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Optimal application of the Contura multilumen balloon breast brachytherapy catheter vacuum port to deliver accelerated partial breast irradiation

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ABSTRACT

PURPOSE: The impact of using the Contura multilumen balloon (MLB) (SenoRx, Inc., Irvine, CA) breast brachytherapy catheter's vacuum port in patients treated with accelerated partial breast irradiation (APBI) was analyzed.

METHODS AND MATERIALS: Data from 32 patients at two sites were reviewed. Variables analyzed included the seroma fluid (SF):air volume around the MLB before and after vacuum port use and on its ability to improve (*1*) the eligibility of patients for APBI and (*2*) dose coverage of the planning target volume for evaluation (PTV_EVAL) in eligible patients.

RESULTS: The median SF/air volume before vacuum removal was 6.8 cc vs. 0.8 cc after vacuum removal (median reduction in SF/air volume was 90.5%). Before vacuum port use, the median SF/air volume expressed as percentage of the PTV_EVAL was 7.8% (range, 1.9–26.6) in all patients. After application of the vacuum, this was reduced to 1.2%. Before vacuum port use, 10 (31.3%) patients were not considered acceptable candidates for APBI because the SF/air volume:PTV_EVAL ratio (SF:PTV) was greater than 10% (range, 10.1–26.6%; median, 15.2%). After vacuum port use, the median SF:PTV ratio was 1.6% for a median reduction of 91.5%. In addition, the percentage of the prescribed dose covering greater than or equal to 90% of the PTV_EVAL proportionally increased a median of 8% (range, 3–10%) in eligible patients.

CONCLUSION: Use of the Contura MLB vacuum port significantly improved the conformity of the target tissue to the balloon surface, leading to reproducible dose delivery and increased target volume coverage. In addition, application of the vacuum allowed the safe treatment of unacceptable patients with APBI.

Keywords: Breast-conserving therapy; Balloon brachytherapy; Contura

Introduction

Accelerated partial breast irradiation (APBI) continues to be explored as a potential alternative to deliver adjuvant radiation therapy after lumpectomy in selected low-risk patients undergoing breast-conserving therapy (BCT) (1). Catheter-based interstitial brachytherapy has been one of the APBI techniques most commonly used in the past. The MammoSite (MS) balloon applicator (Hologic Inc., Bedford, MA) was subsequently developed to help provide a less complex implant with the potential for greater reproducibility of radiation delivery compared with interstitial brachytherapy (2, 3).

The dosimetric capabilities of the original single-lumen MS device were highly dependent on its position within the breast as placed by the surgeon/radiation oncologist and on the conformity of the balloon to the surgical cavity relative

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to the skin surface and/or the rib cage. Because of its single central lumen geometry, the dose to the skin was primarily a direct function of the distance of the balloon surface to the skin. This potentially precludes patients from being treated by APBI secondary to a suboptimal skin distance. Additional limitations of the original device also included difficulties in adequately covering the target volume and in keeping hot spots (V_{150} and V_{200}) at acceptable levels.

The Contura multilumen balloon (MLB) (SenoRx, Inc., Irvine, CA) was developed with the goals of addressing these dosimetric limitations. With the addition of four additional lumens, the ability to alter the dose distribution and reduce the skin dose after device placement is possible. This provides an opportunity to overcome some of the restrictions related to (*1*) limited skin distance, (*2*) close chest wall/rib proximity, and (*3*) balloon asymmetry while concurrently achieving dosimetric planning goals (4, 5). The addition of multiple lumens offers the potential for improved dose delivery in patients presently managed with balloon-based brachytherapy as well as the ability to potentially treat cases that previously would have been excluded (6, 7).

In addition to the four extra treatment lumens for dose "shaping," the Contura also has a vacuum port with cavity access both proximal and distal to the balloon to assist both the surgeon and the radiation oncologist in removing fluid and/or air that has accumulated around the surface of the balloon. Because the prescribed dose (PD) with balloon-based APBI is set at 1.0 cm from the balloon's surface, this fluid–air collection can potentially reduce coverage of the target volume and/or render patients ineligible for APBI because the seroma fluid (SF)/air:planning target volume for evaluation (PTV_EVAL) volume ratio (SF/Air:PTV) exceeds 10% (a constraint established for eligibility in the National Surgical Adjuvant Breast and Bowel Project (NSABP) B39/Radiation Therapy Oncology Group (RTOG) 0413 Phase III trial of APBI vs. whole breast irradiation). This study addresses the impact of the use of this vacuum port on the ability of the Contura catheter both to improve the potential for patients to undergo APBI and its impact on dose coverage of the PTV_EVAL. A subset of patients treated on the Contura registry trial (a study designed to characterize the dosimetric advantages of the device) were analyzed if the vacuum port was used for treatment. These patients constitute the study population (7).

