NICE guidance

Percutaneous cryotherapy for renal cancer

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg402

This guidance replaces IPG207.

1 Guidance

This document replaces previous guidance on cryotherapy for renal cancers (interventional procedure guidance 207).

1.1 Current evidence on the efficacy and safety of percutaneous cryotherapy for renal cancer is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 This procedure should only be offered after assessment by a specialist urological cancer multidisciplinary team.

1.3 NICE encourages collection and publication of data on the outcomes of this procedure in the long term. Further research should compare the

long-term outcomes of cryotherapy with those of other treatments for renal cancer.

2 The procedure

2.1 Indications and current treatments

2.1.1 The most common type of renal cancer in adults is renal cell carcinoma. Symptoms and signs may include pain and haematuria. Some tumours are identified when symptomatic, through imaging. Establishing the diagnosis and assessing the prognosis of some renal tumours may be difficult.

2.1.2 Treatment options include partial or total nephrectomy (laparoscopic or open), and ablation techniques including radiofrequency ablation (RFA).

2.2 Outline of the procedure

2.2.1 Percutaneous cryotherapy for renal cancer is carried out with the patient under general anaesthesia, or local anaesthesia and sedation. A biopsy of the tumour may be carried out. With suitable imaging guidance, a probe is inserted percutaneously into the tumour to deliver a coolant at subfreezing temperatures, creating an ice ball around the probe's tip, which destroys the surrounding tissues. Each freeze cycle is followed by a heat (thaw) cycle, allowing removal of the probe. Two freeze–thaw cycles are usually performed to ablate the tumour (additional cycles may also be performed if necessary), aiming to extend the ice ball approximately 1 cm beyond tumour margins. More than 1 probe can be used.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at www.nice.org.uk/guidance/IP/934/overview

2.3 Efficacy

2.3.1 A non-randomised comparative study of 93 patients treated by laparoscopic or percutaneous cryotherapy reported no disease-related deaths at 22-month and 12-month follow-up respectively.

2.3.2 A meta-analysis of non-randomised comparative studies and case series including a total of 1375 tumours reported that significantly fewer patients treated by cryotherapy had local tumour progression (defined as radiographic or pathological evidence of residual disease after initial treatment, regardless of time to recurrence) compared with those treated by RFA at a mean follow-up of 18.7 months (5% [31/600] vs 13% [100/775], $p < 0.0001$). Repeat ablations were required in fewer patients treated by cryotherapy than RFA (1% [8/600] vs 9% [66/775], $p < 0.0001$). Fewer patients treated by cryotherapy had progression to metastatic disease but this was not significant (1% [6/600] vs 3% [19/775], $p = 0.06$).

2.3.3 A non-randomised comparative study of 93 patients reported that 10% (2/20) of patients who had percutaneous cryoablation and 4% (2/56) of patients treated by laparoscopic cryotherapy had persistently enhancing lesions at early follow-up suggesting incomplete ablation (all patients had further treatment; 3 patients were treated by percutaneous cryotherapy and 1 by radical nephrectomy).

2.3.4 A non-randomised comparative study of 90 patients reported 'primary effectiveness' (complete ablation of tumour after the initial procedure) in 90% (27/30) of patients treated by percutaneous cryotherapy and 93% (56/60) of patients treated by laparoscopic cryotherapy ($p = 0.68$).

2.3.5 In a non-randomised comparative study of 66 patients treated by percutaneous or laparoscopic cryotherapy, further treatment was needed in 25% (5/20) and 4% (2/52) of patients respectively ($p = 0.015$).

2.3.6 In the non-randomised comparative study of 93 patients treated by percutaneous cryotherapy ($n = 20$), or laparoscopic cryotherapy ($n = 59$), or RFA ($n = 15$), patients returned to work within 6.2, 17.5 and 4.0 days respectively. The difference between the percutaneous RFA and

laparoscopic cryotherapy groups was significant ($p < 0.05$).

2.3.7 The Specialist Advisers listed key efficacy outcomes as success rate of cryoablation based on radiological criteria, retreatment rates, recurrence, and disease-specific and overall survival.

2.4 Safety

2.4.1 The non-randomised comparative study of 90 patients reported no major complications in patients treated by percutaneous cryotherapy and 3 major complications in patients treated by laparoscopic cryotherapy (severe respiratory distress in 1, intraoperative bowel injury in 1, and postoperative atrial fibrillation in 1).

2.4.2 The non-randomised comparative study of 37 patients reported that haemorrhage requiring transfusion occurred in 11% (2/18) of patients treated by percutaneous cryotherapy and 28% (5/20) of patients treated by laparoscopic cryotherapy.

2.4.3 The non-randomised comparative study of 93 patients reported significant postoperative prolonged neurapraxia (not otherwise described) in 2 patients treated by percutaneous cryotherapy.

2.4.4 The non-randomised comparative study of 90 patients reported that 4 patients treated by percutaneous cryotherapy had minor procedural complications, including symptomatic perinephric haematoma, asymptomatic and self-limited urine leak identified at imaging, self-limited flank paraesthesia and neuralgia, and intercostal neurapraxia.

2.4.5 The Specialist Advisers stated that the most common complication is bleeding. They stated that ureteric, bowel and pancreatic injury are rare complications. They considered theoretical adverse events to include pneumothorax and thermal injury to the skin.

2.5 Other comments

2.5.1 The Committee noted that most studies of percutaneous cryotherapy for

renal cancer included both malignant and benign lesions, and that histology was unknown for many of the lesions treated by the procedure. This made interpretation of the evidence difficult.

2.5.2 The Committee was advised that the diagnosis of malignancy is typically made by imaging, and that histology is generally not available to confirm the diagnosis; this contrasts with treatment by any kind of nephrectomy which provides tissue for histological diagnosis.

2.5.3 The Committee noted that the maximum renal tumour size for which cryotherapy is recommended is approximately 4 cm (small, stage I tumours) but it has been used recently in larger tumours.

3 Further information

3.1 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/guidance/IPG402/publicinfo

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation