Breast Brachytherapy in the United States: Utilization Patterns in Older Patients after Breast-conserving Surgery

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Purpose/Objective(s):

- Though initial studies of treatment efficacy are promising, randomized Phase III data have yet to mature, and the ideal patient subgroup to receive brachytherapy alone remains controversial.

- Brachytherapy use alone after BCS in the community setting is ongoing, but its actual frequency of use has not been previously studied.
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- Additionally, the clinical and nonclinical factors influencing its use are unknown.
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- We sought to characterize patterns and predictors of breast brachytherapy use in a retrospective, population-based study of older women treated with BCS.

Materials/Methods:

- We used a nationwide database of Medicare beneficiaries (age >65) with private supplemental insurance (MarketScan Medicare Supplemental).
- Claims codes identified patients treated with **BCS followed by brachytherapy alone vs. external beam radiotherapy** for an incident breast cancer diagnosed between 2001 and 2006.
- Logistic regression modeled predictors of brachytherapy use alone, including demographic, clinical, socioeconomic, and provider variables.

Results:

6,854 women

- Mean age was 74 ± 6.
- Frequency of brachytherapy use alone increased over time (<1% in 2001, 1% in 2002, 3% in 2003, 5% in 2004, 8% in 2005, and 10% in 2006; p<0.001),
- **89% of brachytherapy patients receiving balloon-based** treatment by 2006.
- Additionally, brachytherapy use alone was more likely in women who had lymph node-negative disease (OR, 2.04; 95%CI, 1.12–3.73),
- did not receive chemotherapy (OR, 1.77; 95% CI, 1.07–2.94),
- or received an axillary surgery (OR, 1.71; 95% CI, 1.22–2.40).

- Nonclinical factors also affected utilization, including non-HMO insurance (OR, 1.80; 95%CI, 1.25–2.61); or residence in metropolitan areas (OR, 1.79; 95% CI, 1.12–2.86),
- areas with a low density of radiation oncologists (OR, 1.87; 95% CI, 1.16–3.04),
- or high density of surgeons (OR, 1.70; 95%CI, 1.02–2.82).

- Patients living in the West, Midwest, and South were more likely to receive brachytherapy alone compared to the Northeast (OR, 3.48; 95% CI, 1.89–6.39; 1.70, 0.96–3.02; 2.547, 1.38–4.43, respectively).

Conclusions:

Despite ongoing debate, breast brachytherapy is being used as sole radiation treatment after BCS with increasing frequency across much of the United States.

Along with clinical factors, socioeconomic, geographic, and provider characteristics strongly influence utilization.

Five-year Analysis of Treatment Efficacy and Cosmesis by the American Society of Breast Surgeons MammoSite Breast Brachytherapy Registry Trial in Patients Treated with Accelerated Partial Breast Irradiation (APBI)

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Purpose/Objective(s):

Five-year data on treatment efficacy and cosmetic results for patients enrolled on the American Society of Breast Surgeons MammoSite breast brachytherapy registry trial.

Materials/Methods:

- A total of 1,440 patients (1,449 cases) with early-stage breast cancer undergoing breast conserving therapy were treated with the MammoSite device to deliver accelerated partial breast irradiation (APBI)

(34 Gy in 3.4 Gy fractions).

- 1,255 cases (87%) had invasive breast cancer (IBC) (median size = 10 mm)
- 194 cases (13%) had DCIS (median size = 8 mm).

- Median **follow-up** for all surviving patients was 49 months.
- 801 cases (48%) have been followed for at least 48 months,
- 317 cases (22%) for 60 months.

- Follow-up was complete through March 5, 2009.

Results:

- **38 cases (2.6%)** developed an ipsilateral breast tumor recurrence (IBTR) for a 5-year actuarial rate of

  3.84% (3.84% for IBC and 3.75% for DCIS).

- 32 IBTRs (84%) were invasive and 6 (16%) were DCIS.

- No variable was associated with IBTR including patient age<50 ($p = 0.6305$), margins ($p = 0.9997$), tumor size ($p = 0.9997$), or positive nodes ($p = 0.8251$).
- 9 patients (0.6%) developed an axillary failure.

- The percentage of breasts with good/excellent cosmetic results was:

  36 months (n = 753) - 93.2%
  48 months (n = 608) - 90.6%
  60 months (n = 264) - 87.9%.

- The development of an infection (p = 0.0104), and skin spacing (p = 0.0252) were associated with cosmetic results.

- A subset analysis of the first 400 consecutive cases enrolled was performed (352 with IBC, 48 DCIS).

- With a median follow-up of 58 months, the 5-year actuarial rate of IBTR was **3.26%** (3.69% for IBC and 0.0% for DCIS).

Conclusions:

- Treatment efficacy and cosmesis 5 years after treatment with APBI using the MammoSite device are good and similar to those reported with other forms of APBI or whole-breast irradiation with similar follow-up and risk factors for IBTR.
- To our knowledge, this represents the largest group of patients treated with contemporary APBI with 5-years of follow-up.

Interstitial High Dose Rate (HDR) Brachytherapy for Early Stage Breast Cancer: Median 6 Year Followup of 214 Cases using Multi-catheter Technique

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Purpose/Objective(s):

- External Beam Radiation Therapy (EBRT) has been the standard of care for breast conservation radiation therapy.

- Recent data indicates that Interstitial Implant and **High Dose Rate (HDR) radiation** afterloading compares **very favorably** to EBRT in selected patients.

Materials/Methods:

- Tis, T1, and T2 tumors measuring ≤ 4 cm,
- negative surgical margins,
- ≤ 3 axillary lymph nodes,
- were judged to be candidates for interstitial implant.

- Implants were performed under Stereotactic Mammographic guidance with conscious sedation and local anesthesia.
- The implants were placed with a custom designed template using from 3 to 8 planes, and 8 to 62 needles.

- Catheters were subsequently threaded thru the needles, and the needles removed.
- Catheter spacing was 1.0 to 1.5 cm.
- Radiation Treatment planning was performed using CT Scanning and the Plato System.
- Treatment volumes ranged from 25 cm^3 to 359 cm^3.
- HDR treatment was given using the Nucletron afterloading system.
- The breast implant volume received 34 Gy in 10 fractions prescribed to the Planning Target Volume, given BID over 5 days.

Results:

2000 - 2009

- 214 patients - HDR brachytherapy,
- The procedure was well tolerated,
- No patient required hospital admission,
- Median **follow-up - 72 months** (range 6-120 months),
- **Local recurrence** occurred in **4.2%** (9/214).

Cosmetic results were good to excellent in 89.7% (192/214) of the patients.

There were no infections.

- Wound healing complications developed in 3.7% (8/214).
- 3 of these patients had received anthracycline based chemotherapy.
- The other 5 had large (> 200 cm3) implant volumes, catheter spacing of 1.5 cm, and V-150% of > 30%.
- 2 patients healed after 6 months of conservative treatment.
- Surgery was required in 6 patients who developed fat necrosis.

Conclusions:

- With median 72 month follow-up, Breast Conservation radiation therapy utilizing Interstitial Multi-Catheter

  HDR Implant has yielded local recurrence rates and cosmetic results which compare favorably to EBRT in selected patients.
- Treatment with anthracycline based chemotherapy, large (>200 cm3) implant volumes, and V-150% >30%, appear to be relative contraindications to Interstitial HDR Implant.
- Finally, catheter spacing of 1 cm yielded optimal dosimetry and minimized complications.

Compared to MammoSite technique, the Interstitial Multi-Catheter method offers greater flexibility of radiation delivery.

Advantages include:

- no concern regarding surgical cavity shape irregularities,
- balloon conformality to surgical cavity,
- balloon rupture,
- balloon movement,
- air gaps,
- skin balloon proximity to skin,
- balloon shape distortion,
- and catheter movement within the balloon.

A Contura Catheter Offers Dosimetric Advantages Over a MammoSite Catheter that Increase the Applicability of Accelerated Partial Breast Irradiation

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Hypothesis

The hypothesis of this study is that a Contura catheter offers dosimetric advantages over a MammoSite catheter

that increase the applicability of accelerated partial breast irradiation.

Methods

- 182 women with early-stage breast carcinomas were treated with post-lumpectomy brachytherapy

Contura® multi-lumen catheter (n=45)
or a MammoSite® single-lumen catheter (n=137).

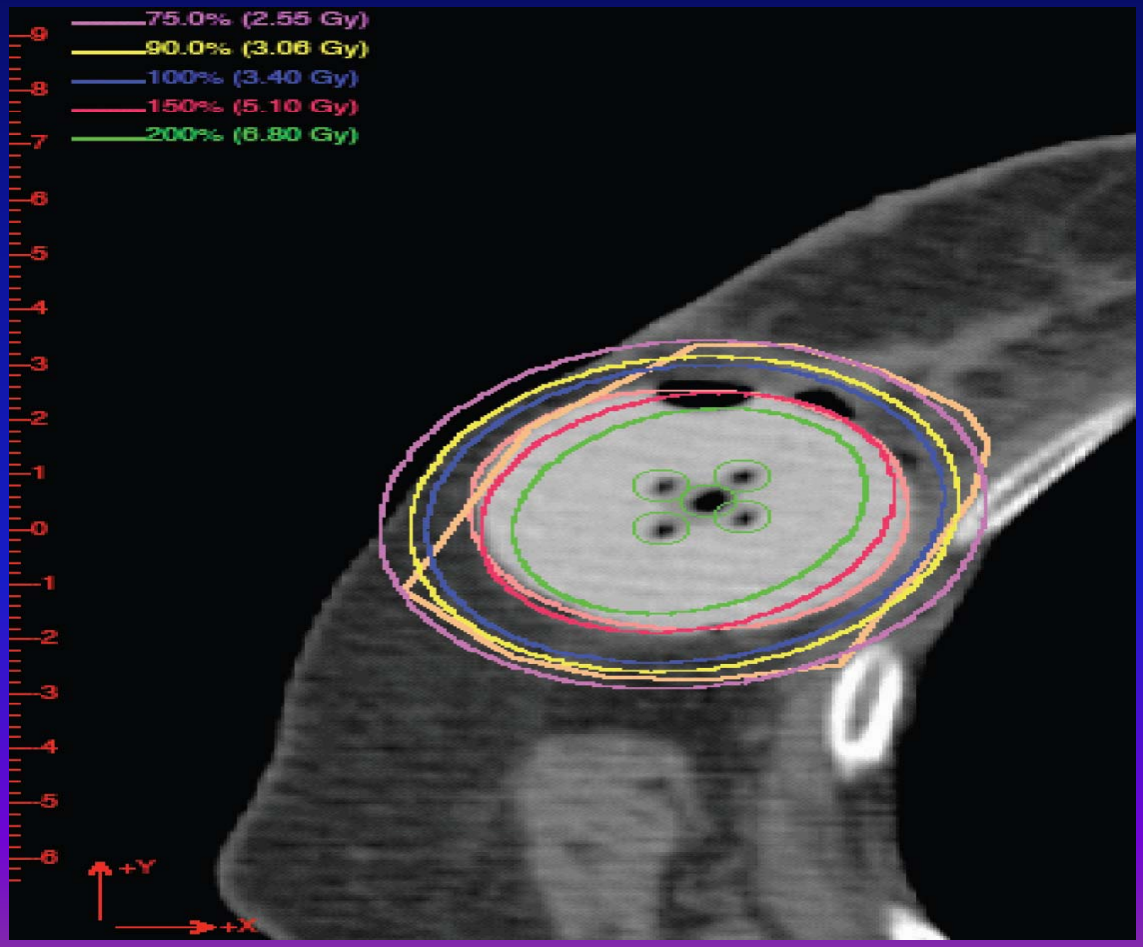
- Hypothetical MammoSite catheter treatment plans were created for the Contura patients.
- Treatment planning goals were to:
- 1) avoid a radiation “hot spot” in the skin,
- 2) have only a small air/fluid pocket next to the balloon.
- Median follow up was 16 months.

