

# NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedures overview of image guided (CT) thermoacoagulation of osteoid osteoma

#### ***Introduction***

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

#### ***Date prepared***

This overview was prepared in May 2003.

#### ***Procedure names***

- Image guided percutaneous thermocoagulation of osteoid osteoma.
- CT guided thermocogulation of osteoid osteoma.

#### ***Specialty societies***

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- *British Society of Interventional Radiology.*
- *British Society of Skeletal Radiologists.*
- *British Orthopaedic Oncology Society.*

#### ***Description***

##### **Indications**

Osteoid osteomas are benign bone-forming tumours. Tumours may occur in any part of any bone, but occur most frequently in the legs, especially the femur and tibia. Osteoid osteomas do not spread to other parts of the body and rarely exceed 15 mm in diameter.

Osteoid osteomas are usually diagnosed in children and young adults. They are rare in very young children and in adults older than 40 years of age.

Almost all patients have pain as a result of the tumour. This begins as a dull aching sensation, becoming sharper and more severe with time and is typically worse at night.

Other symptoms of osteoid osteoma include growth disturbances, bony deformity, scoliosis and, if located within a joint, swelling, synovitis, restricted movement and contracture.

Osteoid osteoma can regress spontaneously without treatment. However, the resolution of symptoms is unpredictable and may take months or years.

### **Current treatment and alternatives**

Initial treatment is focused on pain management using aspirin or other non-steroidal anti-inflammatory drugs.

Surgical excision is offered to patients who continue to have pain despite having had a trial of medical therapy, or for whom the tumour is causing other complications such as curvature of the spine or osteoarthritis.

Surgery requires a hospital stay of several days and the patient cannot undertake weight-bearing activity for a substantial period of time. With aggressive resection there is also a risk of postoperative fracture, infection and haematoma.

In recent years several minimally invasive techniques using medical imaging, such as percutaneous resection and radiofrequency ablation, have been trialled in patients with osteoid osteoma in order to achieve removal or destruction of the tumour without the subsequent morbidity.

### **What the procedure involves:**

Radiofrequency ablation can be performed under intravenous sedation or general anaesthesia with use of CT (computerised tomography) guidance.

The first step is to localise the lesion with CT. A trephine bone biopsy needle is then introduced into the lesion. The needle (or sometimes a drill) is used to create a small entry hole through the bone. CT is used to monitor the progress of the needle to ensure placement near the tumour.

The core of the lesion is then removed with the inner trephine needle for biopsy, and a radiofrequency electrode probe is introduced into the centre of the nidus. The probe is heated to around 85–90°C for 4–6 minutes.

The whole procedure takes around 90 minutes. After removal of the electrode, patients a CT scan is done to assess the outcome of the procedure.

Most patients report having pain for 1–2 days after the procedure. This is different from the pain associated from the osteoid osteoma, which should resolve within 48 hours.

### **Efficacy:**

Resolution of pain was the main outcome reported in the studies. In a case series of 97 consecutive patients with a mean follow up of 41 months, 76% of patients reported a good response after one treatment session and 92% reported a good response after one or two sessions. In the smaller studies resolution of symptoms was reported by 82–95% of patients at final follow up.

Three Advisors considered that this was an established procedure with no concerns or uncertainties about its efficacy, one Advisor stated that the procedure was better than open surgery and there is less risk of recurrence.

### **Safety:**

Few complications were observed in the studies. Five of 239 patients (2%) experienced complications, including three patients who experienced superficial burns.

The Specialist Advisors noted transient pain as the most common complication of the procedure. Infection was also listed, but described as a rare adverse event. One Advisor noted that if the tumour is in a difficult area, adjacent structures may be at risk from inappropriate positioning of the electrode, and it was commented by two Advisors that the procedure is still safer than surgery in similar situations.

