NICE guidance

Laparoscopic cryotherapy for renal cancer

Interventional procedures guidance
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nice.org.uk/guidance/ipg405

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. However, 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.

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.

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

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

1.1 Current evidence on the efficacy and safety of laparoscopic 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 long-term outcomes of this procedure.

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 Laparoscopic cryotherapy for renal cancer is carried out with the patient under general anaesthesia. A transperitoneal or retroperitoneal approach can be used. A biopsy of the tumour may be carried out. Under laparoscopic visualisation, a probe is inserted into the tumour to deliver a coolant at subfreezing temperatures, creating an ice ball around the probe's tip, which destroys the surrounding tissue. 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), with the aim of extending the ice ball approximately 1 cm beyond tumour margins. More than 1 probe can be used.

2.2.2 The maximum renal tumour size for which cryotherapy is recommended is approximately 4 cm (small, stage I tumours).

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/344/overview

2.3 Efficacy

2.3.1 A non-randomised study of 101 patients reported cancer-specific survival to be 89%, 100% and 84% among 36, 36 and 29 patients treated by cryoablation, laparoscopic partial nephrectomy (LPN) and RFA respectively at 2 years (significance not stated).

2.3.2 A meta-analysis of non-randomised comparative studies and case series, including a total of 1375 patients, reported that repeat ablations were required in fewer patients treated by cryotherapy than RFA (1% [8/600] vs 9% [66/775], $p < 0.0001$). Furthermore, 5% (31/600) of cryotherapy-treated patients had local tumour progression (defined as radiographic or pathological evidence of residual disease after initial treatment) compared with 13% (100/775) treated by RFA during a mean follow-up of 18.7 months ($p < 0.0001$).

2.3.3 In a non-randomised comparative study of 264 patients treated by laparoscopic cryotherapy (139 lesions) or by percutaneous RFA (73 lesions), radiographic success (no evidence of central or nodular enhancement) was reported in 90% (125/139) and 85% (62/73) of lesions respectively at 6-month follow-up ($p = 0.62$).

2.3.4 In the non-randomised study of 93 patients comparing laparoscopic cryotherapy versus percutaneous cryotherapy versus RFA, patients returned to work within 18, 6 and 4 days respectively (significant for comparison between percutaneous RFA and laparoscopic cryotherapy, $p < 0.05$). Patient satisfaction (not otherwise described) did not differ significantly between the groups.

2.3.5 Specialist Advisers listed key efficacy outcomes as successful ablation based on radiological criteria, retreatment rates, tumour recurrence, disease-specific survival and overall survival.

2.4 Safety

2.4.1 Haemorrhage requiring transfusion occurred in 26% (5/19) of patients treated by laparoscopic cryotherapy compared with 11% (2/18) treated by percutaneous cryotherapy in a non-randomised study of 37 patients; in 10% (2/20) of patients treated by laparoscopic cryotherapy in a non-randomised study of 66 patients; and in 2% (3/123) and 11% (4/37) in 2 case series of 123 and 37 patients, respectively.

2.4.2 A non-randomised comparative study comparing 29 patients treated by laparoscopic cryoablation, 20 by laparoscopic radical nephrectomy and 17 by LPN reported that conversion to open surgery because of intraoperative complications (including splenic haemorrhage, mesenteric artery haemorrhage and inability to progress due to retroperitoneal scarring) was required in 1 patient in each group.

2.4.3 The non-randomised study of 101 patients reported intraoperative pleural injury in 1 patient among 36 in the cryotherapy treatment group. Other postoperative complications in patients in the cryotherapy group included urine leak, haemothorax and atelectasis in 1 patient each.

2.4.4 A case report described acute obstruction and anuria caused by a blood clot in the renal pelvis in a patient with a single kidney and chronic renal insufficiency, successfully treated by temporary ureteric stent insertion.

2.4.5 Another case report described a patient with a single kidney presenting with left flank pain and fever due to obstruction by urothelial slough 3 months after the procedure. This resolved by ureteroscopic removal of the necrotic tissue and a temporary stent placement.

2.4.6 Specialist Advisers stated that ureteric (including pelviureteric junction), bowel and pancreatic injury have occurred but are rare. They considered theoretical adverse events to include the inherent risks of laparoscopic surgery, such as trocar injury, neurapraxia, port site hernia and CO_2 embolism.

2.5 Other comments

2.5.1 The Committee noted that most reports of laparoscopic 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 data difficult.

2.5.2 The Committee was advised that the diagnosis of malignancy is typically made by imaging and that histology may not be 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 the paucity of comparative evidence on the management of localised renal cancer. It considered that further research into the comparative efficacy and safety of different surgical and ablative treatments would be useful.

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/IPG405/publicinfo

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation