Published in final edited form as:

Brachytherapy. 2014 ; 13(1): 17–22. doi:10.1016/j.brachy.2013.08.002.

RTOG 95-17, A Phase II Trial to Evaluate Brachytherapy as the Sole Method of Radiation Therapy for Stage I and II Breast Carcinoma – Year-5 Toxicity and Cosmesis

Rachel Rabinovitch, MD[1], **Kathryn Winter, MS**[2], **Robert Kuske, MD**[3], **John Bolton, MD**[4], **Doug Arthur, MD**[5], **Troy Scroggins, MD**[6], **Frank Vicini, MD**[7], **Beryl McCormick, MD**[8], and **Julia White, MD**[9]

[1]Radiation Oncology, University of Colorado Hospital, Aurora, CO, 80045

[2]Statistics, Radiation Therapy Oncology Group, Philadelphia, PA

[3]Radiation Oncology, AZ Oncology Services, Scottsdale, AZ; Arizona Breast Cancer Specialists, Scottsdale, AZ

[4]Surgery, Ochsner Clinic, New Orleans, LA

[5]Radiation Oncology, Medical College of Virginia, Richmond, VA

[6]Radiation Oncology, Ochsner Baptist Medical Center, New Orleans, LA

[7]Rad Onc, William Beaumont Hospital, Royal Oak; Michigan HealthCare Professionals/21st Century Oncology, Farmington Hills, MI

[8]Radiation Oncology, Memorial Sloan-Kettering Cancer Center, New York, NY

[9]Radiation Oncology, Medical College of Wisconsin, Milwaukee, WI; Ohio State University Medical Center, Columbus, OH, 43210

Abstract

Introduction—RTOG 95-17, a Phase II trial to evaluate multicatheter brachytherapy (mCathBrachy) as the sole method of radiation therapy (RT) for Stage I-II breast cancer (BrCa), was the first cooperative group trial in North America to evaluate accelerated partial breast irradiation (APBI) and include patient reported outcomes (PROs). This report presents year-5 toxicity and cosmesis data.

Methods—Following lumpectomy and axillary dissection for invasive BrCa (tumor size <3 cm with 0-3 positive lymph nodes), 100 patients (pts), 98 evaluable, were treated (txed) with mCathBrachy from 1997-2000 with 34 Gy in 10 BID high dose-rate fractions or 45 Gy in 3.5-6 days as a low dose-rate implant to 1-2 cm beyond the lumpectomy bed. PROs and physician

Corresponding Author: Rachel Rabinovitch, MD Radiation Oncology, University of Colorado Hospital 1665 Aurora Court, Suite 1032; Mail Stop F-706 Aurora, CO 80045 Phone: 720 848 0156; FAX: 720 848 0234: rachel.rabinovitch@ucdenver.edu.

All authors have no financial disclosures or conflicts of interest to report

reported outcomes of toxicity, cosmesis and tx satisfaction at year-5 are reported here, defined as data submitted 54-78 months after tx.

Results—Grade (G) 1-2 skin toxicity developed in 78% of pts and G3 in 13% (no G4). Tx effects included skin dimpling/indentation (37%), fibrosis (45%), telangiectasias (45%), skin catheter marks (54%), and symptomatic fat necrosis (15%). Breast asymmetry was reported in 73%. Rates of excellent-good cosmesis were similar between PROs (66%) and radiation oncologists (68%). PROs of tx satisfaction at year-5 was 75%.

Conclusion—RTOG 95-17 documents year-5 skin toxicity and tx effects of mCathBrachy APBI which are associated with PROs of good-excellent cosmesis and high tx satisfaction. This emphasizes the importance of PROs when assessing BrCa tx. NSABP B39/RTOG 0413 will allow for definitive comparisons between APBI and whole breast RT.

Keywords

Brachytherapy; Partial Breast Irradiation; Toxicity; Cosmesis; Breast Cancer; Patient Reported Outcomes

Introduction

Accelerated partial breast irradiation (APBI) is an evolving component of breast conserving therapy in which radiotherapy is directed to the tissue at highest risk for in-breast recurrence immediately surrounding the lumpectomy cavity, with treatment delivered over a shortened time course, typically one week. NSABP B39/RTOG 0413[1], and numerous other phase III randomized trials[2,3,4,5,6,7] are ongoing which compare traditional whole breast radiotherapy to APBI delivered with a variety of techniques. Efficacy and toxicity data from these trials will ultimately determine APBI's place in the treatment armamentarium for early stage breast cancer. Multicatheter brachytherapy, an interstitial treatment approach, was one of the earliest treatment techniques developed for APBI. Outcomes from trials conducted in the early years of APBI development provide an opportunity to evaluate mature outcome data.

Radiation Therapy Oncology Group (RTOG) 95-17, *A Phase II Trial to Evaluate Brachytherapy as the Sole Method of Radiation Therapy for Stage I and II Breast Carcinoma*, was the first completed cooperative group trial in North America evaluating APBI and utilized a multicatheter interstitial brachytherapy technique. While treatment efficacy was the primary endpoint, RTOG 95-17 evaluated cosmesis as a secondary endpoint which included patient and physician reported outcomes. Both patients and clinicians were asked to assess treatment toxicity and cosmesis, and patients further scored treatment satisfaction. For APBI to be considered an acceptable treatment option, treatment should result in a well-defined favorable toxicity and cosmesis profile, one that is considered acceptable to both the patient and clinician. This report presents updated cosmesis and toxicity data for patients treated on RTOG 95-17.

Methods

RTOG 95-17 is a single arm prospective phase II cooperative group trial evaluating APBI with multicatheter interstitial brachytherapy for patients with any invasive breast cancer

histology treated with breast conserving surgery. Eligibility criteria included negative surgical lumpectomy margins (no tumor at ink), tumors 3.0 cm or smaller, and placement of six clips marking the borders of the lumpectomy cavity at the time of surgery delineating the lumpectomy bed. All patients were required to undergo axillary staging with complete level I/II axillary node dissection; only patients with 0-3 positive lymph nodes were eligible for enrollment. Extensive intraductal component and extracapsular lymph node extension were exclusion criterion.

Protocol therapy consisted of multicatheter brachytherapy APBI with either high dose-rate (HDR) or low dose-rate (LDR) treatment delivered within six weeks of surgery. HDR treatment consisted of ten 3.4 Gy fractions administered twice daily, with ≥ 6 hours between fractions. LDR treatment delivered 45 Gy over 3.5-6 days as an in-patient. Catheter placement and source loading were designed to deliver the prescription dose to the clinical target volume defined as the tissue 2 cm superior, inferior, medial and lateral to the cavity, and 1 cm anterior and posterior to it. Implants were typically performed using a 2-plane technique and brachytherapy planning for the LDR and HDR implants in this protocol was 2-dimensional. All treatment plans were evaluated through a rapid review process prior to treatment initiation.[8] Systemic therapy was at the discretion of the treating medical oncologist. Tamoxifen during APBI was allowed; chemotherapy could be administered no sooner than 2 weeks following catheter removal.

Patients and physicians were instructed to complete questionnaires at 6 months, 1 year, and annually thereafter. In order to increase the sample size for this cosmesis analysis, responses during years five and six after treatment completion (54-78 months) were grouped together and referred to hereafter as “year-5”.

Evaluated treatment-related effects included the presence of skin marks at catheter entrance/exit sites and fat necrosis; if present, these were graded on a scale of 1-4: 1-assymptomatic clinical findings, 2-mildly symptomatic, 3-moderate to severe pain/inflammation, 4-pain requiring surgical intervention. If present, infection, erythema, skin ulceration, wound dehiscence, skin thickening, skin fibrosis, breast edema, ipsilateral arm edema, pain, tenderness, bleeding, pneumothorax, radiation pneumonitis, and telangiectasias were graded on a scale of 1-5 by the treating physician, corresponding to mild, moderate, severe, life-threatening, and fatal, respectively. Patients were asked to assess breast symmetry by selecting one of the following responses: breast size same on both sides, larger on left, larger on right, or unknown. For this analysis, the data was regrouped into breast size same on both sides, larger in the treated breast, larger in the untreated breast, and unknown. Assessment of breast symmetry was not made prior to brachytherapy. Radiation oncologists were asked to assess for the presence of late treatment effects potentially affecting cosmesis which included skin telangiectasias, skin atrophy, pock marks, hyperpigmentation, erythema, fibrosis, skin dimpling/indentation, and other. These effects were scored as: not present, present on close inspection, or present on casual inspection. Overall cosmesis was assessed by the patient and radiation oncologist with a score of 1-4 corresponding to excellent, good, fair, and poor (see Table 1 for expanded definitions). Finally, patients were asked to describe their satisfaction with treatment: 1-satisfied, 2-not satisfied but would choose multicatheter

brachytherapy if beginning treatment again, 3-not satisfied and would choose external beam radiation if beginning treatment again, and 4-dissatisfied.

Results

One hundred patients were enrolled from 1997-2000 and treated at 10 institutions; 2 patients were excluded for not meeting eligibility criteria, leaving 98 treated patients eligible for evaluation (65 HDR and 33 LDR). Pretreatment patient characteristics have been previously reported[9,10] and were well balanced between LDR and HDR treated patients with regard to age, T stage, menopausal status, and performance status. Analysis of toxicity and cosmesis data was updated in February 2011 at which time 69 patients (70%) were alive and eligible for follow-up with median follow-up time of 11.3 years (min-max: 0.9-13.1 years). At the start of the year-5 follow-up period, 92 (94%) patients were still alive. For this subset, cosmesis data was submitted by patients in 64% and by radiation oncologists in 50%.

Fat necrosis was reported in 15 patients (15%): 10 patients with grade 2 (mildly symptomatic), and 5 with Grade 3-4. Of the patients with G3-4 fat necrosis, one underwent surgical excision and none required mastectomy. Late skin/soft-tissue toxicities at any time in follow up are presented in Table 2, which included 24 grade 3 toxicities in 13 patients (13%). For these parameters, no patient experienced grade 4 toxicity. Treatment effects visible on inspection (casual versus close) assessed by the radiation oncologist in year-5 are presented in Table 3. The most commonly identified treatment effects were skin telangiectasias (45%), fibrosis 45%), and catheter puncture site scarring (54%) which were most often apparent only on close inspection (Table 3).

Patient reported data revealed that most patients (43 of 59 or 73%) identified breast asymmetry at year-5. Of patients reporting asymmetry, the treated breast was described as smaller in 77%. Overall cosmesis assessment of the treated breast as reported by both the patient and radiation oncologist for the same patient at year-5 is presented in Table 4. Cosmesis was assessed as excellent or good by 66% and 68% of patients and radiation oncologists, respectively.

Overall satisfaction with treatment as reported by patients is summarized in Table 5. Seventy five percent of responding patients expressed satisfaction with multicatheter APBI and would choose this treatment again.

Discussion

RTOG 95-17 is the only completed multicatheter APBI cooperative group trial in North America. This trial was designed not only to determine treatment efficacy, but included secondary endpoints of physician and patient reported assessments of toxicity and cosmesis. In the years since the initiation of this interstitial APBI protocol, additional APBI techniques have been developed and dosimetric planning has changed significantly. Multicatheter APBI as it was first developed for this novel breast conserving approach initially depended upon 2-dimensional dosimetric planning. Despite advances in treatment planning, interstitial brachytherapy remains the most complex of the APBI treatment options, with insertion and multi-position loading of numerous catheters (typically 20). While these factors and the