### **Literature review**

The medical literature was searched to identify studies and reviews relevant to image guided thermocogulation of osteoid osteoma. Searches were conducted via the following databases, covering the period from their commencement to April 2003: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts, the full paper was retrieved.

**Table 1 Inclusion and exclusion criteria**

<b>Characteristic</b>	<b>Criteria</b>
Publication type	Clinical studies included. Emphasis was placed on identifying good quality comparative studies. Abstracts were excluded where no clinical outcomes were reported, or the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with osteoid osteoma.
Intervention/test	Image guided thermocogulation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

### **List of studies found**

This overview is based on six studies: one non-randomised comparative study (historical control) and five uncontrolled case-series papers.

Seven other studies were identified but not incorporated in this overview, including four studies from non-English journals<sup>1-4</sup>. These seven studies are listed in Appendix A of this document.

Two articles were identified that reported on laser photocoagulation of osteoid osteomas with use of CT guidance<sup>5,6</sup>. These are also included in Appendix A.

Table 2 Summary of key efficacy and safety findings from non-randomised controlled studies

Study details	Patients	Intervention	Key efficacy findings		Key safety findings		Comments
Rosenthal et al (1998) <sup>171</sup>  Non-randomised comparative study (historical control)  Boston, USA  Retrospective 1978–1995  125 patients <ul style="list-style-type: none"> <li>• 38 RF</li> <li>• 87 surgical excisions</li> <li>• 101 primary lesion</li> <li>• 24 recurrent lesion</li> </ul> Follow up: clinical follow up of at least 2 years	Patients with spinal lesion were excluded	RF electrode  Heating the tip to 90°C  6 minutes	<b>RF (38)</b>  <b>Resolution of symptoms</b> 34/38 (89.5%) one session  <b>Primary (33)</b> 4/33 (12%) had a second session (3.4 years mean follow up)  <b>Recurrence (5)</b> No patients had a second session for subsequent recurrence.  <b>Questionnaire</b> <ul style="list-style-type: none"> <li>• 26/38 (68%) returned form.</li> <li>• 20/26 (77%) reported free from pain</li> </ul>	<b>Surgery (87)</b>  <b>Resolution of symptoms</b> 79/87 (91%) one session  <b>Primary (68)</b> 6/68 (9%) had a second operation (9 years mean follow up)  <b>Recurrence (19)</b> 2/19 (11%) had a second operation for subsequent recurrence.  <b>Questionnaire</b> <ul style="list-style-type: none"> <li>• 27/89 (30%) returned form.</li> <li>• 19/27 (70%) reported free from pain</li> </ul>	<b>RF</b>  <b>Complications</b> None reported	<b>Surgery</b>  <b>Complications</b> 2 patients (resulting in patients having secondary procedures)	Historical control – potential for bias.  Not consecutive.  Follow up done by questionnaire – low response rate 42%.  Independent surgeons reviewed questionnaire responses.  ‘Successful’ defined as free from pain and taking no medication.  Biopsy <ul style="list-style-type: none"> <li>• 52/87 surgery patients</li> <li>• 25/38 RF patients.</li> </ul> Follow-up was shorter for patients who had undergone RF.  Analysis of only patients in whom diagnosis was verified histologically showed that rate of recurrence decreased.

