



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon Scanning Technology Prioritising Summary**

## **Multi-catheter interstitial brachytherapy**

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**Australian  
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of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
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# PRIORITISING SUMMARY

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**REGISTER ID** S000066

**NAME OF TECHNOLOGY** MULTI-CATHETER INTERSTITIAL BRACHYTHERAPY

**PURPOSE AND TARGET GROUP** EARLY STAGE BREAST CANCER IN WOMEN

## STAGE OF DEVELOPMENT (IN AUSTRALIA)

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

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

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

## INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Austria	✓		
Canada	✓		
Germany	✓		
Hungary	✓		
Japan	✓		
United States	✓		

## IMPACT SUMMARY

Accelerated partial breast irradiation using multi-catheter brachytherapy is an alternative to whole breast irradiation for women with early stage breast cancer who require breast conservation therapy. The technology is currently in the investigational stage in Australia.

## BACKGROUND

Breast conservation therapy, consisting of breast conserving surgery (partial mastectomy or lumpectomy) followed by whole breast irradiation (WBI), is the standard of care for women with early stage breast cancer (stage 0, I and II) (Dirbas et al. 2004; Goyal et al. 2007). Radiation therapy was incorporated into breast conservation therapy to reduce the risk of local tumour recurrence (Goyal et al. 2007). In WBI, radiation is delivered to the whole breast five days a week for approximately six to seven weeks (Arthur and Vicini 2005).

Breast conservation therapy has been shown to be as effective, in terms of local tumour control and survival, as radical or modified radical mastectomy in which the entire breast is removed (Fisher et al. 1985; Blichert-Toft et al. 1992). However, irradiation of the whole breast has been associated with a reduced quality of life because of the substantial disruption caused by the lengthy treatment process (Fearmonti et al. 2007). Furthermore, women who have received breast conservation therapy and experience cancer recurrence in the same (ipsilateral) breast must generally undergo mastectomy rather than repeat breast conservation therapy because it is considered unsafe to irradiate the whole breast more than once (Dirbas 2007).

In response to the difficulties presented by WBI, alternative methods of irradiating the breast, such as accelerated partial breast irradiation (APBI) have been developed. In APBI, radiation is only focused on the area of partial mastectomy (plus an additional margin of 1 cm to 2 cm), which has the greatest likelihood of tumour recurrence (Chronowski and Buchholz 2007; Fearmonti et al. 2007). This approach not only offers the patient increased convenience, but also decreases the amount of radiation delivered to the breast and surrounding vital structures (Fearmonti et al. 2007).

The most common method of delivering APBI is multi-catheter interstitial brachytherapy, which delivers a homogenous dose of radiation in a short space of time to the tumour bed (Goyal et al. 2007). Multi-catheter interstitial brachytherapy involves the temporary placement of 10 to 20 flexible catheters in the portion of the breast around the partial mastectomy cavity either intra-operatively or postoperatively (Fearmonti et al. 2007). High dose rate (HDR) radiation treatment is then administered in 30-minute sessions twice daily on an outpatient basis, with approximately 3.4 gray (Gy) being delivered per session over five days (total radiation 34 Gy). Low dose rate (LDR) treatment involves the delivery of approximately 45 Gy to the target area over five days on an inpatient basis (Fearmonti et al. 2007). This compares to approximately 50 Gy delivered to the whole breast during WBI (Dirbas et al. 2004).

Interstitial brachytherapy was originally used to provide a boost dose of radiation to the partial mastectomy cavity following breast conserving surgery and WBI (Frazier et al. 2001). The first studies reporting the use of interstitial brachytherapy as the sole radiation therapy in breast conservation therapy were conducted in the 1990s and reported high local tumour recurrence rates (Chronowski and Buchholz 2007). Since that time,

improvements in treatment planning and much stricter patient selection criteria have been incorporated with the aim of improving local control of tumour recurrence.

## **CLINICAL NEED AND BURDEN OF DISEASE**

Breast cancer is the most common form of invasive cancer amongst Australian women (Paul et al. 1999). It is also the leading cause of cancer death in females. The incidence of breast cancer in Australia is on the rise, with new cases increasing from 5,318 in 1983 to 12,207 in 2002 (AIHW 2006). It is estimated that by 2011 the number of new diagnoses will reach 14,800 (AIHW 2006).

It is estimated that in the United States only one quarter of women eligible for breast conservation therapy actually receive it owing to the lengthy and inconvenient treatment process (Fearmonti et al. 2007). Many women who are unable to commit to several weeks of treatment due to family, work or transport issues may be forced to either decline post-operative radiotherapy or accept mastectomy (Dirbas et al. 2004). Postoperative radiotherapy with reduced treatment periods, such as APBI, is a potential solution for these women.

