

Cryotherapy for renal cancer

1 Guidance

- 1.1 Current evidence suggests that cryotherapy for renal cancer ablates tumour tissue and that its safety is adequate. However, the evidence about its effect on long-term local control and survival is not yet adequate to support the use of this procedure without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake cryotherapy for renal cancer should ensure that patients understand the uncertainties about its effect on quality of life and long-term survival, and provide them with clear written information. Use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG207publicinfo).
- 1.3 The procedure should only be offered after assessment by a specialist multidisciplinary team, which should include a urologist, an oncologist and an interventional radiologist.
- 1.4 Controlled studies into the long-term clinical outcomes will be useful. Clinicians are encouraged to collect long-term data and should enter all patients with renal cancer treated with cryotherapy into the British Association of Urological Surgeons Cancer Registry (www.baus.org.uk/Display.aspx?item=319). The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 The most common type of renal cancer in adults is renal cell carcinoma. Some cases are linked to hereditary syndromes. Symptoms and signs may include pain, blood in the urine (haematuria),

weight loss and a palpable abdominal mass, although some tumours are identified at a preclinical stage through imaging. There are uncertainties about the true prevalence of small, asymptomatic renal tumours.

- 2.1.2 If operable, and depending on the size and location of the tumour (peripheral or central), the treatment for renal cancer has been partial or total nephrectomy. The prognosis is better with small tumours (less than 4 cm) and some of these tumours can be treated with minimally invasive techniques such as laparoscopic partial nephrectomy. Radiofrequency ablation is another treatment option for small tumours.
- 2.1.3 Cryotherapy is a possible treatment option for small tumours, for maximum preservation of renal function in patients with a solitary kidney or compromised renal function, or for those unfit for or unwilling to undergo major surgery.

2.2 Outline of the procedure

- 2.2.1 Cryotherapy is performed under general anaesthesia, either percutaneously under image guidance or laparoscopically.
- 2.2.2 One or more probes are inserted into the tumour to deliver a coolant at subfreezing temperatures. An ice ball is created around the tip of the probe, which destroys cells through a cyclical process of direct freezing, dehydration and hypoxia. Each freeze cycle is followed by a heat (thaw) cycle which allows removal of the probe. A double freeze-thaw cycle is usually performed to ablate the tumour, with the aim of extending the ice ball approximately 1 cm beyond the tumour margins. Additional freeze-thaw cycles may be performed if necessary, and more than one probe can be used.
- 2.2.3 The maximum renal tumour size for which cryotherapy is recommended is approximately 4 cm (that is, small, stage I tumours).

Interventional procedure guidance 207

This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

2.3 Efficacy

- 2.3.1 The evidence for this procedure was based on one non-randomised comparative study and seven case series. In two studies, the diagnosis was based on imaging alone, and was not confirmed histologically. In the five studies where tumour histology was examined, 65% (161/246) of tumours were renal cell carcinomas, 9% (22/246) were other renal tumours (such as oncocytomas and transitional cell carcinomas) and 26% (64/246) were benign or of indeterminate pathology.
- 2.3.2 The longest mean follow-up was reported in a case series of 56 patients undergoing laparoscopic cryotherapy. This study reported an overall 3-year survival rate of 89%.
- 2.3.3 In a study comparing laparoscopic cryotherapy with partial nephrectomy, tumours recurred locally in 2/78 patients (3%) in the cryotherapy group (mean follow-up 24.6 months). In another case series, 2/59 patients (3%) developed local recurrence after laparoscopic cryotherapy (mean follow-up 26.8 months). For more details, refer to the 'Sources of evidence' section.
- 2.3.4 The Specialist Advisers commented that, because only a small number of patients have been treated with this procedure, long-term efficacy has yet to be established. They also noted that the lack of histological data makes it difficult to determine whether total ablation of tumours has been achieved.

2.4 Safety

- 2.4.1 In one study of 271 patients undergoing either cryotherapy or radiofrequency ablation for renal cancer, cryotherapy (performed laparoscopically or percutaneously) was associated with a complication rate of 14% (19/139), including 10 instances of probe-site pain. In another study comparing laparoscopic cryotherapy (n = 78) with partial nephrectomy (n = 153), six complications were reported in the cryotherapy group, compared with 49 in the surgery group. Other complications following cryotherapy reported in the studies included bleeding requiring nephrectomy, haematoma, ileus and respiratory difficulty. For more details, refer to the 'Sources of evidence' section.

- 2.4.2 The Specialist Advisers listed the main adverse events as bleeding, injury to adjacent structures, urinary leakage and infection.

2.5 Other comments

- 2.5.1 The lack of histology and limitations of tumour assessment using imaging techniques alone may make it difficult to determine whether total ablation of tumours has been achieved. In addition, little is known about the natural history of small renal tumours and the survival of patients. The site (whether located centrally or peripherally on the kidney) and size of the tumour appear to be important, and results may be better for smaller and peripheral renal tumours.

3 Further information

- 3.1 The Institute has issued interventional procedure guidance on percutaneous radiofrequency ablation of renal cancer (www.nice.org.uk/IPG091).

Andrew Dillon
Chief Executive
January 2007

Information for patients

The Institute has produced information describing its guidance on this procedure for patients ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG207publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document: 'Interventional procedure overview of cryotherapy for renal cancer', November 2005.

Available from: www.nice.org.uk/IP344overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1197. 'Understanding NICE guidance' can be obtained by quoting reference number N1198.

The distribution list for this guidance is available at www.nice.org.uk/IPG207distributionlist

Published by the National Institute for Health and Clinical Excellence, January 2007; ISBN 1-84629-361-8

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

© National Institute for Health and Clinical Excellence, January 2007. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of the Institute.