**Table 3 Summary of key efficacy and safety findings from uncontrolled studies**

Study details	Patients	Intervention	Key efficacy findings	Key safety findings	Comments
<p>Vanderschueren et al (2002)<sup>8</sup></p> <p>Uncontrolled case series Consecutive</p> <p>Leiden (Netherlands)</p> <p>June 1994 to April 2000</p> <p>97 patients (121 procedures) Age range 4–53 years</p> <p>Duration of symptoms: clinical follow up of at least 3 months</p> <p>Mean follow up: 41 months (5–81 months)</p>	<p><b>Site:</b> 42 femur 14 tibia 8 iliac/acetabulum 5 talus 4 carpal bones of hand 4 ulna 4 humerus 3 lumbar spine 3 metacarpal 2 fibula 2 navicular bone 2 cervical spine 1 cuneiform bone of the foot 1 dorsal spine 1 radius 1 phalanx of the hand</p>	<p>RF electrode</p> <p>Heating the tip to 90°C</p> <p>Heating time: 4 minutes</p> <p>Procedure time: 90 minutes</p>	<p><b>Resolution of symptoms (pain)</b> 74/97 (76%) good response after one session (2 weeks) 95% CI of 68–85%</p> <p>23/97 (24%) had residual (12) or recurrent (11) symptoms after one session (6 months)</p> <p>Patients with residual disease (12) had a second session. 10/12 (83%) had resolution. (2 excision)</p> <p>Patients with recurrent pain (10/11) had a second session. 5/10 (50%) had resolution</p> <p>89/97 (92%) good response after one or two sessions. 95% CI of 86–97%</p>	<p><b>Complications</b></p> <ul style="list-style-type: none"> <li>1 patient fistula</li> <li>1 patient biopsy needle broke in the bone</li> </ul>	<p>13 patients excluded (110) 4 patients with incomplete follow-up data, 9 patients had short-term &lt; 3 months follow-up.</p> <p>9 patients were treated with surgery before they treated with RF.</p> <p>Biopsy was performed when there was uncertainty from clinical and imaging information (53/97 patients). 20/56 biopsy confirmed diagnosis, 35 cases biopsy information was insufficient.</p> <p>Response was determined by clinical examination of postal questionnaire. Unclear about validity.</p> <p>Varying follow up.</p>
<p>Linder et al (2001) and Woertler et al (2001)<sup>9 10</sup></p> <p>Uncontrolled case series Prospective</p> <p>Germany</p> <p>March 1997 to July 2000</p> <p>58 patients. Age range 3–41 years</p> <p>Duration of symptoms: months–4 years</p>	<p><b>Site:</b> 33 femur 16 tibia 2 pelvis 2 calcaneus 1 humerus 2 ulna 1 talus 1 thoracic vertebra</p>	<p>RF electrode</p> <p>Heating the tip to 90°C</p> <p>4–5 minutes</p>	<p><b>Resolution of symptoms (pain)</b> 55/58 (95%) were symptom free at final follow-up (4–41 months)</p> <p>3 patients had recurrent pain. These patients had a second session. 100% had resolution</p>	<p><b>Complications</b> 1 patient mild heat burn (heat caused by drilling)</p>	<p>Patients where there was uncertainty from clinical or imaging evaluation were given surgical excision not RF.</p> <p>In 11 patients a core biopsy was taken before RF, 4 were positive.</p> <p>Follow up occurred in the form of clinical visits.</p> <p>Paper by Woertler et al<sup>10</sup> notes that patients lost to follow up were not included in the study. This has the potential to influence results.</p>

Study details	Patients	Intervention	Key efficacy findings	Key safety findings	Comments
Mean follow up: 23 months (6–41 months)					
Cioni et al (2001) <sup>11</sup> Uncontrolled case series Italy March 1997 to October 2000 17 patients, age: 12–54 years Mean duration of symptoms: 9 months Mean follow up: 28 months	<b>Site:</b> 2 femoral neck 13 femur 3 tibia 1 radius 1 olecranon ulnae	RF electrode  RF energy between 900 and 1200 MA 4–5 minutes  Procedure time: 30–80 minutes	<b>Resolution of symptoms (pain)</b>  14/17 (82%) were symptom free within 2 days post-treatment  2 patients had two treatment sessions – 16/17 patients were symptom free (unclear follow up)  1 patient had surgery	<b>Complications</b> 2 patients superficial burns	15 procedures performed percutaneously, 3 others were performed after surgical exposure of the bone.  Unclear whether biopsies were taken.
de Berg et al (1995) <sup>12</sup> Uncontrolled case series Prospective Leiden (Netherlands) 1994-1995 18 patients, age: 7–33 years Duration of symptoms: not stated Follow up: 3–15 months	<b>Site:</b> 4 femoral neck 2 acetabulum 1 iliac bone 3 tibia bone 1 fibula 2 humerus 2 tarsal 2 carpal bone 1 metacarpal bone	RF electrode  Heating the tip to 90°C  4–5 minutes  Procedure time 45–180 minutes	<b>Resolution of symptoms (pain)</b>  17/18 (94%) were symptom free at follow up (3–15 months)  1 patient with recurrent symptoms. This patient given second treatment	<b>Complications</b> No complications were encountered	Limited information provided in the study.  Histological examination was part of diagnosis.

