
BrachyNext
Working Together to Shape the Future of
Brachytherapy
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Brachytherapy
Results of APBI Clinical Trials Using Intracavitary Single- and Multi-Channel Breast Brachytherapy Applicators
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Disclosure

Frank A. Vicini, MD, FACR, does not have any financial relationships or products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months.

Outline

- Review the latest APBI data
- Update status of APBI (brachytherapy) as an option to deliver adjuvant radiation after lumpectomy using balloon-based brachytherapy

Latest APBI Data — Outcome versus Technique

- Catheter-based brachytherapy
- MammoSite/Contura (balloon devices)
- SAVI

Published APBI Results — Catheter-Based Brachytherapy (>10 years)

Institution	# Patients	Follow-Up (Months)	% Local Recurrence
NIO-Hungary (phase II)	45	**136**	**9.3***
RTOG 95-17	99	**146**	**6.2**
Hungary Phase III	129	**144**	**6**
WBH	199	**113**	**5***
Orebro University	50	**86**	**4+**
MGH	48	**84**	**2**
Tufts/Brown University	33	**84**	**9**
NIO-Hungary (phase III)	128	**81**	**4.7**
Oschner Clinic	51	**75**	**2.0**
RTOG 95-17	99	**74**	**4.0**
Joe Arrington Cancer Center	214	**72**	**4.2**
German-Austrian MC Trial	171	**71**	**--**
University of Wisconsin***	136	**60**	**4.8**
Tufts-Brown University	33	**58**	**6**
Washington University	192	**55**	**2.1**
VCU	59	**50**	**5.1**
University of Wisconsin	247	**48**	**3****
Joe Arrington Cancer Center	136	**48**	**3.7**
German-Austrian MC Trial	274	**38**	**0.4**
University Kansas	24	**37**	**0**
University of Perugia, Italy	80	**30**	**0**
Florence Italy	90	**27**	**4.4**
Totals	**2309**	**27-136**	**0-9%**

*12-year rate, += 7-year rate; ** High-risk patients; ***ASTRO Cautionary Group.

Published APBI Results — Balloon/Device-Based Brachytherapy (<10 years)

Institution	# Cases	Follow-Up (Months)	% Local Recurrence
FDA Trial	43	**66**	**0%**
ASBS Registry	400	**60**	**3.2%**
NY Hospital/Cornell (DCIS)	48	**60**	**6.3%**
University of Wisconsin	26	**48.5**	**3%***
ASBS Registry Trial	1449	**51**	**2.6%**
MUSC	99	**46**	**3.1%**
Texas Cancer Center	573	**31**	**1.0%**
Rush	70	**26**	**6%**
WBH	80	**24**	**2.9%**
VCU	483	**24**	**1.2%**
Tufts/VCU/NEMC	28	**19**	**0%**
Single Institution Experiences	1000	**2-12**	**0-3%**
Totals	**3899**	**2-66**	**0-6.3%**

*High-risk patients

Applicator APBI

- **ASBS MammoSite Registry Trial**
  - 1449 patients prospectively entered
  - 2002-2004
  - Single-lumen catheter (no longer utilized)
  - Final analysis (Shah et al, Ann Surg Onc 2013)
    - Median follow-up: 63 months
    - 5-year local recurrence: *3.8%*
    - 5-year local recurrence DCIS: *4.1%*
    - 5-year local recurrence IDC: *3.7%*
    - 91% excellent/good cosmesis

Applicator APBI

	All		Invasive Cases		DCIS Cases	
Number of breasts (All breasts)	N=1449 5-Yr N (%)	5-yr Actuarial Rate	N=1255 5-Yr N (%)	5-yr Actuarial Rate	N=194 5-Yr N (%)	5-yr Actuarial Rate
Ipsilateral breast tumor recurrence	41 (2.8)	3.8%	34 (2.7)	3.7%	7 (3.6)	4.1%
TR/MM failure	12 (0.8)	1.1%	8 (0.6)	0.9%	4 (2.1)	2.1%
Elsewhere failure	29 (2.0)	2.8%	26 (2.1)	2.9%	3 (1.5)	2.1%
Axillary failures	9 (0.6)	0.8%	8 (0.6)	0.8%	1 (0.5)	0.6%
Distant metastases	26 (1.8)	2.4%	25 (2.0)	2.7%	1 (0.5)	0.6%
Disease-free survival	---	86.1%	---	85.2%	---	92.2%
Cause-specific survival	---	98.7%	---	98.2%	---	99.4%
Overall survival	---	92.4%	---	91.0%	---	96.9%
Contralateral failure	22 (1.5)	2.1%	20 (1.6)	2.2%	2 (1.0)	1.3%

Applicator APBI

- **ASBS MammoSite Registry Trial**
  - Final toxicity analysis (Shah et al, Brachytherapy 2013)
  - Rate of any complication:
    - 24% at 1 year
    - 39% at any time
    - Similar to WBI
  - Noninfectious
    - 15% at 1 year
    - 29% at any time
  - Symptomatic seroma: 13.4% at any time
  - Fat necrosis: 2.5%
  - Infection: 9.6%
  - Telangiectasia: 13.0%

Applicator APBI — Cosmesis

Table 2
Cosmetic outcomes

Visit (mo)	N	Excellent/good cosmesis	N	First 400 cases—excellent/good cosmesis
12	1018	963 (94.6)	277	260 (93.9)
24	859	806 (93.8)	234	217 (92.7)
36	768	716 (93.2)	211	192 (91.0)
48	681	620 (91.0)	182	163 (89.6)
60	484	442 (91.3)	155	136 (87.7)
72	357	323 (90.5)	108	89 (82.4)
84	331	300 (90.6)	96	84 (87.5)
Last visit ≥ 72 months	445	403 (90.6)	135	118 (87.4)

Published Results: Contura MLB

Author/Institution/Title	# of Patients	Publication Status	Journal
Cuttino, et al./VCU – Massey Cancer Ctr A COMPARISON OF SKIN AND CHEST WALL DOSE DELIVERED WITH MULTI CATHETER (MC), CONTURA MULTI LUMEN BALLOON (CMLB), AND MAMMOSITE (MS) BREAST BRACHYTHERAPY	171	Published – November 2010	IJROBP (Red Journal)
Vicini, Arthur, Todor, Julian, Lyden DOSIMETRIC IMPORVEMENTS IN BALLOON BASED BRACHYTHERAPY USING THE CONTURA® MULTI-LUMEN BALLOON (MLB) CATHETER TO DELIVER ACCELERATED PARTIAL BREAST IRRADIATION	194	Published – March 2010	Contemporary Journal of Brachytherapy
Israel, et al./The Breast Center – Marietta, GA INITIAL SURGICAL EXPERIENCE EVALUATING EARLY TOLERANCE AND TOXITICY IN PATIENTS UNDERGOING ACCELERATED PARTIAL BREAST IRRADIATION USING THE CONTURA MULTI LUMEN BALLOON BREAST BRACHYTHERAPY CATHETER	46	Published – November 2009	The American Surgeon
Brown, et al./ WellStar Kennestone A DOSIMETRIC COMPARISON OF THE CONTURA MULTI LUMEN BALLOON (C-MLB) BREAST BRACHYTHERAPY CATHETER VERSUS THE SINGLE LUMEN MAMMOSITE (MS) BALLOON DEVICE IN PATIENTS TREATED WITH ACCELERATED PARTIAL BREAST IRRADIATION AT A SINGLE INSTITUTION	33	Published – September 2010	Brachytherapy
Arthur, Vicini, Todor, Julian, Lyden IMPROVEMENTS IN CRITICAL DOSIMETRIC ENDPOINTS USING THE CONTURA MULTI LUMEN BALLOON (MLB) TO DELIVER ACCELERATED PARTIAL BREAST IRRADIATION: PRELIMINARY DOSIMETRIC FINDINGS OF A PHASE IV TRIAL	144	Published – April 2010	IJROBP (Red Journal)
Wilder, et al./ Irvine, CA CONTURA AND MAMMOSITE BRACHYTHERAPY IN 'INTERMEDIATE-RISK' BREAST CANCER PATIENTS	52	Accepted – October 2009	The Breast Journal
Wilder, et al./ Irvine, CA PRELIMINARY RESULTS WITH ACCELERTED PARTIAL BREAST IRRADIATION IN HIGH-RISK BREAST CANCER PATIENTS	204	Accepted – October 2009	Brachytherapy
McLaughlin et al./ WellStar Kennestone INITIAL RADIATION EXPERIENCE EVALUATING EARLY TOLERANCE AND TOXICITIES IN PATIENTS UNDERGOING ACCELERATED PARTIAL BREAST IRRADIATION USING THE CONTURA MULTI-LUMEN BALLOON (MLB) BREAST BRACHYTHERAPY CATHETER	41	Published – April 2009	Brachytherapy
Wilder, et al./ Irvine, CA A CONTURA CATHETER OFFERS DOSIMETRIC ADVANTAGES OVER A MAMMOSITE CATHETER THAT INCREASE THE APPLICABILITY OF ACCELERATED PARTIAL BREAST IRRADIATION	45	Published – October 2009	Brachytherapy