inherent dose gradients associated with multicatheter brachytherapy raised concerns for the potential impact of multicatheter APBI on cosmesis and toxicity, the experience described above demonstrates a favorable profile. Grade 3 breast toxicities were observed in only 13% of patients at any time during follow-up and no grade 4 toxicities were reported. Symptomatic fat necrosis was unusual (15%), and of these, most (2/3) were described as mildly symptomatic. This rate of fat necrosis is similar to other prospective multicatheter trials: 11.4% fat necrosis rate reported by Lovey et al, 20% by Polgar et al, and 27% reported by Wazer et al.[11, 12, 13] Of note, Lovey et al described symptomatic a fat necrosis rate of 8.5% for patients receiving whole breast radiation.

Breast asymmetry is commonly assessed in breast conserving therapies, with competing issues of volume loss (related to surgery and radiation fibrosis) and breast enlargement (related to breast edema). The data above clearly document that breast asymmetry when reported by the patient is common (73% at year-5), and is usually due to a diminishment in the size of the treated breast (77%). It is notable that while 77% of patients reported asymmetry, 66% scored their cosmetic assessment as excellent or good, demonstrating the numerous factors that influence cosmetic results.

Treatment effects reported by the radiation oncologist (Table 3) demonstrate that the most common changes resulting from multicatheter brachytherapy include skin dimpling or indentation (37% incidence), fibrosis (45% incidence), and skin telangiectasias (45% incidence). Of note, the treatment parameters for this study did not define a skin dose-constraint which likely contributed to the rate of skin telangiectasia reported here. Implants which significantly restrict skin doses (to ≤60% of prescription dose, for example, as utilized by the prospective Hungarian trial[12]) would be expected to yield lower rates of this late skin toxicity. Skin atrophy, hyperpigmentation, and erythema were less commonly observed, all with an incidence of less than 15% at year-5 following treatment. The skin puncture site was appreciated in 54% of patients.

Two-thirds (66%) of patients reporting cosmesis rated their overall cosmesis as good-excellent at year-5 despite the treatment effects described above. Assessments of the same patients by the radiation oncologists at the same follow up period yielded similar rates of good-excellent cosmesis (68%) demonstrating agreement between subjective evaluations by patients and their treating physicians. Comparing our data with multicatheter brachytherapy to prospective trials of whole breast radiotherapy yields similar outcomes, despite the invasiveness of this APBI technique. Whelan et al reported good-excellent cosmesis rates 10 years after treatment in 69-70% of 451 patients treated on a randomized controlled trial comparing standard and accelerated fractionation whole breast radiotherapy.[14] The EORTC in a prospective randomized boost trial described good-excellent cosmesis rates in 86% of 2657 patients treated with whole breast radiotherapy without a boost, and 71% of 2661 patients treated with the addition of a boost.[15]

To the best of our knowledge, this is the first presentation of patient reported cosmesis outcomes in a prospective North American trial of breast conserving therapy. A purview of the literature does indeed yield cosmesis assessments in several prospective trials, however all assessments are the result of clinician evaluation. For example, cosmesis ratings in the

Whelan's hypofractionated whole breast radiotherapy trial were assessed by a “trained clinical-trials nurse.”[14] Cosmesis assessments in the EORTC boost trial were made by the treating physician.[15] As a result of the lack of patient reported cosmesis outcomes following breast conserving therapy, Hill-Kaiser et al performed a web-based survey of patients treated with breast conservation and described the data as the “first assessment of patient-reported cosmetic outcome after BCT”. [16] This survey yielded good-excellent cosmesis ratings in 71% of 331 patients at a median time of 3.6 years after diagnosis. The data presented here provides mature patient reported outcomes related to breast conserving therapy, specifically multicatheter brachytherapy, obtained through a prospective clinical trial.