Methods and materials

The impact of the use of the vacuum port on the Contura MLB catheter on the ability to both improve the opportunity for patients to receive APBI and the impact on dose coverage of the PTV_EVAL was analyzed in a group of patients treated on the Contura registry trial. As reported in a previous manuscript, the Contura Registry Study was designed as a multi-institutional, prospective, nonrandomized, Phase IV protocol comparing the dosimetric success rate of the Contura MLB with a single central lumen balloon device to deliver APBI (7). As per protocol design, "success" was defined as the ability to meet all of the dosimetric criteria as outlined in the protocol design (see in the following). Secondary endpoints include disease control, cosmetic results, and toxicity rates during a followup period of 5 years, as well as identifying the clinical scenarios where only the Contura MLB could be safely used to deliver adjuvant APBI with balloon brachytherapy. The study protocol was approved by the Massey Cancer Center Protocol Review and Monitoring System Committee at the Virginia Commonwealth University. Institutional review board approval was obtained at each participating institution and the study was registered with the National Institutes of Health (www.clinicaltrials.gov No NCT00699101). At the time of this analysis, complete datasets were available on 32 patients where the impact of vacuum port use was documented (e.g., SF:air volume before and after use of the port). These patients constitute the study population. In addition, 8 of the 32 patients (originally deemed acceptable for APBI based on the SF/Air:PTV volume ratio) had dosimetric treatment plans calculated before and after vacuum port use (see Results section). These cases were used to evaluate the improvement in target coverage using the vacuum port in patients already considered acceptable for APBI.

"Standard" brachytherapy procedure

Following successful lumpectomy with documented negative tumor margins, the Contura MLB was placed into the surgical cavity and inflated at a separate procedure under ultrasound guidance either by the surgeon or radiation oncologist. The balloon remained inflated throughout the entire course of radiation treatment. Standard CT-based treatment planning guidelines for APBI were used. CT-based 3-dimensional brachytherapy treatment planning was conducted using commercially available software and equipment specific to each participating site's preferences.

The total PD was 34 Gy delivered to the PTV_EVAL divided in 10 fractions over 5 consecutive working days. Treatment fractions were delivered twice daily with at least 6 h separating each treatment fraction. Before each fraction, the patient's position, balloon inflation, and rotational alignment status was verified to be identical to that at the time of the initial planning CT (mandatory requirements for the protocol). All treatments were completed using a commercially available high–dose rate remote afterloader and ^{192}Ir radioactive source (again, according to the preferences of each individual site). After completion of the treatment, the Contura was deflated and the applicator was removed using site-specific techniques.

Quality assurance criteria and dosimetric guidelines

All participating sites were required to complete and pass physics training before participation in the protocol.

Dosimetric guidelines were provided to each site to ensure maximum dose coverage of the target volume and the lowest possible risk of acute and chronic toxicity. At the time of CT planning, the appropriateness of balloon placement was evaluated directly by the treating physician as per protocol guidelines. Adjustments were made (balloon volume adjustment, removal of trapped air/fluid with the suction port, and improved orientation through catheter rotation) as required. Each patient's position and balloon rotational orientation were documented for comparison during treatment.

Structures that were routinely contoured and/or created as a part of the treatment planning process (as per protocol) included: (*1*) the balloon surface, (*2*) PTV_EVAL, (*3*) trapped air and/or fluid, (*4*) the skin surface, and (*5*) the aspect of the closest rib. Target volumes and normal tissue structures were also routinely outlined on all CT cuts when appropriate and possible. As per standard criteria, the PTV_EVAL was defined and delineated in each case as the breast tissue volume bounded by a uniform expansion of the balloon radius in all dimensions by 10 mm (less than the balloon volume) and limited to 5 mm from the skin surface and by the posterior breast tissue extent (chest wall and pectoralis muscles were not included). When calculating dose coverage of the PTV_EVAL to assure compliance with dose requirements, the volume of trapped air/fluid was accounted for as it displaces a percentage of the target beyond 1 cm from the balloon surface. The area of trapped air/fluid was contoured at each CT level, a total volume obtained and the percentage of the PTV_EVAL that it displaced was calculated. When defining the PTV_EVAL dose coverage, this displaced percentage was subtracted. This calculation is illustrated in the following equation (as per NSABP B-39/RTOG 0413 guidelines):

$$(\%\,\text{PTV\_EVAL coverage}) - [(\text{vol. of trapped air}/\text{vol. of PTV\_EVAL}) \times 100] = \geq 90\%$$

When determining the PTV_EVAL dose coverage, this displaced percentage was subtracted (See Fig. 1). For example, if the percentage of PTV_EVAL displaced by trapped air/fluid is calculated to be 5%, then to comply with criteria, the dose coverage must be at least 95% of the PTV_EVAL receiving 90% of the PD. If the percentage of PTV_EVAL displaced by trapped air/fluid is greater than 10%, then it is not possible to achieve acceptable dose coverage. Again, these dosimetric guidelines were provided in the protocol.

The final treatment plan used for each patient was based on an evaluation of the volumetric dose, including dose–volume histogram analyses of the PTV_EVAL and critical normal tissues.

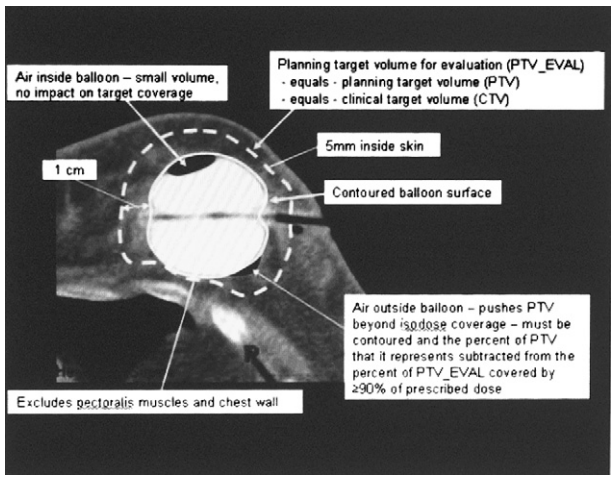

Fig. 1. National Surgical Adjuvant Breast and Bowel Project B39/Radiation Therapy Oncology Group 0413 Phase III Trial Guidelines.

Impact of vacuum port utilization

Sites were requested to measure the volume of trapped air/fluid before and after vacuum port utilization. For this analysis, the percentage of the PTV_EVAL that it displaced was also calculated in these same patients before and after vacuum port utilization. In addition, in 8 patients, the impact of vacuum port use on radiation coverage of the PTV_EVAL was also performed (before and after vacuum port use). As per the NSABP B-39/RTOG 0413 guidelines, the following criteria were used:

1. Acceptable
   Dose–volume histogram analysis of target coverage will confirm ≥ 90% if the PD covered ≥ 90% of the PTV_EVAL. The volume of trapped air/fluid will be accounted for using the methodology described previously.

2. Unacceptable
   Dose–volume analysis of the target volume confirms less than 90% of the PD and/or less than 90% coverage of the PTV_EVAL.

Results

All Patients (N=32)

Of the 32 cases reviewed from both sites, 22 cases initially met B39/0413 criteria (the percentage of PTV_EVAL displaced by trapped air/fluid was ≤ 10%) and 10 cases did not (See Fig. 2a and b). The median SF–air volume measured in cubic centimeters before vacuum removal was 6.8 cc (range, 1.2–28.1) and 0.8 cc after vacuum removal (range, 0.0–6.4) (Table 1). This represents a median reduction of 90.5% for all patients (range, 13.0–100.0). Before vacuum port removal of SF–air, the median percentage of the PTV_EVAL that was displaced

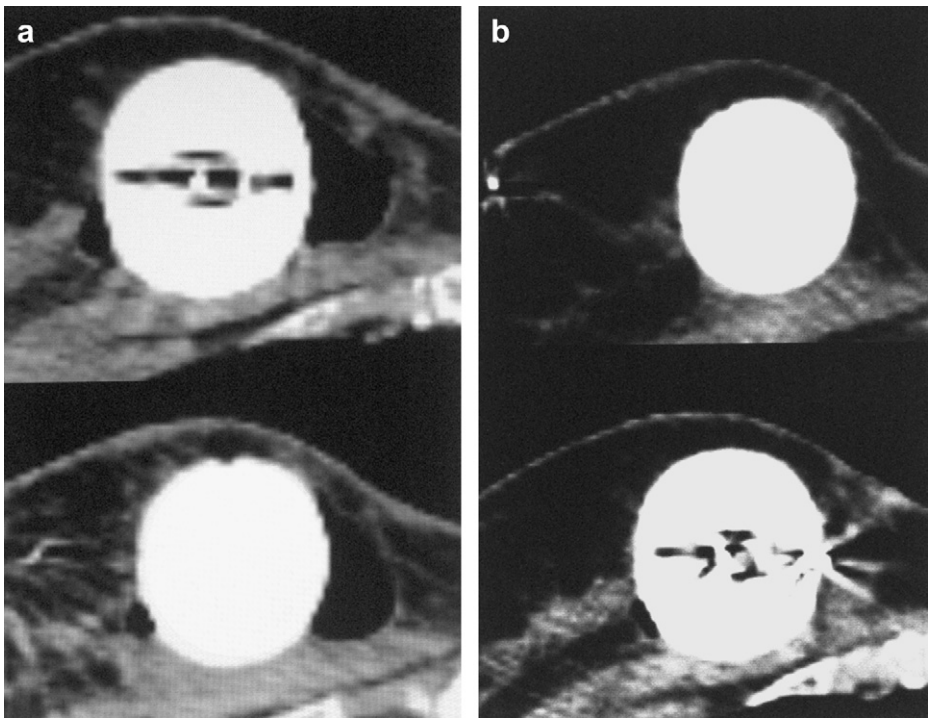

Fig. 2. (a) Initial Images Demonstrating more than 10% air/seroma fluid (SF) in planning target volume (PTV) at planning CT and (b) Postaspiration images demonstrating less than 10% SF/air in PTV.

was 7.8% (range, 1.9–26.6) in all patients. After application of the vacuum port, this was reduced to 1.3% (a median reduction of 90.5%; range, 13.0–100.0%).

Impact of vacuum port on patients ineligible for APBI (N = 10)

Before vacuum port use, 10 (31.3%) patients were not considered acceptable candidates for APBI because the SF volume displaced more than 10% of the PTV_EVAL (median, 15.2%; range, 10.1–26.6%), as per NSABP B39/RTOG 0413 guidelines. After vacuum port removal, this was reduced to a median of 1.6% (range, 0.1–5.2) (Table 2).

Impact of vacuum port on dose coverage in patients currently eligible for APBI (N = 22)

To estimate the value of the port use on improving target coverage for patients initially considered eligible for APBI, an analysis was performed of the PTV_EVAL coverage before and after vacuum port use in 8 evaluable patients (e.g., these patients had dosimetric calculations available on PTV_EVAL coverage before and after use of the vacuum port). Use of the port proportionally increased the percent of the PD that covered 90% and 95% of the PTV_EVAL a median of 8% (see Table 3).

Discussion

The impact of the use of the Contura MLB breast brachytherapy catheter's vacuum port on the ability to both improve the possibility for patients to receive APBI and the impact on dose coverage of the PTV_EVAL was analyzed in a group of patients treated on the Contura registry trial (Fig. 3). Before vacuum port use, the median SF/Air:PTV ratio was 7.8% (range, 1.9–26.6%) in all patients. After application of the vacuum port, this was reduced to a median of 90.5% (range, 13.0–100.0%) down to 1.3%**.** Before vacuum port use, 10 (31.3%) patients were not considered acceptable candidates for APBI because the SF/Air:PTV volume ratio was greater than 10% (median, 15.2%; range, 10.1–26.6%), as per NSABP B39/RTOG 0413 guidelines. After vacuum port removal of SF–air,

Table 1
Reduction of air–seroma fluid with vacuum port in all patients ($N = 32$)

					Air–seroma fluid volume/% of PTV_EVAL		
	Before vacuum (cc)	After vacuum (cc)	% Reduction	PTV_EVAL volume (cc)	Before vacuum	After vacuum	% Reduction
Median	6.8	0.8	90.5	81.7	7.8	1.3	90.5
Range	1.2–28.1	0.0–6.4	13.0–100.0	47.1–144.7	1.9–26.6	0.0–6.2	13.0–100.0

PTV_EVAL = planning target volume for evaluation.

Table 2
Impact of vacuum port on patients ineligible for APBI ($N = 10$)

	Air–seroma fluid volume					
				% of PTV_EVAL		
	Before vacuum (cc)	After vacuum (cc)	% Reduction	Before vacuum	After vacuum	% Reduction
Median	12.7	1.6	91.5	15.2	1.6	93.9
Range	8.2–28.1	0.1–3.8	68.6–99.1	10.1–26.6	0.1–5.2	69.6–121.3

APBI = accelerated partial breast irradiation; PTV_EVAL = planning target volume for evaluation.

100% of these patients were subsequently converted to acceptable candidates for APBI with a median SF/Air:PTV of 1.6%. Finally, in patients initially deemed acceptable for APBI, use of the vacuum port proportionally improved PTV_EVAL coverage a median of 8%.

