



Submission to the Medical Services Advisory Committee (MSAC) Application 1189 – Targeted Intraoperative Radiotherapy for Early Breast Cancer

28 March 2014

About Breast Cancer Network Australia

Breast Cancer Network Australia (BCNA) is the peak national organisation for Australians personally affected by breast cancer. We support, inform, represent and connect people whose lives have been affected by breast cancer. We work to ensure that Australians diagnosed with breast cancer receive the very best support, information, treatment and care appropriate to their individual needs.

BCNA represents more than 90,000 individual members and 300 member groups from across Australia.

Introduction

BCNA is pleased to provide public comment on the applicant submitted proposed protocol for targeted intraoperative radiotherapy for early breast cancer (IORT). As noted in the proposed protocol, the beneficial outcomes of this treatment extend beyond its ability to prevent the local recurrence of breast cancer. Improved cosmetic outcomes, fewer side effects, and the ability of women to complete breast cancer treatment earlier should be considered and given due weight by MSAC and relevant decision-makers.

External beam radiation therapy: the woman's perspective

Radiotherapy is usually delivered towards the end of a woman's active breast cancer treatment. It will usually follow major breast surgery and often chemotherapy. The additional burden of an extensive course of radiotherapy can have a significant impact on a woman's quality of life, the course of her treatment, and her overall health and wellbeing.

Women often report challenges with external beam radiotherapy, including:

- Difficulties accessing radiotherapy. Women who need to travel long distances to receive radiotherapy may experience personal and financial hardship. Clinical decisions may be made based on their geographical living arrangements.
- The side effects of radiotherapy. Women will often experience skin reactions, which can be distressing and often painful. Fatigue is also a very common side effect of radiotherapy, which can impact on a woman's quality of life.

Accessing external beam radiotherapy

The usual course of radiotherapy for women with breast cancer involves six weeks of daily treatment. Though the procedure itself may take minutes, the travel, waiting time, and the time spent away from family and/or work has an adverse impact on many women and their families.

Women living in rural and remote areas are particularly disadvantaged by the requirements of external beam radiotherapy. Women living in geographically isolated areas have less access to breast cancer treatment and care than their metropolitan counterparts, and the evidence suggests a correlation between cancer survival rates and the quality and availability of services.

Rural women are therefore often required to attend a major regional centre or city to have radiotherapy, and may need to spend up to six weeks away from home as a result. The financial burden of six weeks without an income stream or home-based support for their families, particularly with Patient Travel Assistance Schemes providing limited relief, is particularly onerous for women who may have already taken significant amounts of time away from work for breast cancer treatment.

The radiotherapy options for rural women are limited – either take six weeks away from family, work or farms... or have a full mastectomy. – Kerry

Research has found that rural women are more likely to choose mastectomy over breast conserving surgery¹. Anecdotal stories from our members support these findings. Many rural women cite the extended time away from home for radiotherapy as a critical factor for choosing the more invasive surgery. The adverse and beneficial medical and psychosocial impacts of mastectomy and breast conserving surgery are well documented. Many women in rural areas do not have the advantage of making a decision based on these factors alone, and may need to consider travel and time away from families ahead of clinical considerations.

Further, Australian research has found that women treated in rural centres were less likely to receive radiotherapy following breast conserving surgery². The study researchers considered that the impact of extended travel times may contribute to this discrepancy.

The distance to radiotherapy made it hard. It would have been many hours to drive there and back in one day. So we decided to live in the city for the six weeks. But we were lucky to be able to do this. I know of others who have had mastectomies (when lumpectomies were recommended) because the drive to and from radiotherapy would have been too much and they couldn't afford to move. – Woman with breast cancer

¹ Kricker A, Haskill J, Armstrong BK. Breast conservation, mastectomy and auxiliary surgery in New South Wales women in 1992 and 1995. *Br J Cancer*, 2001.

Al-Refaie W, Zhong W, Boughey J, Habermann E. A Comparison of Breast Cancer Quality Measures in Rural and Urban Patients, Academy Health 2013 Research Meeting, Baltimore

² Craft et al. Variation in the management of early breast cancer in rural and metropolitan centres: Implications for the organisation of rural cancer services *Breast* - October 2010 (Vol. 19, Issue 5, Pages 396-401)

The side effects of external beam radiotherapy

Many women experience adverse side effects as a result of radiotherapy. Clinical research has documented these side effects, and the feedback of our membership suggests that the impact of these side effects can be considerable.