SAVI 4.5 Year Comparison

	SAVI 4.5 yr ASTRO 2013[I]	ASBS MammoSite Registry 5 yr Ann Surg Oncol 2013[ii]
# of Pts/Follow-up	101 pts/54 mo	1449 pts/63 mo
Telangiectasia	2.0%	Not reported
Seroma	2.0%	13.4%
Fat necrosis	0.0%	2.5%
Recurrence	2.0%	2.8%

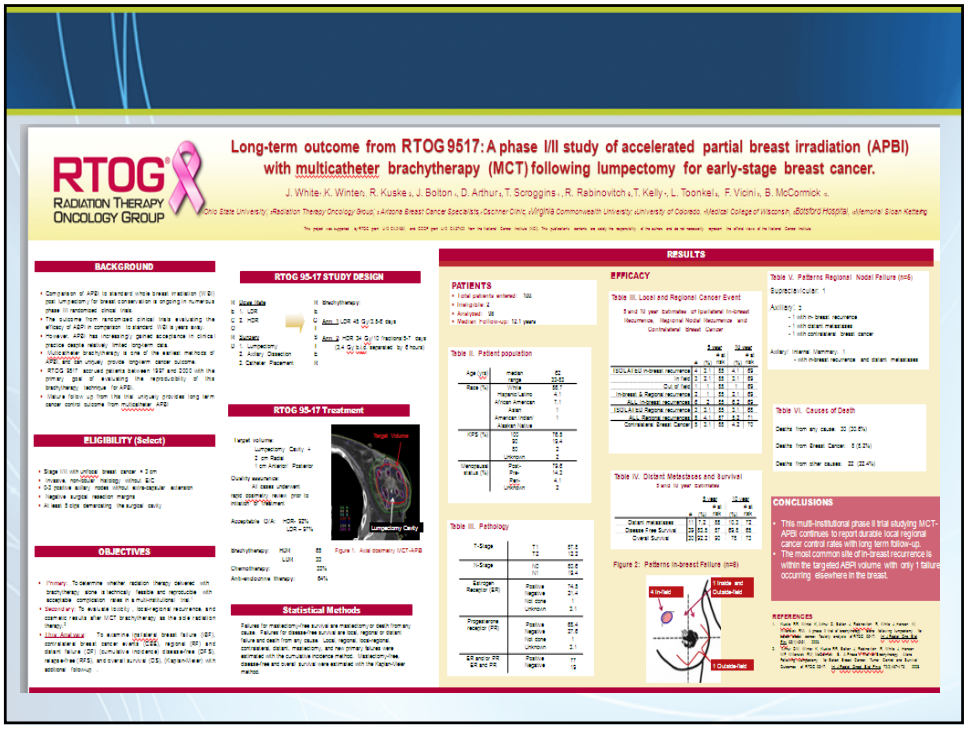
iYashar C, et al. Outcomes for APBI with Strut-based Brachytherapy: 101 Patients at 4.5 Years Median Follow Up. Poster presentation at the 55th Annual Meeting of the American Society for Radiation Oncology, September 22–25, 2013.
iiShah C, et al. Treatment Efficacy with Accelerated Partial Breast Irradiation (APBI): Final Analysis of the American Society of Breast Surgeons MammoSite(®) Breast Brachytherapy Registry Trial. Ann Surg Oncol. 2013 Oct; 20(10): 3279-85.