Contura
Multi-Lumen Catheter

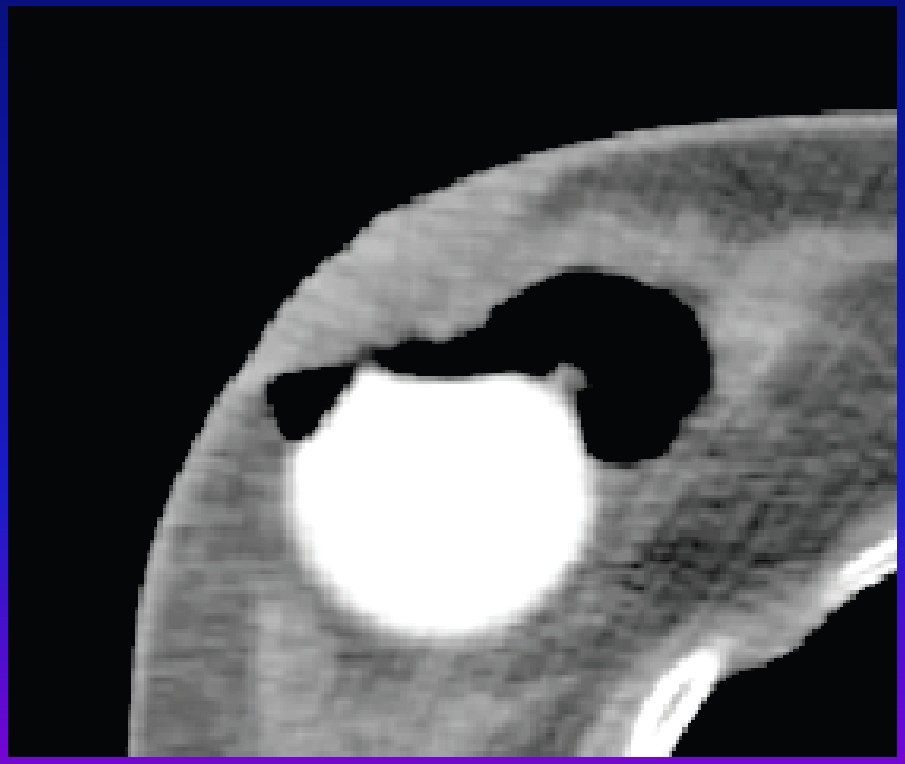

Contura
Multi-Lumen Balloon - MLB
5 Treatment Lumens
Vacuum Ports
Orientation Line
Applicator
Vacuum Luer
Inflation Luer
Radiation Source Lumens
Stiffening Stylet

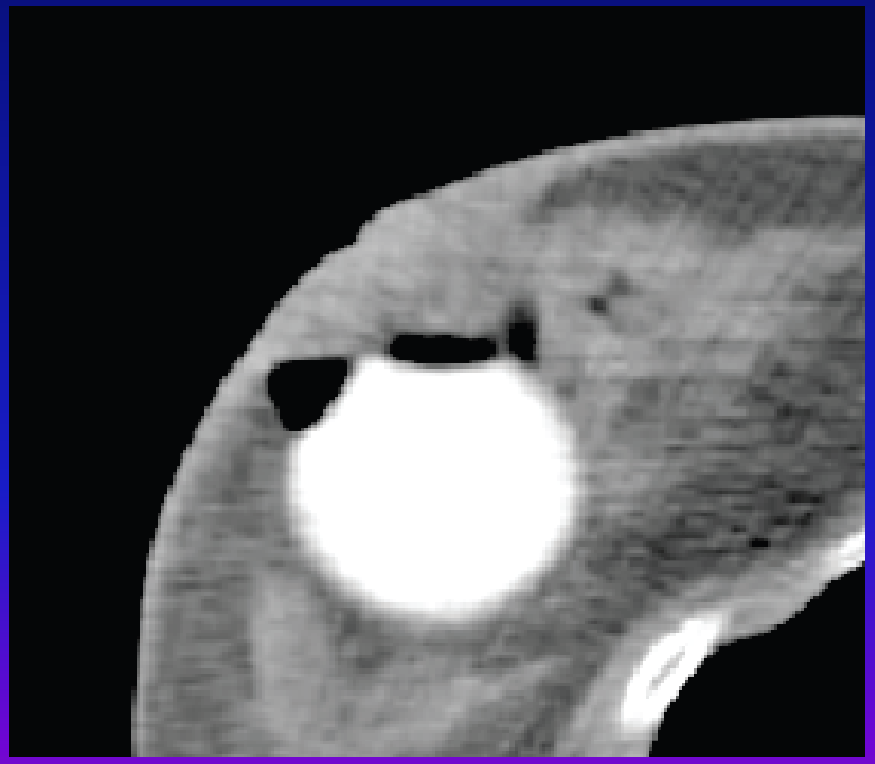
Two Main Advantages of a Contura Multi-Lumen Catheter for Accelerated Partial Breast Irradiation:

1) Avoidance of a Radiation Hot Spot in the skin



2) Suctioning Air/Fluid Adjacent to Balloon Brings Breast Tissue at Greatest Risk of Harboring Residual Tumor Cells Closer to Radiation Source Inside of Balloon



