November 2006

Contact: Liz Dowling, (760) 942-2544
LizDowling@aol.com
Dowling & Dennis Public Relations

Backgrounder

Accelerated Partial Breast Irradiation

Overview

The term *accelerated partial breast irradiation* (APBI) refers to an approach to post-surgical radiation treatment for breast cancer. APBI is associated with breast-conserving therapy (BCT), in which the surgeon removes only the tumor-bearing region of the breast plus tissue immediately surrounding the tumor. The surgical component of BCT is known as lumpectomy -- as opposed to mastectomy, in which the breast is removed.

BCT also includes a radiation component that generally is performed as a follow-up to surgery. Radiation treatment is typically recommended for women receiving a lumpectomy, to reduce the risk that the cancer will reoccur. APBI was developed as an alternative to whole breast irradiation (WBI), which was previously the predominant radiation method used in BCT. For certain women whose condition may qualify them for an alternative to WBI, physicians have developed other radiation regimens because WBI can be inconvenient and expensive for the patient. APBI can be delivered with several different technologies, both internal (breast brachytherapy) and external.

History of APBI

Studies have consistently shown that following lumpectomy, radiation of the entire breast significantly reduced the risk of the tumor recurring in patients with early-stage breast cancer. Indeed, the pairing of lumpectomy with radiation is so effective that the outcomes are comparable to those achieved by mastectomy. Overall survival rates are also comparable. As a result, whole breast irradiation became a standard part of BCT. Today, WBI – specifically, what is called whole breast external beam radiation therapy – remains the standard of care following a lumpectomy.

Whole breast irradiation does have disadvantages, however. The treatment is normally delivered 5 times a week over a 6-7 week period. The schedule can force people to miss work, pay for lodging and other traveling expenses, or disrupt patients' lives in

other ways, particularly if they don't live close to a treatment facility. In fact, research has shown that the potential inconvenience and financial burden of whole breast irradiation is among the reasons that only 10-40 percent of women who are eligible for BCT elect to receive it. In addition, among women patients who have early-stage breast cancer and who opted for BCT, 20 percent decline to receive radiation – which places them at a significantly higher risk for cancer recurrence.

APBI was developed to address some of the drawbacks of whole breast irradiation. The course of treatment for APBI – whether external or internal -- is typically two treatments per day for 5 days, which is believed to deliver an amount of radiation equivalent to what WBI delivers over its 6-7 week span.

Five-year results in most studies show that APBI prevents cancer recurrence at the tumor site about as effectively as conventional WBI. Most of the data in these studies involved an internal form of APBI called interstitial brachytherapy. More extensive, so-called Phase III studies to confirm the long-term effectiveness of APBI have not yet been completed.

Side effects of brachytherapy – which can include skin injury, fat necrosis, pain, and infection -- have been shown to be equal to or less than those with WBI. From a cosmetic standpoint, APBI has also matched, or improved upon, WBI.

APBI Approaches and Issues

Breast radiation therapy expert Robert R. Kuske, Jr., MD has written, "The ideal radiation delivery system seems to conform the dose to the most peripheral cancer cell, sparing normal tissue as much as possible." This is an important consideration in evaluating the various forms of APBI.

The most widely available external form of APBI is three-dimensional conformal external beam radiation therapy (RT), which delivers high-energy X-rays to the tumor site from a source outside the patient's body. In most case that source is a linear accelerator. With careful treatment planning, damage to surrounding normal tissue can be avoided or minimized with this technique. Other external methods include intensity-modulated radiation therapy (IMRT) and intraoperative approaches.

The original form of internal APBI, or brachytherapy, is called interstitial brachytherapy. Interstitial brachytherapy uses multiple catheters that are arrayed in a manner that seeks to achieve Dr. Kuske's ideal. That is, the prescribed dose is directed at the periphery of the lumpectomy site, and only a small dose reaches the surrounding normal tissue. From a dose conformation standpoint, interstitial has been considered the best available approach to post-surgical RT. However, the technique requires complex surgical skills because of multiple incisions. For this reason, researchers have continued to create other brachytherapy technologies.

For example, a technology known as intracavitary ("balloon") brachytherapy utilizes a dual lumen catheter with a balloon that can be inflated at the lumpectomy site. Intracavitary balloon brachytherapy uses only a single entry point, which is an advantage over interstitial. But intracavitary brachytherapy also has a potential downside: Because the radiation dose cannot be shaped, there may be more risk to healthy tissue than with interstitial brachytherapy.

Interstitial brachytherapy and intracavitary brachytherapy are currently the most commonly used methods of internal APBI.

The SAVI™ Applicator

The SAVI applicator has been designed to incorporate the major advantages of both interstitial and intracavitary brachytherapy, and to avoid the major disadvantages. As such, the applicator utilizes multiple catheters to provide conformal dosing, yet requires only a small, single incision.

After the physician inserts the device into the lumpectomy cavity, he/she expands the catheter bundle by turning a mechanism from outside the breast. The mechanism expands the catheter array to form an ellipsoidal shape inside the cavity. Radiation is then delivered and individually controlled through each of the device’s catheters, enabling the doctor to better shape the radiation dose.

This more precise approach to delivering radiation is intended to prevent radiation damage to the skin or chest wall, which can occur with other breast brachytherapy procedures. It is hoped that the SAVI applicator will make the benefits of APBI accessible to a larger group of women, while also giving more flexibility in treatment planning to the radiation oncologist and physicist.

-- END --