SAVI: Favorable Toxicity Rates at 4.5 Years

	Yashar, et al ASTRO 2013[i]	Hong, et al ASTRO 2013[ii]	Yashar, et al IJROBP 2010[iii]
# of Pts/Follow-up	101 pts/54 mo	576 pts/36 mo	102 pts/22 mo
Hyperpigmentation	0%	0.2%	-
Telangiectasia	2%	1%	1.9%
Symptomatic seroma	2%	3.1%	1.9%
Fat necrosis	0%	0.7%	1.9%

Toxicity rates defined by CTCAE v.3

iYashar C, et al. Outcomes for APBI with Strut-based Brachytherapy: 101 Patients at 4.5 Years Median Follow Up. Poster presentation at the 55th Annual Meeting of the American Society for Radiation Oncology, September 22–25, 2013.
iiHong R, et al. Outcomes for APBI with the Strut-based Brachytherapy Applicator in 576 Patients. Poster presentation at the 55th Annual Meeting of the American Society for Radiation Oncology, September 22–25, 2013.
iiiYashar C, Scanderbeg D, et al. Initial Clinical Experience with the Strut-Adjusted Volume Implant (SAVI) Breast Brachytherapy Device for Accelerated Partial-Breast Irradiation (APBI): First 100 Patients with More than 1 Year of Follow Up. Int J Radiat Oncol Biol Phys. 2011 Jul 1; 80(3): 765-70.



Long-term outcome from RTOG 9517: A phase I/II study of accelerated partial breast irradiation (APBI) with multicatheter brachytherapy (MCT) following lumpectomy for early-stage breast cancer.

RTOG Radiation Therapy Oncology Group

J. White, K. Winter, R. Kuske, J. Bolton, D. Arthur, T. Scroggins, R. Rabinovitch, T. Kelly, L. Toonkel, F. Vicini, B. McCormick

BACKGROUND

RTOG 95-17 STUDY DESIGN

RTOG 95-17 Treatment

ELIGIBILITY (Select)

OBJECTIVES

Statistical Methods

RESULTS

PATIENTS

EFFICACY

Table II. Patient population

Table III. Pathology

Table III. Local and Regional Cancer Event

Table IV. Distant Metastases and Survival

Table V. Patterns Regional Nodal Failure (n=6)

Table VI. Causes of Death

Figure 2: Patterns in-breast Failure (n=6)

CONCLUSIONS

- This multi-institutional phase II trial studying MCT-APBI continues to report durable local regional cancer control rates with long term follow-up.
- The most common site of in-breast recurrence is within the targeted ABPI volume with only 1 failure occurring elsewhere in the breast.

REFERENCES

RTOG 95-17: Treatment Details

Brachytherapy:

Arm 1:

- LDR 45 Gy/3.5–6 days

Arm 2:

- HDR 34 Gy/10 fractions/5–7 days (3.4 Gy twice daily separated by 6 hours)

Patients

- Total patients entered: 100
- Ineligible: 2
- Analyzed: 98
- Median follow-up: 12.1 years

RTOG 95-17: Efficacy

			5 year		10 year	
	#	(%)	# at risk		(%)	# at risk
ISOLATED in-breast recurrence	4	3.1	84		4.2	68
In field	3	2.1	85		3.1	69
Out of field	1	1.0	85		1.0	69
In-breast & regional recurrence	2	1.0	84		2.1	68
ALL In-breast recurrences	6	4.1	86		6.2	69
ISOLATED regional recurrence	3	3.1	84		3.1	68
ALL regional recurrences	5	4.1	87		5.2	71
ANY local-regional recurrence	9	7.2	84		9.3	68
Contralateral breast cancer	5	3.1	88		4.2	70