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Version 3.2
User: fizyk666
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Baloon 129.19 60040.96 297.78 510.12 1013.91 64871 64.700 3 Avoidance ROI
skin 21.99 110.86 61.39 63.02 18.44 21879 22.016 4 Avoidance ROI
pectoralis 20.16 142.02 63.22 66.48 23.51 46169 45.738 5 Avoidance ROI
rib 11.91 73.30 39.40 40.26 14.17 6724 6.768 6 Avoidance ROI
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PTV_EVAL 73.30 7052.27 129.19 141.27 60.42 100395 100.089 8 Planning target ... ROI
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Results

- 89 % (40/45) of Contura plans satisfied both treatment planning goals vs only 36% (16/45) of MammoSite plans ($p<0.0001$).
- A Contura catheter did not require explantation in 16% (7/45) of patients where balloon-to-skin spacing was only 3-6 mm and 11% (5/45) of patients where there was initially an air/fluid pocket >10% of the planning target volume for plan evaluation (PTV_EVAL).
- A MammoSite catheter was explanted in 10% of cases where the minimum balloon-to-skin distance was <7 mm and in 13% of cases where there was a large air/fluid pocket.

Conclusion

A Contura catheter provides important dosimetric advantages over a MammoSite catheter and does not require explantation in cases where balloon-to-skin spacing is only 3-6 mm

or

an air/fluid pocket next to the balloon is >10% of PTV_EVAL.

Consistent Skin and Rib Dose Reduction Using the Contura Multi-Lumen Balloon (MLB) Breast Brachytherapy Catheter: Preliminary Dosimetric Findings of a Phase II Trial

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Purpose/Objective(s):

Initial dosimetric findings in patients treated with the Contura Multi-Lumen Balloon (MLB) breast brachytherapy catheter to deliver accelerated partial breast irradiation (APBI) on a multi-institutional phase I/II registry trial are presented.

Materials/Methods:

- Patients were enrolled prior to catheter placement.
- CT-based 3D planning with dose optimization based on specific dosimetric goals was completed.
- APBI treatment of **34 Gy in 3.4 Gy fractions** was delivered.
- Dosimetric planning goals were set to reflect reported best anticipated outcome and lowest toxicity as experienced with a single lumen balloon.
- Specifically, skin thickness required to be <5mm (i.e.<145% of prescribed dose (PD)) and decreased toxicity when skin thickness and rib distance <7mm (i.e.<125% of PD).

- For this trial, dosimetric goals included >95% of PD covering >90% of the target volume

  while assuring that:

  max skin dose <125% of PD,

  max rib dose <145% of PD

  V150 < 50cc and V200 < 10cc.
- The ability to achieve these dosimetric goals using the Contura MLB in relationship to the balloons proximity to skin and rib was analyzed.

Results:

- To date, 100 cases have complete data sets available for review.
- Median age is 65.6 years.
- 25% had stage Tis, 66% with T1N0 and 9% with T2N0 (<3cm).
- Median tumor size was 1.2 cm.
- Utilizing the multi-lumen capabilities, all dosimetric criteria were met in 77% of cases.

- Evaluating dosimetric criteria individually:
  89% and 90% of cases met skin and rib dose criteria, respectively.
- In 96% of cases, target volume coverage goals were met,
- In 99%, dose homogeneity criteria of V150 and V200 were satisfied.
- In all cases when skin and rib distances were judged to be close, dosimetric improvements were documented.

- When skin thickness was 5mm -7mm (19), median skin dose was limited to 121% (74 - 131.5) of PD
- When < 5mm (12), median skin dose was 124.8% (100-134).
- When rib distance was <5mm (31), median rib dose was reduced to 135% (104-178) of PD.
- In those cases (10) when both skin thickness was < 7mm and distance to rib was < 5mm, median skin and rib dose were jointly limited to 120.6% and 140.1% of PD, respectively.

Conclusions:

- Dose delivered by single lumen balloon based brachytherapy is directly related to skin thickness and distance to rib.
- A multi-lumen design removes the reliance of dose on device placement geometry.
- Contura MLB catheter use produced potential improvements in dosimetric capabilities (i.e., reduced skin and rib doses and improved PTV_EVAL coverage) in most clinical scenarios and allowed safe treatment in a group of patients previously unable to be treated with balloon based brachytherapy.