

Associate Professor Anne Kolbe Chair National Health Committee Ministry of Health PO Box 5013 Wellington

19th November 2013

Dear Associate Professor Kolbe,

Re: Request to consider introducing intraoperative radiotherapy using Intrabeam for selected patients with breast cancer

I write on behalf of the Breast Cancer Aotearoa Coalition (BCAC), an incorporated society with charitable status representing more than 30 New Zealand breast cancer-related organisations as well as individual members throughout the country.

BCAC requests that the National Health Committee consider introducing intraoperative radiotherapy (IORT) using Intrabeam as a radiation therapy option for selected breast cancer patients within the public health system.

The provision of a single treatment of radiotherapy intra-operatively using Intrabeam provides an extremely convenient and efficient option for patients as well as for radiation treatment clinics. This is in contrast to current standard courses of treatment with whole breast external beam radiation therapy (EBRT) given each weekday for three to five weeks. The extended treatment period required for EBRT is often stressful and disruptive to the lives of patients, and we are hopeful that this may be avoided for appropriately selected patients. The introduction of Intrabeam into our public health system would reduce the level of time and resource needed to treat qualifying patients and has the potential to reduce waiting times for the treatment of other patients with the standard linear accelerator machines.

The Intrabeam technique delivers radiation directly to the tumour bed, the most common site of breast cancer recurrence. The TARGIT-A (Targeted Intra-operative Radiotherapy) clinical trial randomised patients to receive either whole breast EBRT or IORT using Intrabeam, with updated results recently published in The Lancet (Vaidya et al. 2010; 2012; 2013). The trial began recruiting patients in 2000 and closed after the enrollment of 3451 women. The 3451 patients have had a median follow-up of 2 years and 5 months, while four-year follow-up is available for 2020 patients and five-year follow-up for 1222 patients.



Some patients received IORT to the tumour bed at the time of initial surgery to remove the tumour (pre-pathology group, n=2298), and some had it during a second surgical procedure (post-pathology group, n=1153). The local recurrence rate for the pre-pathology IORT group of 2.1% (1.1 - 4.2) was not significantly different from that in the standard EBRT treatment arm of 1.1% (0.5 - 2.5) (p= 0.31)). The recurrence rate was somewhat higher in the post-pathology group.

Breast cancer mortality did not differ between the combined pre- and post-pathology IORT group at 2.6% (1.5 - 4.3) and the EBRT group at 1.9% (1.1 - 3.2) (p=0.56). However, there were significantly fewer non-breast cancer deaths with IORT at 1.4% (0.8 - 2.5) compared to 3.5% (2.3 - 5.2) for EBRT (p=0.0086). This was due to fewer cardiovascular deaths (2 vs 10) and fewer deaths from cancers other than breast (8 vs. 16). In the pre-pathology group, at 5 years (n=2298), there were 29 deaths in those receiving IORT and 42 in those receiving EBRT. Overall 5 year mortality was 3.9% (2.7 - 5.8) (37 deaths) for the combined IORT group vs 5.3 (3.9 - 7.3) (52 deaths) for EBRT (p=0.099) (n = 3451).

We suggest that patient selection criteria for the use of Intrabeam IORT in New Zealand be set to be the same as those used for the TARGIT trial. We further suggest that every effort be made to use the therapy at the time of initial surgery, as this appears to achieve the best result in disease-free survival.

Thirty-three centres in 10 countries recruited patients to the TARGIT-A trial and we note that IORT using Intrabeam is now gaining rapid and wide uptake around the world. More than 5000 women with breast cancer have been treated worldwide with this form of IORT. We are pleased to see the introduction of IORT with Intrabeam into New Zealand at a private Auckland clinic and hope to see this adopted for appropriately selected patients in the public health system in the near future.

BCAC therefore asks that the National Health Committee look into the Intrabeam IORT technology with a view to introducing this option into our public hospitals for appropriately selected women with early, low-risk breast cancer.

Yours sincerely,

Libby Burgess, MNZM Chairperson Breast Cancer Aotearoa Coalition www.breastcancer.org.nz

References:

Vaidya JS, Joseph D, Tobias JS, et al. 2010 Targeted intraoperative radiotherapy versus whole breast radiotherapy for breast cancer (TARGIT-A trial): An international, prospective, randomized, non-inferiority phase 3 trial. *Lancet*: 376 (9735): 91-102.

JS Vaidya, F Wenz, M Bulsara, et al. 2012. Targeted intraoperative radiotherapy for early breast cancer: TARGIT-A trial- updated analysis of local recurrence and first analysis of survival. *Cancer Res*: 72 (24 Suppl): Abstract nr S4-2.

Prof Jayant S Vaidya, Prof Frederik Wenz, Prof Max Bulsara, et al. 2013. Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer: 5-year results for local control and overall survival from the TARGIT-A randomised trial. *Lancet*: Nov online.