10-Year Published Data WBI vs. APBI With Interstitial

- Matched Pair Analysis – Beaumont/F. Vicini
  - 199 patient clinical match
    - Tumor size, nodal status, age, margins, ER status, Tam
  - Comparing WBRT to APBI (interstitial)
  - Results
    - Local control rates: WBI = 4%, APBI = 5%

Int. J. Radiation Oncology Biol. Phys., Vol. 74, No. 2, pp. 447–452, 2009

APBI — Phase III Trials

- Ten Phase III trials
- Four PBI techniques:
  - Brachytherapy RT (Interstitial/MammoSite)
    - NSABP B-39/RTOG 0413
    - GEC-ESTRO Working Group
    - National Institute of Hungary
  - Single-Fraction Intra-Operative RT
    - European Institute of Oncology
    - University College of London
  - Fractionated External Beam RT
    - NSABP B-39/RTOG 0413
    - National Institute of Hungary
    - Canadian Phase III trial
    - Medical Research Council-UK
    - Barcelona
    - Florence
    - Spain

National Institute of Oncology
- Budapest, Hungary -

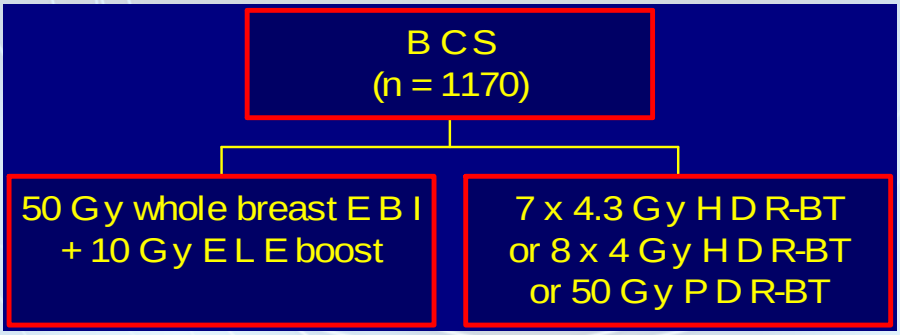
- Schema:
  - Arm I: External Beam Whole Breast RT
    - 50 Gy in 25 fractions
  - Arm II: Partial Breast Irradiation
    - Brachytherapy: 5.2 Gy x 7
  - 258 enrolled (Trial Closed)
  - Trial closed to support GEC-ESTRO Phase III trial

National Institute of Oncology
- Budapest, Hungary -

- Results/New Data:
  - Presented at ESTRO 2012
  - 10-year update (median f/u: 120 months)
  - No differences noted in local failure
    - 5.9% vs. 5.1%
  - 81% E/G cosmesis with APBI vs. 63% with WBI

Radiother Oncol 2013
Jun 3
S0167-8140(13)00220-X

GEC-ESTRO — Multicenter Phase III Trial



Status:
Activated May 2004
Accrual:
1195 enrolled, 2009 (closed)

GEC-ESTRO — Multicenter Phase III Trial

Presented at ESTRO 2012

No differences in toxicity at 5 years!
Outcome data not yet reported

Results should be available on efficacy in 2014

NSABP B-39/RTOG 0413
Phase III APBI Trial

Eligible Patients with Lumpectomy

RANDOMIZED

Whole Breast Irradiation after Adjuvant Chemotherapy

50 Gy (2.0 Gy/fraction) or
50.4 Gy (1.8 Gy/fraction) to whole breast, followed by optional boost to ≤60 Gy

Partial Breast Irradiation prior to Adjuvant Chemotherapy

For a total of 10 treatments given on 5 days over 5 to 10 days:

34 Gy in 3.4 Gy fractions
Interstitial Brachytherapy or
MammoSite Balloon Catheter
or
38.5 Gy in 3.85 Gy fractions
3D Conformal External Beam