In April 2011, BCNA surveyed members of our Review & Survey Group about the issues faced by women who require radiotherapy³. Two hundred and sixty-six members completed the survey. Most women told us they experienced skin changes that were like sunburn, including redness and burning. Thirty four per cent of women told us that their skin blistered, while just under a quarter experienced weeping. Nearly a third of women rated their discomfort level at eight out of 10 or more.

I have terrible radiation burns that are very sore and weepy near my underarm on the bra line. This area has been radiation free for about a week, but continues to give me grief. I have been using Solugel and dressings, but it doesn't seem to be making a difference. – BCNA Online Network member

In addition to adverse skin reactions, many women experience fatigue. Our 2011 survey results, in addition to multiple reports from our membership and academic research, suggest that the fatigue can be extreme, debilitating, and will often develop at the end of the course of radiotherapy or even following its completion. In the 2011 survey, some women reported that the daily travel to the radiotherapy facility may have contributed to their fatigue.

I underestimated the effects of radiotherapy on me. I was too fatigued to work, although I had just finished aggressive chemotherapy treatment as well, so I think I was pretty whacked to begin with. – Woman with breast cancer

The benefits of intra-operative radiotherapy

BCNA considers that affordable access to intra-operative radiotherapy will go some way to improving outcomes for women with breast cancer who require radiotherapy. As outlined above, six weeks of treatment – especially for rural and remote women – is burdensome and can result in women making sub-optimal choices about surgery.

BCNA considers that a safe and effective dose of radiation during the surgical phase of their treatment will mean women spend less time travelling for treatment and experience less travel-related fatigue, which even for short distances can be exhausting. A woman's experience with radiotherapy must take into account the arduous treatments, such as chemotherapy and surgery, she experiences in the months preceding radiotherapy.

BCNA members participated in the Western Australia TARGIT trial and reported to us they were pleased with the process and outcome.

I was happy not to have to leave home for six weeks of radiotherapy in Perth. The procedure was straightforward, with no side effects and only a little pain afterwards. – Carol, IORT trial participant

³ Breast Cancer Network Australia, Radiotherapy Skin Changes Survey, May 2011
http://www.bcna.org.au/sites/default/files/radiotherapy_burns_-_full_report_v5-_ag_-_20110624.pdf

BCNA also considers that evidence relating to better outcomes for skin preservation should be considered during the decision-making process related to this application. We understand that the IORT technique involves less skin exposure than external beam radiotherapy. Any beneficial outcomes for women, such as reduced pain, redness, blistering, and other skin changes frequently reported should be reviewed and considered alongside other clinical considerations.

Although BCNA is not aware of any evidence related to the effect of IORT on fatigue, we consider that the reduced time spent travelling to, waiting in, and being treated in a radiotherapy clinic is very likely to have some impact on the fatigue levels of women with breast cancer following treatment. Fatigue is a commonly reported side effect of radiotherapy, and many of our members feel that the impact of this fatigue on their quality of life and recovery is frequently underestimated by medical professionals. We consider that any treatment option that reduces the fatigue of women with breast cancer will be a significant improvement.

BCNA supports the application to include IORT on the Medicare Benefits Schedule. We note the findings of the international randomised TARGIT clinical trial which found that, for women with low risk breast cancers, IORT was safe, equivalent to whole breast radiotherapy in terms of local recurrence and breast cancer-specific mortality, and better than whole breast radiotherapy in terms of deaths from other causes (such as cardiovascular disease), toxicity, tolerability and cosmetic outcomes.

We believe IORT is a valuable treatment option that offers women real benefits, including fewer side effects of treatment, better cosmetic outcomes and just one radiotherapy treatment session instead of the ~30 sessions women currently receive as standard care.

If you require further information or wish to discuss our submission further, please contact Nicca Grant at ngrant@bcna.org.au or (03) 9805 2585.

Yours sincerely



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