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Australia and New Zealand Horizon Scanning Network

ANZHSN

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National Horizon Scanning Unit

Horizon scanning prioritising summary

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**Intra-operative radiation therapy: Applied
to women undergoing breast cancer surgery
aimed at reducing tumour recurrence.**

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PRIORITISING SUMMARY

REGISTER ID: 0000047

NAME OF TECHNOLOGY: INTRA-OPERATIVE RADIATION THERAPY

PURPOSE AND TARGET GROUP: INTRA-OPERATIVE RADIATION THERAPY
APPLIED TO WOMEN UNDERGOING BREAST
CANCER SURGERY AIMED AT REDUCING
TUMOUR RECURRENCE

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|--|
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Established <i>but</i> changed indication
or modification of technique |
| <input type="checkbox"/> Nearly established | <input type="checkbox"/> Should be taken out of use |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|------------------------------|--|
| <input type="checkbox"/> Yes | ARTG number |
| <input type="checkbox"/> No | <input checked="" type="checkbox"/> Not applicable |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
RCT, Italy	✓		
Cohort study, France	✓		
Consecutive patients, Italy	✓		
Case series, Italy	✓		
Case series, USA	✓		

IMPACT SUMMARY:

Intra-operative radiation therapy is aimed at reducing the recurrence of breast carcinoma in women who are undergoing the removal of a primary breast carcinoma. Radiation therapy aims to destroy residual cancer cells in the area surrounding the primary tumour. Current standard treatment involves a standard 6-week course of radiation delivered externally to the whole breast post-operatively. Eighty-five per cent of breast relapses occur in the same quadrant as the primary tumour, which provides the rationale for conducting intra-operative radiation therapy.

The AIHW reported 11,400 new cases of breast cancer in Australia with a crude mortality rate of 26.1 per 100,000 in the year 2000. Breast cancer is the most common registered cancer and the leading cause of mortality for women in Australia. The AIHW reported the number of separations for the AR-DRG numbers J06A and J07A (major and minor procedures for malignant breast conditions) as 10,222 and 6,599 respectively for the year 2001-02. It is difficult to estimate the number of women who undergo post-operative radiation, however the HIC report 7,567 claims processed for the MBS item numbers 15221, 15236 and 15251 (oncology treatment for a primary cancer site – breast).

Two different techniques of intra-operative radiation therapy (IORT) have been utilised; the linear accelerator electron beam and the high dose remote afterloading system (Veronesi et al 2003b). The linear accelerator system employs a robotic arm that can be moved into the operating theatre and manipulated by the radiation oncologist and surgeon. The tumour is surgically excised, however to perform IORT the remaining breast tissue must be detached from the underlying skin and the skin retracted to avoid skin necrosis. An aluminum-lead disc is then placed between the breast tissue and the chest wall. An electron beam is delivered to the exposed breast tissue via a perspex tube. The high dose afterloading system avoids the need to surgically excise the breast tissue. Radiation is applied directly to the tissue via catheters embedded in a silastic template. A major concern of IORT treatment is the delivery of high-dose radiation in a single fraction, which may lead to necrosis of the tissue and in turn lead to increased post-operative complications such as fibrosis. This technique, however, does reduce radiation exposure of the lung, subcutaneous tissues and the contralateral breast.

Controlled studies comparing intraoperative and externally applied radiation therapy are lacking. Cuncins-Hearn (2002) described an RCT conducted by Fortuna et al (2001), of 41 IORT compared to 29 conventional radiotherapy patients. However, only data on post-operative infection (2.9% of IORT patients, no figure stated for controls) and cosmetic appearance was reported. The study conducted by Veronesi et al (2001) on 101 consecutive patients, utilised the linear accelerator electron beam. Reported side effects included acute toxicity (10% patients), mild pain (2%) and transitory oedema (3%). One patient reported recurrent bone metastases three months after surgery. The 2003 study by Veronesi et al reported 3/237 (1.3%) patients developed ipsilateral breast carcinoma outside of the radiation field 9, 14 and 17 months after being treated. It has been reported that after a median follow-up of 65 months, the incidence of tumor recurrence, following conventional radiation therapy on the affected breast, is 7% (Ribeiro et al 1993). Conventional radiotherapy may damage surrounding normal breast tissue, coronary vessels, lungs and skin (Cuncins-Hearn et al 2002).

Veronsi et al (2003) stated the cost of IORT treatment is significantly less than the conventional 6-week radiation therapy, however, no data was presented to support this.

CONCLUSION:

It appears from the available level IV evidence that intraoperative radiation therapy may reduce breast cancer recurrence and have fewer side effects than conventional radiation therapy. In addition, there is a high level of clinical need in Australia for more effective and safe treatments for breast cancer.

HEALTHPACT ACTION:

Therefore it is recommended that a Horizon Scanning report be conducted.

SOURCES OF FURTHER INFORMATION:

- Cuncins-Hearn et al (2002). 'A Systematic Review of Intraoperative Radiotherapy for Early Stage Breast Cancer.', ASERNIP-S Report No. 27, Adelaide, South Australia: ASERNIP-S.
- Narayanan, S. S., Goel, V. et al (2003). 'Intraoperative high-dose-rate 192Ir radical implant in early breast cancer: a quality assurance and dosimetry study', *Int J Radiat Oncol Biol Phys*, 56 (3), 690-696.
- Orecchia, R., Ciocca, M. et al (2003). 'Intraoperative radiation therapy with electrons (ELIOT) in early-stage breast cancer', *Breast*, 12 (6), 483-490.
- Reitsamer, R., Peintinger, F. et al (2003). 'Intraoperative electron boost radiotherapy (IORT) versus postoperative external electron beam boost radiation in breast cancer patients - A sequential intervention study on local recurrence rates', *Breast*, 12 Suppl 1, S33.
- Ribeiro, G. G., Magee, B. et al (1993). 'The Christie Hospital breast conservation trial: an update at 8 years from inception', *Clin Oncol (R Coll Radiol)*, 5 (5), 278-283.

Takei, H., Suemasu, K. et al (2002). 'Sentinel lymph node biopsy without axillary dissection after an intraoperative negative histological investigation in 358 invasive breast cancer cases', *Breast Cancer*, 9 (4), 344-348.

Veronesi, U., Gatti, G. et al (2003a). 'Full-dose intraoperative radiotherapy with electrons during breast-conserving surgery', *Arch Surg*, 138 (11), 1253-1256.

Veronesi, U., Gatti, G. et al (2003b). 'Intraoperative radiation therapy for breast cancer: technical notes', *Breast J*, 9 (2), 106-112.

Veronesi, U., Orecchia, R. et al (2001). 'A preliminary report of intraoperative radiotherapy (IORT) in limited-stage breast cancers that are conservatively treated', *Eur J Cancer*, 37 (17), 2178-2183.

SEARCH CRITERIA TO BE USED:

Breast Neoplasms/pathology/*radiotherapy/surgery

Carcinoma/*pathology/radionuclide imaging/therapy

Iridium Radioisotopes/*therapeutic use

Mastectomy, Segmental/methods

Breast Neoplasms/pathology/*radiotherapy/*surgery

Dose-Response Relationship, Radiation

Radiotherapy Dosage

Radiotherapy, Adjuvant

Radiotherapy, High-Energy/instrumentation/*methods