## **DIFFUSION**

Multi-catheter interstitial brachytherapy is currently in the investigational stage in Australia and around the world.

## **COMPARATORS**

Breast conservation therapy using breast conserving surgery and WBI is the current standard of care for early stage breast cancer, and is the main comparator for multi-catheter brachytherapy.

However, three other forms of APBI also exist (Fearmonti et al. 2007).

- Intra-operative radiation therapy – this involves the delivery of the entire radiation dose in a single fraction while the patient is in the operating room.
- Three-dimensional conformal radiation therapy (3D-CRT) – this postoperative method delivers radiation to the lumpectomy cavity externally via custom-configured beams.
- Balloon-based intra-cavitary radiation therapy – this approach utilizes the MammoSite® Radiation Therapy System to deliver radiation to the lumpectomy cavity.

## SAFETY AND EFFECTIVENESS ISSUES

No randomised controlled trials of multi-catheter interstitial brachytherapy were found. Two non-randomised comparative studies were retrieved for inclusion in this summary. Both studies compared patients who underwent LDR and HDR brachytherapy with those undergoing WBI.

### a) Safety

In one study conducted at the William Beaumont Hospital, women with early stage invasive breast cancer underwent interstitial brachytherapy as part of breast conservation therapy between 1993 and 2001 (Vicini et al. 2003). One hundred and fifty eight women with stage I/II breast cancer and gross total resection of the primary tumour were prospectively enrolled to undergo one of three brachytherapy protocols. An additional 41 women who did not meet all the eligibility criteria for minor reasons that were not likely to affect the recurrence rate were also included. The three protocols were: LDR brachytherapy delivering 50 Gy over 4 days at 0.52 Gy/hour (n = 120); HDR brachytherapy delivering 32 Gy in eight fractions (n = 71); and 34 Gy in 10 fractions (n = 8). All of the patients were 40 years of age or younger and had infiltrating ductal carcinomas smaller than 3.0 cm in diameter, as well as negative surgical margins ( $\geq 2$  mm) and lymph nodes. Each of the 199 patients was matched with a patient who had received breast conservation therapy with WBI at the same institution between 1980 and 1997.

Although patients received three different brachytherapy protocols, complications were reported in a combined fashion (brachytherapy group). The complications reported during the median follow-up of 60 months included asymptomatic fat necrosis in eight patients (4%), grade II<sup>1</sup> fibrosis in eight patients (4%) and grade I<sup>2</sup>/II persistent oedema in 12 patients (6%). Safety outcomes were not reported for the control group (Vicini et al. 2003).

King et al. (2000) conducted a comparative study of interstitial brachytherapy in 50 women (n = 51 breast cancers) undergoing breast conservation therapy that included lumpectomy and axillary lymph node dissection. The study protocol mandated that only women who had opted to undergo breast conservation therapy and had intraductal or invasive tumours smaller than 4 cm (stages Tis, T1 and T2), negative inked surgical margins,  $\leq 3$  positive axillary nodes and no evidence of multi-centricity could enrol. An average of 15 catheters per patient were placed in a double plane fashion either intra-operatively (n = 23) or postoperatively (n = 28) under ultrasound guidance. The target breast treatment volume treated by interstitial brachytherapy was defined by a 2 cm to 3 cm perimeter beyond the lumpectomy cavity and covered approximately one-third to one-half of the breast. Alternating groups of 10 patients were treated with either LDR

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<sup>1</sup> Grade II defined as moderate radiation effects.

<sup>2</sup> Grade I defined as mild radiation effects.

brachytherapy (45 Gy over four days; n = 25) or HDR brachytherapy (32 Gy over four days in twice daily fractions; n = 26). The charts of an additional 94 patients, who met the eligibility criteria but were treated with segmental mastectomy and WBI, were retrospectively reviewed as a control group (King et al. 2000).

Although the brachytherapy patients received both LDR (n = 25) and HDR (n = 26), complications were reported in a combined fashion (brachytherapy group). The safety analysis revealed significantly fewer grade I<sup>3</sup> and grade II<sup>4</sup> complications in brachytherapy patients, compared to the control group (22% versus 80%, P < 0.001). Grade III<sup>5</sup> complications requiring surgical intervention, on the other hand, were more common after brachytherapy than WBI (8% versus 5%), although the difference was not statistically significant. The grade III complications in the brachytherapy group included one surgical complication (wound haematoma), one infectious complication (infected seroma four months after completion of brachytherapy while receiving chemotherapy) and two cases of fat necrosis. The two patients with fat necrosis presented with skin discoloration and indurated, painful masses at the segmental mastectomy site, which required extensive surgery (King et al. 2000).

