.7 Taken together, this study update continues to support the safety of MammoSite-delivered APBI for appropriately selected patients with DCIS.

The ASBS has been consistently following up and reporting on the use of the MammoSite device during the past 5 years.[17] Both initial studies as well as studies evaluating 3- and 4-year follow-up results have found the device to be well tolerated and to result in a favorable cosmetic outcome.18,19 These early results have also been reported in smaller, single-institution studies.20,[21] Concern regarding the durability of cosmetic results reported in earlier studies of MammoSite outcomes stem from the relatively long duration (approximately 3 years), of dynamic change associated with breast findings after treatment with lumpectomy and radiation. In light of this, 5-year results reported in this update,

showing a majority of patients having excellent to good cosmetic results and minimal long-term device-related adverse events, adds further validation of the device's utility.[13,17–19] Additionally, a recent study comparing toxicity of APBI with MammoSite to whole-breast radiation found patients treated with APBI to have a higher performance status, less acute skin toxicity, and decreased fatigue.22 Increased seroma pain was the primary finding for patients treated with MammoSite.[22]

Seroma formation was the most commonly reported device-related adverse event in this study and was associated with the open-cavity placement technique. Additional single-institution studies have reported a similar correlation between the open-cavity technique and seroma formation.[23,24] Use of prophylactic antibiotics has been suggested to help reduce the risk of device-related infection, which has also been linked to clinically significant seroma formation.[24] Postoperative placement of the MammoSite has been recommended previously to allow selection of eligible patients based on findings from the final pathologic analysis.[25] Collectively, these findings support the recommendation that, if possible, the MammoSite device be placed postoperatively using the closed-cavity technique.

Additional results from this registry trial update demonstrate the importance of adequate resection margins and appropriate patient selection for treatment with APBI, as close margins and younger patient age were associated with an increased risk of local recurrence. Furthermore, the 6 patients in this study who experienced a recurrence had intermediate- or high-grade disease, suggesting a decreased recurrence risk for lower-grade DCIS patients treated with MammoSite APBI. Up to this point, there has been an accepted paradigm of treatment for the management of DCIS that includes surgery and whole-breast radiation for patients undergoing breast conservation. However, the rationale for this standard treatment is open to further investigation, secondary to knowledge gaps that exist between the current favorable outcomes for patients with DCIS, the initiative to tailor therapy on a more patient-specific basis, and a fundamental lack of information about the biological differences of the DCIS subtypes. Consequently, these gaps encourage further study of less-extensive approaches for the treatment of DCIS, including MammoSite APBI.

The complexity of obtaining a standard 6-week course of whole-breast radiation remains unworkable for many patients diagnosed with DCIS. Since the initial ASBS report on the use of MammoSite for DCIS in 2005, patients with DCIS continue to be undertreated. Factors contributing to this undertreatment include employment issues, which may only be exacerbated by the current economic climate. Furthermore, transportation, insurance status, age, and physical limitations continue to be key obstacles to care.[26,27] The favorable results for MammoSite reported in this update should encourage clinicians to offer APBI on a clinical trial to appropriately selected patients who would otherwise not get treated with radiation or who would potentially choose mastectomy to avoid the adverse effects of whole-breast radiation. The recently published ASTRO guidelines for the use of APBI outside of a clinical trial delineated patient groups as "suitable," "cautionary," or "unsuitable" for treatment with APBI.[12] Of note, patients with DCIS were not included in the "suitable" group, as currently there is a dearth of data available regarding outcomes for these patients. As a result, patients with small (≤3 cm) DCIS lesions were listed in the "cautionary" group, and patients with larger-size DCIS were deemed "unsuitable."[12] Thus, while the use of APBI targeted to the tumor bed may ultimately provide a logical implementation of radiation therapy for patients with unifocal low-risk disease, this treatment approach has yet to achieve a "suitable" status for the management of DCIS outside of a clinical trial.12

This update of the ASBS MammoSite registry trial provides encouraging results regarding cosmesis and recurrence, with 5-year follow-up. The safety and efficacy of APBI continues

to be assessed, and the role of this treatment for patients with DCIS and invasive disease is being actively studied through the NSABP-RTOG B-39 trial. As outcomes from the NSABP trial are years away, the favorable results from the ASBS trial are critical to clinicians who are actively using this radiation therapy device. While APBI may ultimately only apply to specific patient subsets, the shorter treatment time made possible by MammoSite may make radiation therapy, as well as breast conservation, feasible for patients who would otherwise go untreated or feel forced to opt for mastectomy. Finally, while data available from the ASBS registry trial are encouraging, these results are subject to the inherent limitations of a voluntary registry study. Implicit to the retrospective nature of the study are concerns regarding selection bias and the lack of uniformity of patient enrollment, which may affect the validity of the current study in terms of cosmetic results and adverse events.[17,18] We look forward to additional follow-up results from the ASBS MammoSite registry trial and the results of the NSABP-RTOG trial to help further determine the safety and efficacy of APBI.

