



Australian Government
Department of Health and Ageing



Horizon Scanning Technology Prioritising Summary

Percutaneous radiofrequency ablation for osteoid osteoma

February 2007



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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PRIORITISING SUMMARY

REGISTER ID: S000016

NAME OF TECHNOLOGY: PERCUTANEOUS RADIOFREQUENCY ABLATION

PURPOSE AND TARGET GROUP: PATIENTS DIAGNOSED WITH OSTEOID OSTEOMA

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
United States	✓		
Germany	✓		
Israel	✓		
Japan	✓		
China	✓		

IMPACT SUMMARY:

Percutaneous radiofrequency ablation is available through radiologists as an alternative to conventional surgical excision for the treatment of osteoid osteomas.

BACKGROUND

Osteoid osteomas are small, localised growths of bone, usually found in the lower extremities of children and young adults (Torriani and Rosenthal 2002). They have a slow rate of growth and rarely exceed a diameter of 1-1.5 cm. They are considered to be neoplastic and are thought to have a monoclonal origin, but are benign (Mahnken et al. 2006).

As the growth itself is not dangerous, diagnosis is usually as a result of secondary problems such as pain which normally responds well to non-steroidal anti-inflammatory medication. This pain is due to the fact that osteoid osteomas release pro-inflammatory prostaglandins, and also contain sensory nerve fibres. The pain can also be as a result of the location of the growth. In rare cases, osteoid osteoma can lead to profound muscle atrophy in the affected extremity (Rosenthal 2006). Computed tomography (CT) scans may be used to confirm the diagnosis and location of the lesion. Magnetic resonance imaging (MRI) may also be used although they are less sensitive. The lesions may spontaneously regress (Rosenthal 2006, Shinozaki et al. 2005).

The standard treatment for osteoid osteoma is surgical excision. However, surgical excision has several disadvantages: due to the surrounding bone formation and reactive tissue, the identification of the tumour margin can be difficult and this may lead to wide resection margins; resection within weight-bearing bones usually requires a relatively long recovery period to prevent fractures (sometimes internal fixation and/or bone grafting is required); and subtotal resection may lead to recurrence (Torriani and Rosenthal 2002). In view of these issues, percutaneous radiofrequency ablation (RFA) was developed as potential alternative to surgical excision. In this procedure, a small hole is drilled to enable the placement of a radiofrequency electrode within the tumour. The application of radiofrequency will result in thermal necrosis, therefore ablating the tumour. Biopsy specimens may be retrieved via the 2mm hole using a 16-G needle if required (Torriani and Rosenthal 2002).

CLINICAL NEED AND BURDEN OF DISEASE

In 2004/05, 1,428 people were diagnosed with a benign neoplasm of bone or articular cartilage in Australia (AIHW 2005, ICD-10 code D16). These figures include people with benign neoplasms of long and short bones of the upper and lower limbs, facial bones and vertebral bones. It is difficult to estimate how many patients go on to receive osteoplasty. Osteoid osteomas are very uncommon, accounting for 10% of all benign bone tumours (Rosenthal 2006), and usually found in children and young adults (Rosenthal *et al.* 1998). Therefore, if we extrapolate from the above figures for 2004/05, it may be estimated that about 140 people are diagnosed with osteoid osteomas annually in Australia.

DIFFUSION

RFA is a technique which may be used for a variety of disorders, such as for liver tumours (Schumacher *et al.* 2006), colorectal cancer (Ryan 2006), and renal tumours (Wen and Nakada 2006). A number of RFA devices are listed on the Australian Register of Therapeutic Goods (ARTG) (58706, 61468, 72400, 72400) although none are registered for this particular indication.

COMPARATORS

The only comparator to RFA is surgical excision / *en bloc* resection. The pain associated with the lesion can be controlled through chronic use of non-steroidal anti-inflammatory medications.

SAFETY AND EFFECTIVENESS ISSUES

The comparative study by Rosenthal *et al.* (1998) investigated percutaneous RFA of osteoid osteoma (n=38) compared with surgical excision (n=87). The average length of hospital stay for the subgroup of patients treated for *primary lesions* was substantially lower for RFA patients (0.18 days, n = 33) compared to patients treated with surgical excision (4.7 days, n = 68). The authors reported that no significant difference was noted for the rate of recurrence in this study. Of the patients treated with surgical excision, 6 (9%) returned for an additional procedure (5 surgical excision, 1 RFA), while 4 (12%) patients treated with RFA returned for a second procedure (2 surgical, 2 RFA) (p=0.725 between both groups). Meanwhile, in the subgroup of patients treated for *recurrent lesions* (19 surgical excision, 5 RFA), two patients treated with surgical excision experienced recurrence while no recurrence was noted in the RFA patients. The overall recurrence rate was 9% for patients treated with surgical excision and 11% for patients treated with percutaneous RFA (p = 0.75) (Rosenthal *et al.* 1998).

