EDITORIAL

Spacer Balloons prior to Partial Breast Irradiation: Helpful or Hurtful?

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Spacer balloons, otherwise known as “cavity evaluation devices” (CEDs), are frequently placed intraoperatively at the time of lumpectomy to facilitate accelerated partial breast irradiation (PBI). CEDs provide a pathway to the excision cavity, preserve cavity shape/volume, and simplify delayed insertion of a single-entry brachytherapy device such as MammoSite, Contura or SAVI.¹ Despite these intentions, significant issues have become apparent with widespread utilization of CEDs:

1. The unavailability of a pathology report documenting PBI eligibility;
2. The possible necessity for re-excision after the CED has been placed;
3. The tendency of some surgeons to seek multidisciplinary consultation after the lumpectomy with the CED in place;
4. Increased risk of infection;
5. Barrier to entry to the phase III randomized prospective clinical trial NSABP-B39/RTOG 0413;
6. With improved, user-friendly techniques of catheter/device insertion, the need for a CED is diminished;
7. Patient disappointment.

When a surgeon places a CED at the time of lumpectomy, it is difficult to predict whether the total tumor extent [invasive and ductal carcinoma in situ (DCIS)] will be less than or equal to 3 cm, the maximum size recommended for PBI.² Likewise, it is uncertain whether the axillary lymph nodes are positive or negative, nor is it known whether 0–3 nodes or >3 nodes are positive. Sometimes, extracapsular

nodal extension is discovered on the ultimate pathology evaluation, a contraindication to PBI. Each of these histologic features impacts on the patient’s eligibility for accelerated PBI. The final pathology report, on average, is available 3 days after the date of surgery.

It might be said that “This lack of pathology data is not a problem. The CED can simply be extracted, a re-excision performed, or mastectomy, or whole breast + nodal irradiation offered.” This perspective ignores the cost of the procedure and device, the risk of infection, and the emotional toll on the patient who has been prepped for PBI. There is also an additional scar on the breast.

Multidisciplinary and interdisciplinary breast cancer care has been shown to have a positive influence on outcomes.³ When a CED is placed before consultation between the surgeon and medical and radiation oncologist, this defeats the very premise of interdisciplinary care. When the patient arrives in the oncologist’s office with a CED in place, it changes the very nature of the patient–consultant discussion. The presence of the CED could potentially influence a consultant’s recommendation for reexcision of a close or positive margin.

The risk of infection and premature catheter removal increases with intraoperative placement of a balloon.⁴ In a nine-institution study with 483 patients published by Cuttino et al., MammoSite placement using a closed-cavity technique significantly reduced the risk of infection ($p = 0.001$ on univariate and 0.0267 on multivariate analysis) over intraoperative insertion.⁵ Overall, 9% of patients experienced infection, but only 4.8% when the device was placed as a separate procedure after the time of lumpectomy. Since the second most important risk factor for infection was the catheter being in place for >14 days ($p = 0.0679$), these data add further evidence that adding a CED before the device will significantly increase the risk of infection. The number of procedures performed on the breast and the length of time that a device has been left in place within the breast can also

increase the risk of infection.⁴ If a CED is placed on day 0, an exchange of CED for single-entry device in the best of circumstances takes place on day 3, 4 or 5. Since we allow our medical physics team 1 day for dose calculation and high-dose-rate (HDR) dosimetry, the 5-day brachytherapy course will be complete nearly 2 weeks after the first foreign object was inserted into the patient's breast. This time exceeds the usual 7–8 days of device implantation when brachytherapy is done as a separate procedure 2–5 weeks after lumpectomy with pathology available, wounds healed, and eligibility assured.

In the MammoSite registry trial, of 1,403 patients implanted with MammoSite, 619 (44%) had placement at the time of lumpectomy or reexcision, while 773 (56%) had delayed ultrasound-guided insertion.⁶ Forty-eight of 488 patients (10%) in the open-cavity group had infection compared with 43 of 646 patients (6.6%) in the delayed insertion group. In the ASBS MammoSite Registry, the open-cavity technique accounted for all explantations caused by disqualifying pathology [tumor size >2 cm, positive margins, lobular histology, extensive intraductal component (EIC), and positive nodes], whereas delayed insertion had no explantations for this reason. No pathology-related removals occur with our recommended delayed insertions. While neither of these studies deals specifically with the CED device, the increase in both the frequency of explantation and the rate of infection with immediate insertion of a balloon into a fresh cavity makes the case for delayed image-guided insertion as “best practice.”

Those patients who may be eligible to enroll onto the high-priority North America-wide randomized clinical trial NSABP B39/RTOG 0413 lose their eligibility when a CED has been inserted at the time of surgery.⁷ Currently, patients who are under the age of 50 years, or with minimal involvement of 1–3 axillary nodes, or invasive cancers that are estrogen receptor (ER)-negative are candidates for this trial. This trial randomizes eligible women to either 5 days of PBI versus 6 weeks of external-beam whole-breast irradiation (WBI). Since patients with balloon spacers have already been advised by their surgeon to have PBI, subsequent enrolment onto a randomized trial becomes impractical. These patients are therefore lost to medical science.

Numerous investigators are reporting better results with fewer infections and persistent seromas with improved cosmetic outcomes when PBI is performed 2–6 weeks after lumpectomy.^{4,8–10} The single-entry device manufacturers have provided an insertion trocar with tear-away plastic sheath that opens an easy pathway for ultrasound-guided catheter insertion. The surgical wound has had time to heal, and the team knows that there is no postoperative infection, minimizing the risk of brachytherapy procedure complication. Many experienced PBI teams now prefer

to separate the lumpectomy procedure from the brachytherapy.^{8,11,12}

Lastly, we should not underestimate the powerful impact of patient expectations.¹³ When the patient goes to surgery expecting to recover from anesthesia with a spacer balloon in place on the road to 5-day PBI, and is surprised by the pathology report, it can be devastating. The disappointment is compounded by the need to extract the CED balloon, an unnecessary burden. We recommend a return to stepwise determination of patient eligibility for PBI and insertion of the brachytherapy device as a separate procedure without CED.

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