## **b) Effectiveness**

Of the 199 patients assessed by Vicini et al. (2003), five had an ipsilateral breast tumour recurrence, which is equivalent to a five-year actuarial ipsilateral tumour recurrence rate of 1% (95% confidence interval 0% to 2.8%). Two of these recurrences were thought to be a regrowth of the primary tumour, while the remaining three were new cancers in the non-irradiated breast tissue. In 79 patients who were followed up for a minimum of five years, cosmetic results were rated as good or excellent by 99% (78/79 patients) and fair in the remaining patient. There was no statistically significant difference in the median time to local recurrence or five-year actuarial rates of ipsilateral breast tumour recurrence or regional failure between the brachytherapy and control group. In addition, there were no statistically significant differences between the groups with respect to five-year actuarial rates of distant metastases, disease-free survival, overall survival, or cause-specific survival (Vicini et al. 2003).

In the study by King et al. (2000), the mean tumour size was 1.4 cm (n=51), and 45% of the tumours were occult (King et al. 2000). A subset of the control group, matched for pathologic stage, tumour size and breast size to the interstitial brachytherapy patients, was used to compare cosmetic outcomes at a median follow-up of 20 months. Cosmetic outcomes were considered good to excellent in 75% of women who had received brachytherapy and 84% of control patients (P > 0.05). In the remaining patients, cosmetic outcomes were judged as fair, except for one control patient with a poor result (King et al. 2000).

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<sup>3</sup> Grade I complications were defined as mild, self-limited treatment toxicities, including skin erythema and desquamation, that required no specific treatment.

<sup>4</sup> Grade II complications were defined as moderate treatment toxicities that required non-surgical treatment.

<sup>5</sup> Grade III complications were defined as severe and required surgical intervention.

A comparative analysis of the two groups at a median of 74 months (control group) and 75 months (brachytherapy group) revealed one local failure and three regional nodal recurrences in the brachytherapy group (8% recurrence rate) and five local failures in the control group (5% recurrence rate;  $P > 0.05$ ). While the difference in local failure and total recurrence rates between groups was not statistically significant, regional recurrences among brachytherapy patients were significantly lower compared to the control group ( $P = 0.04$ ). At the last follow-up (time not stated), 88% of brachytherapy and 92% of control patients were disease free. Similar overall recurrence rates were achieved even though the brachytherapy patients were significantly older (63.0 years versus 56.9 years;  $P < 0.05$ ) and had more invasive lesions (90% versus 64%;  $P < 0.005$ ). However, the authors noted that the rate of regional lymph node failure in the brachytherapy group was higher compared to the 1% to 3% normally reported after breast conserving therapy with WBI, which suggests that women at higher risk of nodal involvement may be better suited for WBI.

#### **COST IMPACT**

The cost of APBI using multi-catheter brachytherapy is currently unknown.

#### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified from the retrieved material.

#### **OTHER ISSUES**

No issues were identified from the retrieved material.

#### **SUMMARY OF FINDINGS**

Evidence from two non-randomised comparative studies indicates that patients with early stage breast cancer who undergo breast conservation therapy with multi-catheter interstitial brachytherapy have similar rates of ipsilateral breast tumour recurrence compared to those treated with whole breast irradiation. However, further research is needed to determine which of the two treatment regimens, LDR or HDR, is the most effective. Studies with longer follow-up periods are also required to determine the long-term safety and effectiveness of the therapy. There is some suggestion that women at higher risk of nodal involvement may not be suitable candidates for the procedure, so further refinement of the patient selection criteria may be required. Furthermore, although not investigated in the studies presented, patient acceptance of this technology will substantially impact the uptake of this technology and should be considered in future studies.

If the technology proves to be as safe and effective as breast conserving surgery with WBI, the uptake of this technology is likely to be rapid because of its more convenient treatment schedule.

### **HEALTHPACT ACTION**

Based on the potential uptake and rapid diffusion of this technology, multi-catheter interstitial brachytherapy will be monitored for 12 months.

### **NUMBER OF STUDIES INCLUDED**

Total number of studies	2
Level III-2	1
Level III-3 evidence	1

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#### **SEARCH CRITERIA TO BE USED**

Brachytherapy

Multi-catheter

Interstitial

APBI

Accelerated partial breast irradiation