RTOG 95-17 and other multicatheter APBI trials[17] using similar techniques yielded valuable information which was incorporated into the subsequent generation of RTOG APBI trials (RTOG 0319[17][18] and NSABP B39/RTOG 0413[1]). Adjustments to the clinical target volume, dose homogeneity index, and other dose-volume constraints were made to subsequent trials as a result of these early experiences. It is relevant to note that dosimetry planning for 95-17 utilized 2D planning methods dependent upon orthogonal or variable-angle films of the implanted breast. CT imaging and 3D brachytherapy planning software have since allowed for greatly enhanced treatment planning design and greater dose homogeneity and conformality. Since the design of this trial, Wazer et al have demonstrated that fat necrosis is associated with the volume of breast tissue receiving 150% and 200% of the prescribed dose (V150 and V200).[13]

Despite the prevalence of telangiectasias (45%), skin fibrosis (45%), puncture site skin marks (54%), and breast asymmetry (73%), the reported rate of satisfaction with this treatment was extremely high among patients who provided data. Seventy five percent of patients at year-5 described satisfaction with their treatment. It is not possible to determine if there is a correlation between patients reporting a lack of satisfaction and those experiencing toxicities. The higher rate of satisfaction with treatment (75%) compared to the rate of good-excellent cosmesis assessment (66%) could indicate that the parameters used to assess breast cosmesis in clinical trials do not correlate with measures that impact treatment satisfaction for patients themselves. It is also possible that the disparity is due to reporting of treatment satisfaction and cosmesis by different patients, a psychological bias by patients to feel satisfied with a treatment received despite cosmesis or toxicities experienced, or the possibility that the treatment efficacy and time savings of this treatment approach was of greater importance than these other factors. An additional limitation of the cosmesis portion of this report is the lower than expected submission rate of cosmesis data. The cosmesis results presented here should be considered in that context.

Conclusion

RTOG 95-17 is the first cooperative group trial of APBI performed in North America and the first North American breast cancer clinical trial to incorporate patient reported outcomes. Follow up at year-5 after treatment demonstrates high good-excellent cosmesis rates as reported by both patient and physician and not dissimilar to those reported in external beam whole breast radiotherapy trials. The high patient treatment satisfaction and good-excellent cosmesis rates alongside variable rates and grades of skin dimpling, fibrosis, puncture site

scarring, and skin telangiectasias emphasize the importance of patient reported outcomes in assessing the significance of treatment toxicities. Data from NSABP B39/RTOG 0413 and other randomized trials will allow for definitive tumor control, toxicity, and cosmesis comparisons between numerous techniques of APBI and whole breast radiotherapy.

Acknowledgments

This trial was conducted by the Radiation Therapy Oncology Group (RTOG), and was supported by RTOG grant U10 CA21661 and CCOP grant U10 CA37422 from the National Cancer Institute (NCI). This manuscript's contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Cancer Institute.

Supported by RTOG U10 CA21661 and CCOP U10 CA37422 NCI grants.

Appendix

RTOG 95-17 is the first cooperative group trial of APBI performed in the North America and the first to incorporate patient reported outcomes. Follow up at year-5 after treatment demonstrates high good-excellent cosmesis rates as reported by both patient and physician and not dissimilar to those reported in external beam whole breast radiotherapy trials. The high patient treatment satisfaction and good-excellent cosmesis rates alongside variable rates and grades of skin dimpling, fibrosis, puncture site scarring, and skin telangiectasias emphasize the importance of patient reported outcomes in assessing the significance of treatment toxicities. Data from NSABP B39/RTOG 0413 and other randomized trials will allow for definitive tumor control, toxicity, and cosmesis comparisons between numerous techniques of APBI and whole breast radiotherapy.

