

Percutaneous cryotherapy for renal cancer

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg402

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG207.

1 Guidance

- 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.

2.3 Efficacy

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](#).

- 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 1,375 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 out of 600] versus 13% [100 out of 775], $p < 0.0001$). Repeat ablations were required in fewer patients treated by cryotherapy than RFA (1% [8 out of 600] versus 9% [66 out of 775], $p < 0.0001$). Fewer patients treated by cryotherapy had progression to metastatic disease but this was not significant (1% [6 out of 600] versus 3% [19 out of 775], $p = 0.06$).
- 2.3.3 A non-randomised comparative study of 93 patients reported that 10% (2 out of 20) of patients who had percutaneous cryoablation and 4% (2 out of 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 out of 30) of patients treated by percutaneous cryotherapy and 93% (56 out of 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 out of 20) and 4% (2 out of 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 out of 18) of patients treated by percutaneous cryotherapy and 28% (5 out of 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 1 tumours) but it has been used recently in larger tumours.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).