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Horizon scanning prioritising summary

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Thermal ablation of small breast tumours: A minimally invasive technique for the destruction of breast tumours.

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PRIORITISING SUMMARY

REGISTER ID: 000119

NAME OF TECHNOLOGY: THERMAL ABLATION OF SMALL BREAST TUMOURS

PURPOSE AND TARGET GROUP: A MINIMALLY INVASIVE TECHNIQUE FOR THE DESTRUCTION OF BREAST TUMOURS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|---|-------|
| <input checked="" type="checkbox"/> Yes | ARTG number | 72400 |
| <input type="checkbox"/> No | <input type="checkbox"/> Not applicable | |

In Australia, there are currently several radiofrequency ablation units, designed for cardiac ablation, registered by the Therapeutic Goods Administration (TGA). However, Taylor Bryant Ptd Ltd distribute the RITA radiofrequency interstitial tissue ablation system, which is registered on the TGA and is currently used for the ablation of liver metastases.

INTERNATIONAL UTILISATION:

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

IMPACT SUMMARY:

Thermal ablation is a minimally invasive technique for the treatment of benign and malignant breast tumours. This procedure would be available through major public and private hospitals that are equipped with ultrasound and a radiofrequency ablation device.

BACKGROUND

A radiofrequency generator is a small unit capable of producing monopolar radiofrequency energy that can be utilised for the coagulation and ablation of soft tissue (Figure 1). Radiofrequency ablation (RFA) is produced from high-frequency, alternating current, which is passed between an electrode placed within the treatment site (breast) and a grounding pad placed on the outer body (thigh) (Figure 2). Heat is not generated by the application of the current; rather, the rapid movement of ions in the breast tissue causes frictional heat. Thermal injury to tumour cells will occur at 41°C and cell death will occur between 45°to 50°C. Ultrasound or magnetic resonance imaging is used to determine the size and location of the

tumour. Imaging is then used to guide the placement of the RFA electrode and to monitor the progress of the ablation (Singletary et al 2004). To assess the tumour grade, the lymphovascular invasion and oestrogen receptor status, a core biopsy would need to be performed prior to RFA (Hayashi et al 2003).



Figure 1 Radiofrequency ablation unit
(Printed with permission: Rita Medical Systems)

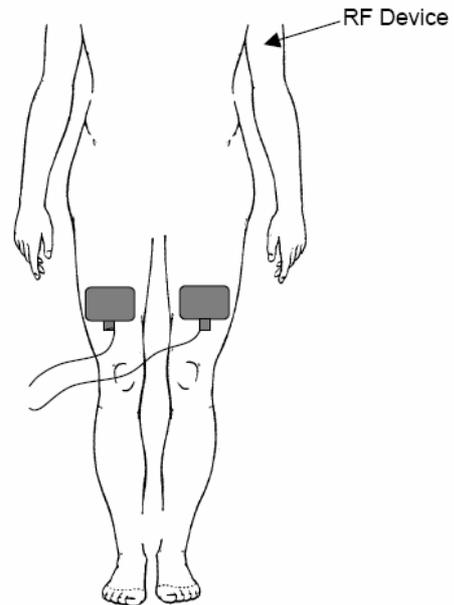


Figure 2 Dispersive electrode placement, place pads on thighs when conducting RF on breast
(Printed with permission: Rita Medical Systems)

CLINICAL NEED AND BURDEN OF DISEASE

In Australia, breast cancer is the most common registrable cancer in females. There were 11,314 new cases of breast cancer and 2,521 deaths from breast cancer reported in Australia for the year 2000. Australian women have an approximate lifetime risk of one in eleven of developing breast cancer before the age of 75 years (AIHW and AACR 2003). The number of public hospital separations in Australia associated with breast neoplasms in 2001-02, was 21,191 (AR-DRG number C50) (AIHW 2004).

DIFFUSION

This procedure is currently not performed in Australia (personal communication, Professor Saunders¹). Taylor Bryant Ptd Ltd has sold approximately 10 RITA radiofrequency units throughout Australia. These units are currently utilised for the ablation of hepatocellular carcinoma, and these units would be suitable for the ablation of breast tumours.