Clinical success (no pain), determined via a questionnaire, was achieved in a total of 19/27 (70%) patients who had surgical excision (mean follow-up: 9 years). Of the remaining

patients, 4 had improved symptoms while 4 patients failed to achieve resolution of symptoms. Meanwhile 20/26 (77%) RFA patients were completely free of pain; the remaining 6 patients did not experience improvement in their symptoms. Therefore, with regard to pain as a measure of clinical success, there was no significant difference between surgical excision and percutaneous RFA treatment ($p=0.722$). Over the course of this study, two patients (2.3%) had complications following surgical resection while no complications were reported for RFA patients (Rosenthal et al. 1998).

Numerous case series studies have been performed on percutaneous RFA for osteoid osteoma. The case series study by Lindner et al. (2001) reported an initial (primary) clinical success rate of 94.8% (55/58 patients). Similar initial clinical success rates were reported in other studies, 95.8% (23/24 patients) in the retrospective review by Kjar et al. (2006), 91.7% (11/12 patients) in the case series by Mahnken et al. (2006) and 100% (51/51 patients) in the case series by Peyser et al. (2006). However, the rate of recurrence varied substantially between these studies, Kjar et al. (2006) reported a recurrence rate of 34.8% (8/23 patients, median: 8 months), a substantially larger proportion compared to 5% in Lindner et al. (2001), 8% in Mahnken et al. (2006) and 2% in Peyser et al. (2006). The higher recurrence rate observed by Kjar et al. (2006) may be related to the size of the lesion previous studies have noted that recurrence was higher in lesions ≥ 10 mm. However, it is unclear if there were a higher proportion of patients with lesions ≥ 10 mm in diameter in the cohort examined by Kjar et al. (2006).

In the case series studies included, complications were rare, with Lindner et al. (2001) reporting one case of mild skin burn due to the heat generated by drilling in the anterior tibia and Peyser et al. (2006) reporting one incidence of wound infection where the nidus was located in the superficial anterior aspect of the tibial shin. Overall, percutaneous RFA appears to be a safe procedure with low incidences of complications. In addition to this, none of the included studies reported any incidences of long-term complications as a result of this procedure.

COST IMPACT

The cost impact of a programme of RFA for the treatment of osteoid osteoma is currently unknown. The main initial cost would be for the purchase and maintenance of the RFA machine and electrode. Although RFA may be used for the treatment of other indications, and numerous RFA machines are listed on the ARTG, it is unknown how many Australian hospitals currently have access to this device. Imaging costs associated with the use and possible purchase of CT machines would also need to be considered. Cost savings would mainly be related to hospital stay, as patients recover much more quickly from percutaneous RFA compared with the more invasive option of open surgery. The reduction of theatre time and the use of local anaesthesia would also be reduced using RFA. However, due to the fact that osteoid osteoma is a relatively uncommon disease, the overall costs savings that can be achieved in the health care system would likely be low. However, if a centre is equipped with a RFA machine already, percutaneous RFA may be the treatment of choice for osteoid osteoma at this centre due to the potential advantages in cost reduction and patient comfort.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

The choice of using RFA or surgical excision in the treatment of osteoid osteoma may depend on the location of the lesion and its accessibility to either technique.

HEALTHPACT CONCLUSION

The limited evidence currently available on percutaneous RFA for osteoid osteoma suggests that this procedure has similar level of effectiveness as conventional surgical excision (Rosenthal et al. 1998) with few complications. However, further long-term studies and cost effectiveness calculations would be required before this procedure can be recommended as the standard treatment for osteoid osteoma. Based on the limited evidence available, and the lack of studies showing substantial advantages to conventional surgical excision, HealthPACT has recommended that further assessment of this technology is no longer warranted.

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input checked="" type="checkbox"/> Archive |
| <input type="checkbox"/> Refer | <input type="checkbox"/> Decision pending |

SOURCES OF FURTHER INFORMATION:

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LIST OF STUDIES INCLUDED

Total number of studies 5
Level III-2 and level IV intervention evidence

SEARCH CRITERIA TO BE USED:

Osteoma, osteoid/radiography
Osteoma, osteoid/therapy
Catheter ablation*
Percutaneous radiofrequency
Radiofrequency ablation

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Ryan DP. Nonsurgical approaches to colorectal cancer. *Oncologist* 2006; 11(9):999-1002.

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Shinozaki T, Sato J, Watanabe H, Takagishi K. Osteoid osteoma treated with computed tomography-guided percutaneous radiofrequency ablation: a case series. *Journal of Orthopaedic Surgery* 2005; 13(3): 317-322.

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Wen CC, Nakada SY. Energy ablative techniques for treatment of small renal tumors. *Current Opinion in Urology* 2006; 16(5):321-6.