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TABLE 1

Patient, tumor, and treatment characteristics for the entire study population of 194 patients

Variable	Number
Median age (years)	62; range, 40–88
Median tumor size (mm)	8; range, 1–45
Axillary nodal management	
Level I dissection	3 (1.50%)
Sentinel node biopsy	50 (25.80%)
No axillary dissection	141 (72.70%)
Final surgical margin	
Negative	171 (88.10%)
Positive	2 (1.00%)
Close (<2 mm)	21 (10.80%)
Nuclear grade	
Grade 1	34 (17.5%)
Grade 2	61 (31.4%)
Grade 3	71 (36.6%)
Could not be assessed	28 (14.4%)
Necrosis	
Absent	67 (34.5%)
Comedo	82 (42.3%)
Punctate	15 (7.7%)
Not available	30 (15.5%)
Adjuvant therapy	
Antihormonal therapy	102 (52.6%)

TABLE 2

MammoSite device data

Variable	No. patients
Insertion method	
Open-cavity technique	87 (44.80%)
Closed-cavity technique	107 (55.2%)
Ultrasound-guided[a]	84 (78.50%)
Scar-entry technique[a]	21 (19.60%)
Not recorded[a]	2 (1.90%)
Device-to-skin distance	
Median, mm (range)	10.0 (2–60)
≥10 mm	115 (59.3%)
≥9 mm	126 (64.9%)
≥8 mm	143 (73.7%)
≥7 mm	167 (86.1%)
≥6 mm	178 (91.8%)
≥5 mm	188 (96.9%)
Radiation therapy	
34 Gy/10 fractions	191 (98.5%)
32 Gy/8 fractions	2 (1.0%)
Other treatment regimens	1 (0.5%)
APBI dose specification	
100% at 1.0 cm	180 (92.8)
Alternative dosing	14 (7.2)
Time length of catheter implantation (days)	12

[a]Percentage of subjects with closed-cavity placement

TABLE 3

Cosmetic results at 5 years or greater of follow-up

Factor	60 months[a]		
	Excellent/good, *n* (%)	Fair/poor, *n* (%)	*P* value[b]
No. breasts (*N* = 63)	58 (92.1)	5 (7.9)	
Skin spacing [mean (std)], mm	11.9 (5.34)	8.2 (2.39)	0.1266
Skin spacing (<7 mm vs ≥7 mm)	3 (75.0) vs 55 (93.2)	1 (25.0) vs 4 (6.8)	0.2877
Method of placement (open-cavity vs closed-cavity)	22 (84.6) vs 36 (97.3)	4 (15.4) vs 1 (2.7)	0.1501
Breast-related wound infection (yes vs no)	4 (100.0) vs 54 (91.5)	0 (0.0) vs 5 (8.5)	1.0000
Seroma (yes vs no)	18 (90.0) vs 40 (93.0)	2 (10.0) vs 3 (7.0)	0.6488
Telangiectasia (yes vs no)	7 (70.0) vs 51 (96.2)	3 (30%) vs 2 (3.8%)	0.0251
Balloon fill (≤50 cc vs >50 cc)	30 (93.8) vs 28 (90.3)	2 (6.3) vs 3 (9.7)	0.6719

[a] Last available cosmesis evaluation after 59 months

[b] Dichotomous characteristics or 3 × 2 analyses: Fisher exact test: comparing Excellent/good vs Fair/poor results between characteristic categories; continuous characteristics: logistic regression of continuous measure on Excellent/good response rate

TABLE 4

Device-related events

Variable	No. patients
All patients	194
Breast infection	16
Open-cavity technique	7 (43.75%)
Closed-cavity technique	9 (56.25%)
Telangiectasia	24
Open-cavity technique	13 (54.2%)
Closed-cavity technique	11 (45.8%)
Fat necrosis (open-cavity technique)	1
Seroma formation[a]	46
Open-cavity technique	26 (56.50%)
Closed-cavity technique	20 (43.50%)

[a]Only the correlation between technique for device placement and seroma formation was statistically significant ($P = 0.0013$)

TABLE 5

Factors related to ipsilateral breast tumor recurrence (IBTR)

Variable	IBTR	No IBTR	*P* value
Age at diagnosis (%) <50 years vs ≥50	14.29 (3/21) vs 1.73 (3/173)	85.71 (18/21) vs 98.27 (170/173)	0.0178
Tumor size (odds ratio)	0.77		0.7045
Margin status (%) (positive/close vs negative)	13.04 (3/23) vs 1.75 (3/171)	86.96 (20/23) vs 98.25 (168/171)	0.0231
Estrogen receptor status (%) (positive vs negative)	6.90 (2/29) vs 0.00 (0/6)	93.10 (27/29) vs 100.0 (6/6)	1.0000
Histologic grade (%) (grade I/II vs grade III/IV)	3.67 (4/109) vs 2.35 (2/85)	96.33 (105/109) vs 97.65 (83/85)	0.6972
Adjuvant hormone therapy (%) (yes vs no)	1.96 (2/102) vs 4.35 (4/92)	98.04 (100/102) vs 95.65 (88/92)	0.4254

With exception of tumor size, all variables were dichotomous. DCIS cases: $N = 194$