NSABP B-39/RTOG 0413

- Open:
  - March 21, 2005
- Accrual:
  - Completed May 2013: *4216*
- Participating Sites:
  - 78 – NSABP
  - 142 – RTOG/CTSU
- PBI Technique:
  - 71.0%: 3D Conformal
  - 23.3%: MammoSite
  - 5.7%: Interstitial
  - 0.2%: SAVI (5 cases)
  - 0.1%: Contura (3 cases)

NSABP B-39/RTOG 0413

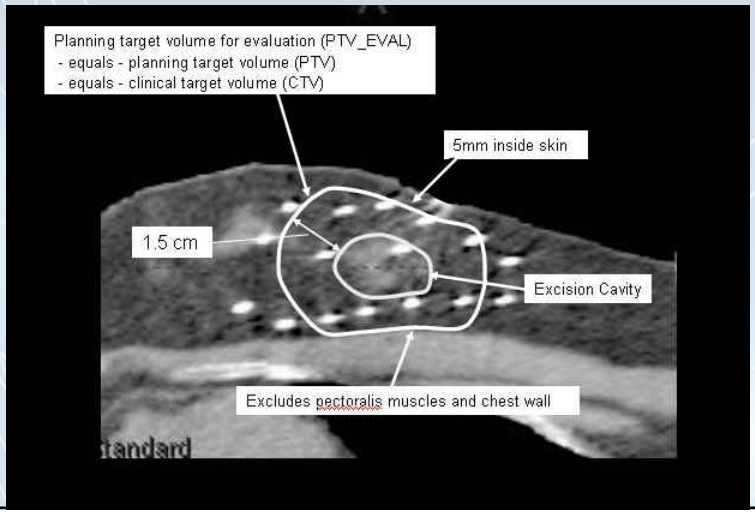
- Open:
  - March 21, 2005
- Accrual:
  - Completed May 2013: *4216*
- Participating Sites:
  - 78 – NSABP
  - 142 – RTOG/CTSU
- PBI Technique:
  - 71.0%: 3D Conformal
  - 23.3%: MammoSite
  - 5.7%: Interstitial
  - 0.2%: SAVI (5 cases)
  - 0.1%: Contura (3 cases)

NSABP B-39/RTOG 0413
- Current Status -

- **Toxicity:**
  - Adverse events, including toxicities, second primary cancers and deaths monitored continuously (q/month)
  - Progress reports presented to Data Monitoring Committee (DMC) at 6-month intervals (reviewed internally monthly)
    - To date, DMC has found no reason for concern
    - Majority of dermatologic toxicities, pain, fibrosis-cosmesis, infection, etc., have been Grade 1 and 2 (<2% grade III)
- *Int J Radiat Oncol Biol Phys*. 2010 May 1;77(1):317

Multicatheter Brachytherapy Target Volume Definitions

CTV = PTV = PTV_EVAL = 1.5-cm expansion of cavity
(5 mm within skin and bounded by posterior breast extent)



Multicatheter Brachytherapy

Dose: 3.4 Gy bid x 5 days – 34 Gy

Normal tissue: <60% of the whole breast reference volume should receive ≥50% of the prescribed dose

Dose homogeneity:
Volume of tissue receiving:
150% (V150) of the prescribed dose ≤70 cc
200% (V200) of the prescribed dose ≤20 cc

Dose Homogeneity Index will be ≥ .75
DHI = the volume ratio (1 – V150/V100)

Multicatheter Brachytherapy

Acceptable:

- Dose volume analysis of target will:
  - Confirm that ≥90% of the prescribed dose is covering ≥90% of the PTV_EVAL
- Dose homogeneity criteria met
- Critical normal tissue DVHs within 5%
- Dose delivered over 5–10 days

