Percutaneous radiofrequency ablation for renal cancer

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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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG91.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of percutaneous radiofrequency ablation (RFA) for renal cancer in the short and medium term appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit, and provided that patients are followed up in the long term.
- 1.2 Patient selection for percutaneous RFA for renal cancer should be carried out by a urological cancer multidisciplinary team.
- 1.3 NICE encourages data collection to provide information about the outcomes of this procedure in the long term. Further research should compare the long-term outcomes of RFA with those of other treatments for renal cancer.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 There are few symptoms in the early stages of renal cancer. Typically, symptoms develop as the disease progresses. The first symptom is often blood in the urine; pain and flank mass are other classic symptoms.
- 2.1.2 Renal cancer may be diagnosed incidentally on imaging studies or patients may

present with symptoms. Conventional treatment for renal cancer is total or partial nephrectomy (open or laparoscopic). One of a range of non-resectional ablative procedures such as cryoablation and radiofrequency ablation (RFA) may be selected for some smaller tumours.

2.2 Outline of the procedure

2.2.1 Percutaneous RFA for renal cancer is carried out with the patient under either local anaesthesia and sedation or general anaesthesia. Hydrodisplacement may be used to displace the bowel away from the tumour. One or more radiofrequency electrodes are inserted percutaneously into the tumour under imaging guidance. Radiofrequency energy is delivered via the electrode(s) to coagulate and destroy the tumour tissue in the target area. The procedure can be repeated if necessary.

2.3 Efficacy

This section describes efficacy 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 <u>overview</u>.

- 2.3.1 A meta-analysis of 47 studies (non-randomised comparative studies and case series) including a total of 1,375 tumours treated by RFA (n=775) or cryoablation (n=600) reported local tumour progression (defined as radiographic or pathological evidence of residual disease after initial treatment, regardless of time to recurrence) in 13% (100 of 775) and 5% (31 of 600) of tumours respectively at a mean 19-month follow-up (p<0.001). The meta-analysis reported progression to metastatic disease in 2% (19 of 775) of tumours treated by RFA and 1% (6 of 600) of tumours treated by cryoablation (p=not significant).
- 2.3.2 In a non-randomised comparative study of 233 patients (260 tumours), residual or recurrent tumour on follow-up MRI was reported in 11% (9 of 81) of tumours treated by percutaneous RFA and 2% (3 of 179) of tumours treated by laparoscopic cryotherapy (1-year and 3-year median follow-up respectively).

- 2.3.3 A non-randomised comparative study of 264 patients (301 tumours) reported radiographic success (defined as no evidence of central or nodular enhancement after treatment) in 85% (62 of 73) of patients treated by percutaneous RFA and 90% (125 of 139) of patients treated by laparoscopic cryoablation at 6-month follow-up.
- 2.3.4 The case series of 151 patients reported a 3-year recurrence-free survival probability of 92% for all patients and 87% for the 84 patients with confirmed renal cell carcinoma. The case series of 31 patients reported disease-specific survival of 100%, recurrence-free survival of 89% and overall survival of 63% (all at 80 months).
- 2.3.5 The specialist advisers listed key efficacy outcomes as radiological confirmation of tumour devascularisation, imaging follow-up to confirm tumour involution at 2 and 5 years, and overall and disease-free survival. They indicated that there is uncertainty about the procedure's efficacy in tumours 4 cm or greater in diameter.

2.4 Safety

This section describes 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 <u>overview</u>.

- 2.4.1 Haemorrhage was reported in 6% (5 of 85) of patients in a case series of 85 patients. Life-threatening haematuria approximately 42 hours after RFA treatment which required transcatheter embolisation was described in a case report.
- 2.4.2 Haematoma requiring blood transfusion was reported in 1% (1 of 104) of patients in a case series and 1% (1 of 82) of RFA procedures in the non-randomised comparative study of 233 patients. Haematoma not requiring blood transfusion was reported in 5% (4 of 82), including 3 perirenal requiring no treatment and 1 retroperitoneal, of RFA procedures in the non-randomised comparative study of 233 patients. Asymptomatic perirenal haematoma development was reported in 12% (4 of 34; managed conservatively with no sequelae) of RFA procedures in the case series of 31 patients.

- 2.4.3 Ureteric stricture development was reported after 1% (1 of 120) of treatments and in 1% (1 of 85) and 2% (2 of 104) of patients in case series of 97, 85 and 104 patients respectively.
- 2.4.4 Urinoma (a collection of fluid resulting from a urine leak) was reported in 1 patient each in the case series of 97 and 85 patients. Ureteropelvic junction obstruction requiring nephrectomy was described in a case report.
- 2.4.5 Thermal injury to the duodenum requiring laparotomy was reported in 1 patient in the case series of 97 patients.
- 2.4.6 Renoduodenal fistula was diagnosed 5 days after the procedure in 1 patient in a case report. A CT scan at 6 months showed that the tumour (a clear cell carcinoma) was growing again and an open nephrectomy was performed.
- 2.4.7 Neuromuscular complications after RFA treatment were reported in 3 of 48 patients in one series. One patient developed persistent laxity of flank muscles. The other 2 developed sensory loss and paraesthesia of the lateral abdominal wall (resolved after 3 months).
- 2.4.8 The specialist advisers stated that theoretical adverse events include bowel perforation, perirenal haematoma, pelvicalyceal injury, and pain due to intercostal nerve damage.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced information on this procedure for patients and carers. 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 <u>Healthcare Improvement Scotland</u>.