Study details	Patients	Intervention	Key efficacy findings	Key safety findings	Comments																														
Barei et al (2002) <sup>13</sup> Uncontrolled case series Canada June 1995–February 1998 11 patients (3 different centres) <ul style="list-style-type: none"> <li>• 10 primary</li> <li>• 1 recurrence</li> </ul> Age: 8–45 years (8 patients younger than 22 years of age) Duration of symptoms: 6 (55%) patients had symptoms > 12 months Mean follow up: 18.7 months	<b>Site:</b> Slightly more than 50% of patients had their osteoid osteoma localised to femoral head or neck	RF electrode Heating the tip to 90°C 4 minutes	<b>Daytime pain</b> (Visual analogue scale [VAS] 1–10, where 10 = worst pain) <table> <thead> <tr> <th>VAS</th> <th>Pre-op (number of patients)</th> <th>Post-op</th> </tr> </thead> <tbody> <tr> <td>0–2</td> <td>1</td> <td>11</td> </tr> <tr> <td>3–5</td> <td>4</td> <td>0</td> </tr> <tr> <td>6–8</td> <td>4</td> <td>0</td> </tr> <tr> <td>9–10</td> <td>2</td> <td>0</td> </tr> </tbody> </table> <b>Night pain</b> (VAS 1–10, where 10 = worst pain) <table> <thead> <tr> <th>VAS</th> <th>Pre-op (number of patients)</th> <th>Post-op</th> </tr> </thead> <tbody> <tr> <td>0–2</td> <td>0</td> <td>9</td> </tr> <tr> <td>3–5</td> <td>0</td> <td>2</td> </tr> <tr> <td>6–8</td> <td>7</td> <td>0</td> </tr> <tr> <td>9–10</td> <td>4</td> <td>0</td> </tr> </tbody> </table> <b>Recurrence</b> 1 patient had recurrence (7 months) 91% no recurrence <b>Activities</b> All patients able to resume activities	VAS	Pre-op (number of patients)	Post-op	0–2	1	11	3–5	4	0	6–8	4	0	9–10	2	0	VAS	Pre-op (number of patients)	Post-op	0–2	0	9	3–5	0	2	6–8	7	0	9–10	4	0	<b>Complications</b> None reported	Two patients lost to follow-up. Possible that the 2 patients had pain/recurrence. Follow up by telephone questionnaire. Questionnaire has not been validated. Pre-operative pain measures were recalled at interview (recall bias). Unclear when pain was measured postoperatively. Biopsy (histological examination) of the lesion was not taken. Patients concerns regarding recurrence also assessed and reported in this paper.
VAS	Pre-op (number of patients)	Post-op																																	
0–2	1	11																																	
3–5	4	0																																	
6–8	4	0																																	
9–10	2	0																																	
VAS	Pre-op (number of patients)	Post-op																																	
0–2	0	9																																	
3–5	0	2																																	
6–8	7	0																																	
9–10	4	0																																	