References

1. NSABP B39/RTOG 0413. [Accessed on February 15, 2013] http://www.cancer.gov/clinicaltrials/search/view?cdrid=409590&version=HealthProfessional
2. RAPID-Randomized Trial of Accelerated Partial Breast Irradiation. [Accessed on February 15, 2013] http://clinicaltrials.gov/ct2/show/NCT00282035
3. Vaidya JS, Joseph DJ, Tobias JS, et al. Targeted intraoperative radiotherapy versus whole breast radiotherapy for breast cancer (TARGIT-A trial): an international, prospective, randomised, non-inferiority phase 3 trial. Lancet. 2010; 376:91–102. [PubMed: 20570343]
4. Eliot R, Orecchia M, Ciocca R, et al. Intraoperative radiation therapy with electrons (ELIOT) in early-stage breast cancer. Breast. 2003:483–490. [PubMed: 14659125]
5. RAPID - OCOG. [Accessed on February 15, 2013] Ontario Clinical Oncology Group (OCOG), Canadian Institutes of Health Research (CIHR), Canadian Breast Cancer Research Alliance. RAPID: Randomized Trial of Accelerated Partial Breast Irradiation. 2008. Available from: http://clinicaltrials.gov/ct2/show/NCT00282035
6. IRMA. [Accessed on February 15, 2013] http://groups.eortc.be/radio/res/irma/synopsis_trial_irma1.pdf
7. GEC ESTRO APBI Trial. [Accessed on February 15, 2013] http://www.apbi.uni-erlangen.de/outline/outline.html
8. Ibbott GS, Hanson WF, O'Meara E, et al. Dose specification and quality assurance of radiation therapy oncology group protocol 95-17; a cooperative group study of iridium-192 breast implants as sole therapy. Int J Radiat Oncol Biol Phys. 2007; 69:1572–1578. [PubMed: 18035213]
9. Kuske RR, Winter K, Arthur DW, et al. Phase II trial of brachytherapy alone after lumpectomy for select breast cancer: toxicity analysis of RTOG 95-17. Int J Radiat Oncol Biol Phys. 2006; 65:45–51. [PubMed: 16503383]

10. Arthur DW, Winter K, Kuske RR, et al. A Phase II trial of brachytherapy alone after lumpectomy for select breast cancer: tumor control and survival outcomes of RTOG 95-17. Int J Radiat Oncol Biol Phys. 2008; 72:467–473. [PubMed: 18294778]
11. Lövey K, Fodor J, Major T, et al. Fat necrosis after partial-breast irradiation with brachytherapy or electron irradiation versus standard whole-breast radiotherapy--4-year results of a randomized trial. Int J Radiat Oncol Biol Phys. 2007; 69:724–731. [PubMed: 17524571]
12. Polgar C, Major T, Fodor J, et al. Accelerated partial-breast irradiation using high-dose-rate interstitial brachytherapy: 12-year update of a prospective clinical study. Radiother Oncol. 2010; 94:274–279. [PubMed: 20181401]
13. Wazer DE, Lowther D, Boyle T, et al. Clinically evident fat necrosis in women treated with high-dose-rate brachytherapy alone for early-stage breast cancer. Int J Radiat Oncol Biol Phys. 2001; 50:107–111. [PubMed: 11316552]
14. Whelan TJ, Pignol JP, Levine MN, et al. Long-term results of hypofractionated radiation therapy for breast cancer. N Engl J Med. 2010; 362:513–520. [PubMed: 20147717]
15. Poortmans PM, Collette L, Bartelink H, et al. The addition of a boost primary tumour bed after lumpectomy in breast conserving treatment for breast cancer. A summary of the results of EORTC 22881-10882 “boost versus no boost” trial Cancer Radiother. 2008; 12:565–570. [PubMed: 18760649]
16. Hill-Kayser CE, Vachani C, Hampshire MK, et al. Cosmetic outcomes and complicationsreported by patients having undergone breast-conserving treatment. Int J Radiat Oncol Biol Phys. 2012; 83:839–44. [PubMed: 22137022]
17. Wazer DE, Kaufman S, Cuttino L, et al. Accelerated partial breast irradiation: an analysis of variables associated with late toxicity and long-term cosmetic outcome after high-dose-rate interstitial brachytherapy. Int J Radiat Oncol Biol Phys. 2006; 64:489–495. [PubMed: 16246495]
18. Vicini F, Winter K, Wong J, et al. Initial efficacy results of RTOG 0319: three-dimensional conformal radiation therapy (3D-CRT) confined to the region of the lumpectomy cavity for stage I/II breast carcinoma. Int J Radiat Oncol Biol Phys. 2010; 77:1120–1127. [PubMed: 19910132]