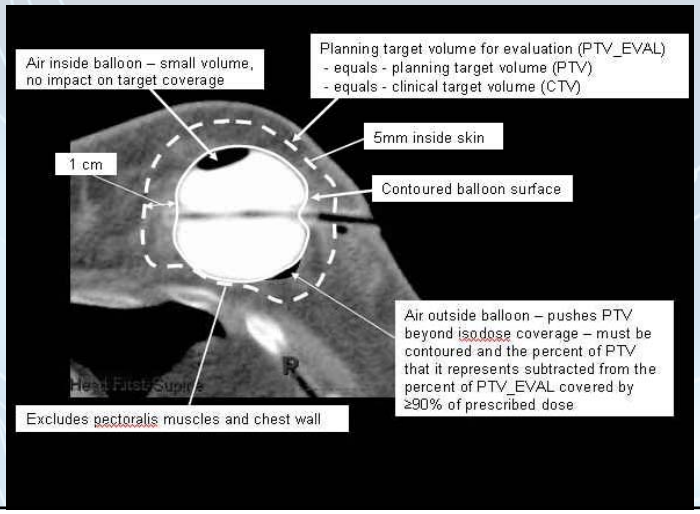
Multicatheter Brachytherapy

Unacceptable:

- Dose volume analysis of the target volume
  - <90% of the prescribed dose and/or <90% coverage of the PTV_EVAL
- Dose homogeneity criteria are not met
- Critical normal structure DVH exceeds 5%
- Dose delivered over a period of time extending >10 days

MammoSite Brachytherapy Target Volume Definitions

CTV = PTV = PTV_EVAL = 1.0-cm expansion of cavity
(5 mm within skin and bounded by posterior breast extent)



MammoSite Brachytherapy

Dose: 3.4 Gy bid x 5 days – 34 Gy

Normal tissue:
- <60% of the WBRV should receive ≥ 50% of the prescribed dose

Tissue-balloon conformance:
- measure trapped air

Balloon symmetry:
- physical geometry will not deviate >2 mm

Minimal balloon surface-skin distance:
- ideally ≥7 mm,
- if 5–7 mm, then confirm skin dose <145%

Dose homogeneity:
- Volume of tissue receiving:
  - 150% (V150) of the prescribed dose ≤50 cc
  - 200% (V200) of the prescribed dose ≤10 cc

MammoSite Brachytherapy

Acceptable:

- All four parameters must be met
- Dose volume analysis of target will:
  - Confirm that ≥90% of the prescribed dose is covering ≥90% of the PTV_EVAL
  - The volume of trapped air/fluid will be accounted for:

%PTV_EVAL coverage – [(vol trapped air/vol PTV_EVAL) x 100] = ≥ 90%

- Critical normal tissue DVHs within <5%
- Dose delivered over 5–10 days

MammoSite Brachytherapy

Unacceptable:

- Any of the parameters not met
- Dose volume analysis of the target volume
  - <90% of the prescribed dose and/or <90% coverage of the PTV_EVAL
  - The volume of tapped air/fluid will be accounted for as previous
- Critical normal structure DVH exceeds 5%
- If dose delivered over a period of time extending >10 days

IORT?

- Radiation delivered without final pathology
  - Re-excision required?
  - Nodal radiation required?
- Dedicated equipment in the O/R
- Scheduling surgeon and radiation oncologist
- Lack of dosimetric Q/A
  - Tissue to applicator conformance?
  - True margin/target coverage

Brachytherapy Alternative to Intra-op RT? 2-Day Device-based APBI (4 fractions)

- Post-pathology patient selection
- Image-guided treatment with recordable parameters of quality
- Familiar technique, no added cost to implement
- Established RTOG/NSABP sites active in breast brachytherapy

Four-Year Results Using Balloon-Based Brachytherapy to Deliver Accelerated Partial Breast Irradiation With a Two-Day Dose Fractionation Schedule

Ben Wilkinson, MD
Frank A. Vicini, MD, FACR

Methods

- Prospective, Phase II trial, 45 patients, activated Jan 2004
- APBI using MammoSite RTS (single-lumen)
- Incl: age >40 years, T <3 cm, N+ <3, negative margin, skin distance >7 mm
- Excl: >3 LN, ECE, prior BrCa, DM, EIC, Collagen Vasc Dz
- 2800 cGy in 4 fractions over 2 days, Rx to 1 cm from surface
- Dwell positions: single (n=35), three (n=9), five (n=1)
- Primary endpoints: OS and LR
- Secondary endpoints: acute/chronic toxicity, adverse events, RNF, DM, DFS, and CSS