## **Validity and generalisability of the studies**

- The small number of patients included in the studies may be explained by osteoid osteoma being a relatively rare condition.
- Patient characteristics such as age, location of tumour, duration of symptoms and type of lesion varied among the studies.
- The main outcome measure in the studies was resolution of pain. This is a difficult outcome to measure objectively. In the majority of studies pain was measured postoperatively by telephone or mail questionnaire and this may have led to an inaccurate reporting of symptoms because of recall bias. It is also unclear whether younger patients were assessed in the same manner or whether caregivers were surveyed.
- Uncontrolled studies also do not allow the natural history of the disease to be assessed – some patients will have resolution of symptoms (that is, pain) because of natural improvement rather than as a result of the intervention. Therefore the data on resolution of symptoms may be overestimated.
- In the majority of studies mean follow up was greater than 12 months (range 18–41 months mean follow-up). Duration of follow up is important to consider in assessing recurrence of symptoms.
- Not all patients had a histological verification of the condition. This may mean that a proportion of treated patients did not have the condition, leading to an overestimate of the rate of recurrence. In the paper by Rosenthal et al <sup>7</sup> the authors note that the rate of recurrence decreased when analysing only the results of patients in whom the diagnosis had been confirmed by biopsy at the time of the operation.

## ***Specialist advisors' opinions***

- Less than 10% of specialists are engaged in this area of this work.
- Both orthopaedic surgeons and interventional radiologists perform this procedure.
- This procedure is the only way in which osteoid osteoma should be treated.
- It is important that clinicians who undertake this procedure are sufficiently skilled in imaging.
- Procedure does require specialist equipment.
- The diffusion of the procedure may increase as more surgeons realise that radiofrequency ablation is an alternative to surgery.
- Currently three centres undertaking this procedure, each with its own registry.

## ***Issues for consideration by IPAC***

- Limited data will be available on this procedure because of the rarity of this condition.
- This procedure can also be undertaken using a laser. The use of laser may reflect the availability of this equipment at the given institution. There is also some suggestion that the use of laser minimises the damage to the surrounding bone (personal communication Defriend, DE 30<sup>th</sup> July 2003).

## References

- 1 Lindner NJ, Scarborough M, Ciccarelli JM, Enneking WF. [CT-controlled thermocoagulation of osteoid osteoma in comparison with traditional methods]. [German]. *Zeitschrift fur Orthopadie und Ihre Grenzgebiete* 1997; 135(6):522–7.
- 2 Martel J, Ortiz E, Bueno A, Dhimes P. Percutaneous radiofrequency ablation of osteoid osteoma. *Radiologia* 2001; 43(7):337–40.
- 3 Gallazzi MB, Arborio G, Garbagna PG, Perrucchini G, et al. [Percutaneous radio-frequency ablation of osteoid osteoma: technique and preliminary results]. [Italian]. *Radiologia Medica* 2001; 102(5-6):329–34.
- 4 Adam G, Keulers P, Vorwerk D, Heller KD, et al. [The percutaneous CT-guided treatment of osteoid osteomas: a combined procedure with a biopsy drill and subsequent ethanol injection]. [German]. *ROFO-Fortschritte auf dem Gebiet der Rontgenstrahlen und der Bildgebenden V* 1995; 162(3):232–35.
- 5 DeFriend DE, Smith SP, Hughes PM. Percutaneous Laser Photocoagulation of Osteoid Osteomas under CT Guidance. *Clinical Radiology* 2003; 58(3):222–6.
- 6 Teeuwisse WM, Geleijns J, Broerse JJ, Obermann WR, et al. Patient and staff dose during CT guided biopsy, drainage and coagulation. *British Journal of Radiology* 2001; 74(884):720–6.
- 7 Rosenthal DI, Hornicek FJ, Wolfe MW, Jennings LC, et al. Percutaneous radiofrequency coagulation of osteoid osteoma compared with operative treatment.[comment]. *Journal of Bone & Joint Surgery – American Volume* 1998; 80(6):815–21.
- 8 Vanderschueren GM, Taminiau AH, Obermann WR, Bloem JL. Osteoid osteoma: clinical results with thermocoagulation. *Radiology* 2002; 224(1):82–6.
- 9 Lindner NJ, Ozaki T, Roedl R, Gosheger G, et al. Percutaneous radiofrequency ablation in osteoid osteoma. *Journal of Bone & Joint Surgery - British Volume* 2001; 83(3):391–6.
- 10 Woertler K, Vestring T, Boettner F, Winkelmann W, et al. Osteoid osteoma: CT-guided percutaneous radiofrequency ablation and follow-up in 47 patients. *Journal of Vascular & Interventional Radiology* 2001; 12(6):717–22.
- 11 Cioni R, Armillotta N, Marchetti S, Consoli V, et al. Osteoid osteoma: CT-guided radio-frequency ablation. *International Congress Series* 2001; 1230:197–202.
- 12 de Berg JC, Pattynama PM, Obermann WR, Bode PJ, et al. Percutaneous computed-tomography-guided thermocoagulation for osteoid osteomas. *Lancet* 1995; 346(8971):350-351.
- 13 Barei DP, Moreau G, Scarborough MT, Neel MD. Percutaneous radiofrequency ablation of osteoid osteoma. *Clinical Orthopaedics & Related Research* 2000;(373):115-124.