COMPARATORS

Current treatments for breast cancer include radiotherapy, chemotherapy, lumpectomy or total mastectomy.

¹ Professor Saunders is the Professor of Surgical Oncology, University of Western Australia

EFFECTIVENESS AND SAFETY ISSUES

Fornage et al (2004) reported on a case series (level IV evidence) of 20 women with 21 malignant breast lesions. Invasive breast cancer was histologically confirmed prior to RFA and the size of the lesion (≤ 2 cm) was confirmed by ultrasound. Surgery was scheduled for all women immediately after RFA to confirm the ablation of the tumour and the margin around the tumour. Ablation time was approximately 15 minutes at 95°C. Histologic examination of the specimens removed at surgery revealed no staining of the cells within the volume of ablation consistent with loss of cell viability. RFA was aborted in one patient due to equipment failure. No other adverse events were reported.

Hayashi et al (2003) reported a similar case series (level IV evidence) of 22 women with histologically confirmed breast lesions that were between 0.5 and 2.6 cm (median size 0.9 cm). Median ablation time was 15 minutes (range 15 to 20.5 minutes) at 95°C. The ablated tumour was removed at surgery 1 to 2 weeks after RFA. Histology of the resected volume of ablation revealed that coagulative necrosis was complete in 19/22 (86%) of women. Disease at the ablation zone was evident in 3/22 (14%) of patients. Of these patients, one woman had dense breast tissue, which bent the RFA probe resulting in incomplete deployment. The size of the tumour at the initial ultrasound was underestimated in the remaining two women. In addition, five women were found to have foci of viable cancer distant from the index lesion, which were not detected by ultrasound or mammography prior to RFA. No adverse events were reported after the RFA procedure.

There were no studies reporting on women who had undergone RFA without follow-up surgery to resect the ablated volume; and no controlled studies assessing the effectiveness of RFA compared to standard treatments.

COST IMPACT

The cost of the RITA radiofrequency interstitial tissue ablation unit is approximately \$40,000. The single use electrodes come in two sizes, one for small (3cm lesions) tumours and one for larger tumours (5cm lesions) and cost \$1200 and \$2000, respectively (personal communication, Taylor Bryant). For comparison the Medicare Benefits Schedule currently lists two item numbers for the radiofrequency ablation of non-resectable hepatocellular carcinoma (item numbers 50950 and 50952), including any associated imaging service, with an associated fee of \$679.10 for each item number. There are no MBS items for RFA for breast tumours.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

Several problems have been identified with using thermal ablation as a method of treating breast tumours. In addition to not allowing histopathological evaluation of the surgical margins of the tumour, thermal ablation leaves the treated tumour behind in the breast to either be absorbed or calcified. This may result in painful and hard areas in the breast and may result in retraction and scarring with palpable masses. This may also result in serious psychological disturbances where women would not be convinced of tumour removal when a palpable mass is still felt in the breast (Wood 2003).

CONCLUSION:

The evidence base for radiofrequency ablation of breast tumours is limited (level IV) and the number of women enrolled in these case series was small. However, the potential for uptake of this procedure, in Australia, is large, and the benefit uncertain.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be referred to ASERNIP-S who are conducting a review of tumour radiofrequency ablation for all indications.

SOURCES OF FURTHER INFORMATION:

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Vargas, H. I., Dooley, W. C. et al (2004). 'Focused microwave phased array thermotherapy for ablation of early-stage breast cancer: results of thermal dose escalation', *Ann Surg Oncol*, 11 (2), 139-146.

Wood, W. C. (2003). 'The future of surgery in the treatment of breast cancer', *Breast*, 12 (6), 472-474.

SEARCH CRITERIA TO BE USED:

Breast/pathology/surgery

Breast Neoplasms/classification/*diagnosis/*therapy/pathology/*surgery/ultrasonography

Carcinoma, Ductal, Breast/classification/*diagnosis/*therapy

Carcinoma, Intraductal, Noninfiltrating/classification/diagnosis/therapy

Carcinoma in Situ/pathology/*surgery/ultrasonography

Catheter Ablation

Hyperthermia, Induced

Ultrasonography, Mammary

Surgical Procedures, Minimally Invasive