Results

- Median age 66 (range 48–83), size 0.6 cm (0.2–2.3 cm), 5% LN + (n=2), median f/u: 3.7 years (2.4–7.0 years)
- Toxicities (all chronic toxicities ≤ grade 2)
- Fat necrosis and seroma associated with incr. balloon fill vols ($P = 0.01$)
- Rib fx (n=3) not associated with D_{max} rib ($P = 0.31$); 2 fx patients D_{max} ≥160% Rx

	Erythema/ Hyperpigmentation		Induration (Fibrosis)		Fat Necrosis		Seroma		Rib Fx
	Gr 1	Gr 2	Gr 1	Gr 2	Gr 1	Gr 2	Gr 1	Gr 2	Gr 2
Acute	53%	9%	4%	0%	0%	0%	7%	0%	4%
3 yrs	27%	2%	32%	2%	29%	0%	51%	7%	7%
4 yrs	18%	2%	44%	7%	18%	0%	42%	0%	0%

Results

- Length of implant: 4.8 days (range 3–10 days) with current trial vs. 8.6 days (range 6–14 days) institutional average for typical 5-day fractionation pattern (79% reduction) ($P < 0.001$)
- Cosmesis: 65% good + 31% excellent = 96% overall good or excellent cosmetic result
- Clinical outcomes: (no local/regional failure, 2 patients with DM)

IBTR	RNF	DM	DFS	CSS	OS
0%	0%	4%	96%	100%	93%

Limitations

- Small sample size, non-randomized
- Short follow-up

Conclusions

- Similar clinical outcomes vs. historical reports of APBI using 5-day fractionation
- Acceptable rates of chronic toxicity
- 7-year data recently analyzed: No change!!!!

Update on Phase II "Overnight" Study

PIs: Khan, Arthur, Vicini
Sponsor: CR Bard (Murray Hill, NJ)

- 3 cohorts of 30 patients (n=90) with predefined stopping criteria for toxicity
- 4 fractions (7 Gy x 4), 3 fractions (8.25 Gy x 3), 2 fractions (10.25 Gy x 2)
- Primary endpoint: Assuming true LRR is 3%, upper limit of a 95% confidence interval (calculated using the Wilson method) will exclude 10% rate with 90 patients
- 30 women on cohort 1, median f/u 28 months
- 30 women on cohort 2, >6 months f/u
- No > grade 2 toxicity events, no safety events

Contura Overnight Trial Study Design

- Acceptable rates of toxicities in each 30 patient cohort includes:
  - ≤10 in-breast complications > Grade II
    i.e.,
    Acute skin toxicity
    Severe fibrosis
    Telangiectasia
    Infection
    Symptomatic fat necrosis
    Breast pain requiring narcotics
  AND
  - ≤1 non-breast complication > Grade II
    i.e.,
    Rib fracture
    Acute pneumonitis

Study Endpoints

Primary: Local control

- Success if locoregional failure rate is ≤10% at 3 years

Secondary:

- Toxicity: acceptable rates (as previously stated)
- Cosmesis: good/excellent rates exceed 80% at 3 years

Dosimetric Criteria

- Target coverage: 95/95 (with 5% relaxation)
- V150: ≤40 cc
- V200: ≤10 cc
- Max skin dose: 100% PD
- Max rib dose: 100% PD

Future Goals

- Continue and complete accrual to Overnight trial
- Randomized phase II or III in NRG with toxicity/QOL endpoints?
- Readjust dose to reflect 50 Gy = 6.25 Gy x 4
- "Suitable" patients are eligible
- Conduct Registry Trial:
  - Any intracavitary device that meets dosimetric criteria!
  - ASTRO suitable patients only

Thank You!