**Appendix A: Additional relevant papers not included in the summary tables.**

<b>Name</b>	<b>Number of patients</b>	<b>Mean follow up</b>
Adam G, Keulers P, Vorwerk D, Heller KD, et al. [The percutaneous CT-guided treatment of osteoid osteomas: a combined procedure with a biopsy drill and subsequent ethanol injection]. [ <b>German</b> ]. <i>ROFO-Fortschritte auf dem Gebiet der Rontgenstrahlen und der Bildgebenden V</i> 1995; 162(3):232–5.	6	6–24 months (range)
Cove JAM. Osteoid Osteoma of the Spine Treated With Percutaneous Computed Tomography-Guided Thermocoagulation. <i>Spine</i> 2000; 25(10):1283–6.	2	24 months
* DeFriend DE, Smith SP, Hughes PM. Percutaneous Laser Photocoagulation of Osteoid Osteomas under CT Guidance. <i>Clinical Radiology</i> 2003; 58(3):222–6.	5	14 months
Gallazzi MB, Arborio G, Garbagna PG, Perrucchini G, et al. [Percutaneous radio-frequency ablation of osteoid osteoma: technique and preliminary results]. [ <b>Italian</b> ]. <i>Radiologia Medica</i> 2001; 102(5-6):329–34.	15	Unclear
* Gangi A, Dietemann J-L, Gasser B, Mortazavi R, et al. Interstitial laser photocoagulation of osteoid osteomas with use of CT guidance. <i>Radiology</i> 1997; 203(3):843–8.	15	15.7 months
Lindner NJ, Scarborough M, Ciccarelli JM, Enneking WF. [CT-controlled thermocoagulation of osteoid osteoma in comparison with traditional methods]. [ <b>German</b> ]. <i>Zeitschrift fur Orthopadie und Ihre Grenzgebiete</i> 1997; 135(6):522–7.	91	Unclear
Martel J, Ortiz E, Bueno A, Dhimes P. Percutaneous radiofrequency ablation of osteoid osteoma.[ <b>Spanish</b> ] <i>Radiologia</i> 2001; 43(7):337–40.	3	3–4 months (range)
Rosenthal DI, Springfield DS, Gebhardt MC, Rosenberg AE, et al. Osteoid osteoma: percutaneous radio-frequency ablation. <i>Radiology</i> 1995; 197(2):451–4.	18	12 months
Venbrux ACM. Image-guided Percutaneous Radiofrequency Ablation for Osteoid Osteomas. <i>Journal of Vascular &amp; Interventional Radiology</i> 2003; 14(3):375–80.	9	10.3 months

\* Papers that reported on laser photocoagulation