NSABP B39/RTOG 0413 Phase III trial guidelines

To provide a therapeutic dose of irradiation to the partial breast target (e.g., PTV_EVAL) with balloon-based APBI, care must be taken to insure that all variables that could potentially negatively impact this coverage are taken into consideration. In the initial design of the NSABP B39/RTOG 0413 Phase III trial, careful consideration was given to the potential negative effects SF and air, which accumulate around the balloon surface, could have on the dose delivered to the target tissues. As a result, when calculating dose coverage of the PTV_EVAL in the Phase III trail, to assure compliance with dose requirements, the volume of trapped air/fluid must be accounted for as it displaces a percentage of the target beyond 1 cm from the balloon surface. The Phase III trial guidelines provide very strict criteria on how to calculate this coverage and even set stringent criteria for acceptability. As per the guidelines, unacceptable coverage is defined when dose–volume analysis of the target volume confirms less than 90% of the PD and/or less than 90% coverage of the PTV_EVAL. If the percentage of the PTV_EVAL volume displaced by trapped air/fluid is greater than 10%, it is unlikely that these minimum target volume coverage guidelines can be met. When this unacceptable coverage is encountered in clinical practice, physicians are forced to either (*1*) abandon the case, (*2*) accept suboptimal target coverage, (*3*) wait and see if the SF/air resolve with time, and/or (*4*) apply the vacuum port and correct the problem. The current analysis indicates that the use of the vacuum port provides a reliable mechanism for improving dosimetric coverage by reducing this air and fluid accumulation around the balloon.

Table 3
Impact of vacuum port on patients eligible for APBI ($N = 8$)

	% of PD to 90% of PTV_EVAL	% of PD to 95% of PTV_EVAL
	After vacuum	After vacuum
Proportional increase in coverage (median)	8	8
Proportional increase in coverage (range)	3–10.4	3–16

APBI = accelerated partial breast irradiation; PD = prescribed dose; PTV_EVAL = planning target volume for evaluation.

Considerations on the use of the vacuum port in clinical practice

Although the results of this analysis confirm the utility of using the Contura vacuum port, care must be taken to insure that the SF and air do not reaccumulate immediately or shortly after removal. To avoid this scenario, physicians must re-evaluate the volume of fluid/air that has reaccumulated prospectively or routinely apply the vacuum port before each fraction of radiation delivered. Nonetheless, the improvement the vacuum port can provide is important and offers a useful mechanism to assist the brachytherapist in delivering a more optimal dose of radiation to the target.

Impact of vacuum port use on patients eligible for APBI

In a separate analysis, we also reviewed how much the use of the vacuum port directly improved target coverage even in patients initially considered acceptable candidates for APBI. As Table 3 illustrates, use of the vacuum port provides an additional mechanism (beyond the use of multiple lumens) to further improve target volume coverage (e.g., PTV_EVAL) and to improve the standard of care when applying balloon-based brachytherapy to deliver APBI. Although clinical results using the single-lumen MS seem to be quite good with 5-years of followup (e.g., local tumor control), there is no reason to believe further improving dose coverage of the target will not be beneficial. Clearly, certain patients may benefit from this

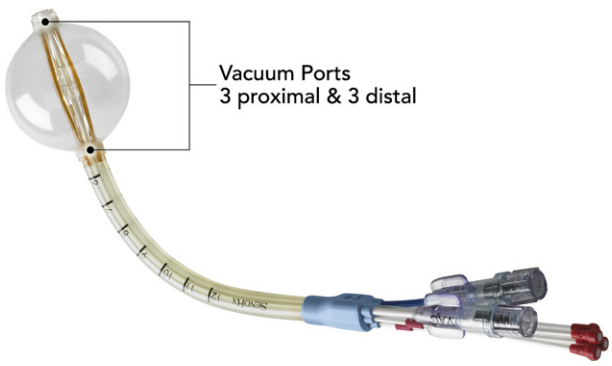

Fig. 3. Contura multilumen balloon—Vacuum lumens labeled.

additional dose coverage. Results from ongoing clinical trials of balloon-based brachytherapy will be useful in helping to establish the optimal coverage of the PTV_EVAL necessary to provide ideal tumor control in all patients. Until then, use of the vacuum port is one more additional tool that can be used to currently help achieve optimization for coverage of the target tissues in most patients.

Conclusion

Use of the Contura MLB vacuum port significantly improved target volume coverage by reducing the SF/Air:PTV ratio in all cases. In addition, application of the vacuum port allowed the safe treatment of borderline or unacceptable patients with APBI thereby increasing the use of this treatment technique.

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