Abbreviation list

APBI	accelerated partial breast irradiation
RTOG	Radiation Therapy Oncology Group
HDR	high dose-rate
LDR	low dose-rate
NCI	National Cancer Institute

Table 1

Scoring Definitions for Overall Cosmesis

Excellent:	When compared to the untreated breast or the original appearance of the treated breast, there is minimal or no difference in the size or shape of the treated breast. The way the breast feels (its texture) is the same or slightly different. There may be thickening, scar tissue, or seroma within the breast but not enough to change the appearance.
GOOD:	There is mild asymmetry between the breasts, which means that there is some acceptable difference in the size or shape of the treated breast as compared to the opposite breast or the appearance of the breast before treatment. There may be some mild reddening or darkening of the breast. The thickening or scar tissue within the breast causes a mild change in its shape or size.
FAIR:	Moderate deformity of the breast, with an obvious difference in the shape and size of the treated breast. This change involves 1/4 or less of the breast. There can be moderate thickening or scar tissue of the skin and the breast, and there may be obvious color changes.
POOR:	Marked change in the appearance of the treated breast involving more than 1/4 of the breast tissue. The skin change may be obvious and detract from the appearance. Severe scarring and thickening of the breast which clearly alters its appearance may be present. In retrospect, the breast may have been better treated by a mastectomy.

Table 2

Toxicities Reported in Follow-Up (n=98)

Toxicity	Grade 1	Grade 2	Grade 3	Median Time (minimum-maximum) in Years from Treatment to Grade 3 Toxicity
Breast infection	0	2	2	4.1 (0.4-7.8)
Breast erythema	22	8	1	3.1
Breast skin ulceration	2	3	1	10.9
Wound dehiscence	0	1	1	2.4
Breast skin thickening	39	12	5	8.1 (2.7-10.9)
Breast skin fibrosis	36	23	7	2.7 (1.7-10.9)
Breast pain	28	9	2	0.8 (0.6-0.9)
Telangiectasia	26	5	5	4.0 (2.1-5.2)
Total number of patients experiencing toxicity*	33	44	13	

* More than one toxicity could be reported for a single patient.

Table 3
Treatment Effect Evaluation by Radiation Oncologist, Year-5

Treatment Effect		(n=46) %
Skin Telangiectasia	None	54.4
	Yes-Close	15.2
	Yes-Casual	30.4
	No response	0
Skin Atrophy	None	91.3
	Yes-Close	6.5
	Yes-Casual	0
	No response	2.2
Catheter Puncture Marks	None	43.5
	Yes-Close	41.3
	Yes-Casual	13.0
	No response	2.2
Hyperpigmentation	None	80.4
	Yes-Close	4.4
	Yes-Casual	10.9
	No response	4.4
Erythema	None	93.5
	Yes-Close	0
	Yes-Casual	4.4
	No response	2.2
Fibrosis	None	50.0
	Yes-Close	30.4
	Yes-Casual	15.2
	No response	4.4
Skin Dimpling or Indentation	None	60.9
	Yes-Close	13.0
	Yes-Casual	23.9
	No response	2.2

Table 4

Overall Cosmesis Results Reported by the Patient and Radiation Oncologist, Year-5

	(n=44)			
	Patient		Radiation Oncologist	
	n	%	n	%
Excellent/Good	29	66	30	68
Fair/Poor	14	32	14	32
No response	1	2	0	0

Table 5

Patients Satisfaction with Treatment at Year-5

Score	(n=59)
Satisfied	44 (74.6%)
Not satisfied/Brachytherapy again	12 (20.3%)
Not satisfied/External Beam Radiation Therapy again	2 (3.4%)
Dissatisfied	1 (1.7%)